# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

# EMERGENT BIOSOLUTIONS INC.

**Delaware**(State or Other Jurisdiction of Incorporation or Organization)

(Exact Name of Registrant as Specified in Its Charter)
2834
(Primary Standard Industrial
Classification Code No.)

14-1902018 (I.R.S. Employer

300 Professional Drive, Suite 250 Gaithersburg, Maryland 20879 (301) 944-0290

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Fuad EI-Hibri
Chief Executive Officer
Emergent BioSolutions Inc.
300 Professional Drive, Suite 250
Gaithersburg, Maryland 20879
(301) 944-0290

(Name, address, including zip code, and telephone number including area code, of agent for service)

#### Copies to:

David E. Redlick, Esq. Wilmer Cutler Pickering Hale and Dorr LLP 1875 Pennsylvania Avenue, NW Washington, DC 20006 (202) 663-6000 Daniel J. Abdun-Nabi, Esq. General Counsel Emergent BioSolutions Inc. 300 Professional Drive, Suite 250 Gaithersburg, Maryland 20879 (301) 944-0290 James A. Lebovitz, Esq. Brian D. Short, Esq. Dechert LLP 2929 Arch Street Philadelphia, Pennsylvania 19104 (215) 994-4000

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this form are offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), please check the following box. o

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering, o

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering, o

## CALCULATION OF REGISTRATION FEE

Title of Each Class of	Proposed Maximum	Amount of
Securities to be Registered	Aggregate Offering Price(1)	Registration Fee(2)
Common stock, \$0.01 par value per share	\$86,250,000	\$9,229
Series A junior participating preferred stock purchase rights(3)	_	

- (1) Estimated solely for the purpose of computing the registration fee pursuant to Rule 457(o) under the Securities Act.
- (2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price
- (3) Each share of common stock includes one series A junior participating preferred stock purchase right pursuant to a rights agreement to be entered into between the Registrant and the rights agent. The series A junior participating preferred stock purchase rights will initially trade together with the common stock. The value attributable to the series A junior participating preferred stock purchase rights, if any, is reflected in the offering price of the common stock.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities, and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated August 14, 2006

**Prospectus** 

### shares



## Common stock

This is an initial public offering of common stock by Emergent BioSolutions Inc. No public market currently exists for our common stock. We are offering our common stock. The estimated initial public offering price is between \$ and \$ per share.

We have applied to have our common stock listed on The NASDAQ Global Market under the symbol "EBSI."

	Per share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions	\$	\$
Proceeds to Emergent, before expenses	\$	\$

The selling stockholders identified in this prospectus have granted the underwriters an option for a period of 30 days to purchase up to common stock to cover over-allotments. We will not receive any proceeds from the sale of shares by the selling stockholders.

additional shares of

Investing in our common stock involves a high degree of risk. See "Risk factors" beginning on page 8.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about , 2006

**JPMorgan** 

# **Cowen and Company**

**HSBC** 

, 2006

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You should rely only on the information contained in this prospectus or to which we have referred you. We and the selling stockholders have not authorized anyone to provide you with different information. We and the selling stockholders are offering to sell, and are seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock. Our business, financial conditions, results of operations and prospects may have changed since that date.

No action is being taken in any jurisdiction outside the United States to permit a public offering of the common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in any jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

## **Prospectus summary**

This summary highlights information contained elsewhere in this prospectus. This summary may not contain all of the information that is important to you. Before investing in our common stock, you should read this prospectus carefully in its entirety, especially the risks of investing in our common stock that we discuss under "Risk factors," and our financial statements and related notes beginning on page F-1.

#### Our business

We are a biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics. Immunobiotics are pharmaceutical products, such as vaccines and immune globulins, that induce or assist the body's immune system to prevent or treat disease. We operate in two business segments: biodefense and commercial. In our biodefense business, we develop and commercialize immunobiotics for use against biological agents that are potential weapons of bioterrorism. In our commercial business, we develop immunobiotics for use against infectious diseases with significant unmet or underserved medical needs.

BioThrax. We manufacture and market BioThrax®, also referred to as anthrax vaccine adsorbed, the only anthrax vaccine approved by the U.S. Food and Drug Administration, or FDA. Our total revenues from BioThrax sales were \$55.5 million in 2003, \$81.0 million in 2004 and \$127.3 million in 2005. The U.S. Department of Defense, or DoD, and the U.S. Department of Health and Human Services, or HHS, have been the principal customers for BioThrax. Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we have supplied over eight million doses of BioThrax through July 2006 to the DoD for immunization of military personnel. Since March 1998, the DoD has vaccinated more than 1.5 million military personnel with more than 5.5 million doses of BioThrax. Our current contract with the DoD provides for the supply of BioThrax to the DoD through September 30, 2006. We expect to deliver all of the remaining doses of BioThrax under our contract with the DoD within the contract term. In April 2006, the DoD issued a notice that it intends to negotiate a sole source fixed price contract for the purchase of up to an additional 11 million doses of BioThrax over one base contract year plus four option years. In May 2005, we entered into an agreement to supply five million doses of BioThrax to HHS for placement into the strategic national stockpile for a fixed price of \$123 million. We completed delivery of all five million doses by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007 for a fixed price of \$120 million.

The National Institutes of Health, or NIH, originally approved the manufacture and sale of BioThrax in 1970. In December 2005, in reaffirming the approval of BioThrax, the FDA concluded that BioThrax is safe and effective for the prevention of anthrax infection by all routes of exposure, including inhalation. A study published in 2002 by the Institute of Medicine, which is a component of The National Academy of Sciences, supports the FDA ruling. In its study, the Institute of Medicine found that BioThrax is an effective vaccine for protection against anthrax, including inhalational anthrax, caused by any known or plausible engineered strains.

Biodefense market opportunity. The biodefense market for immunobiotics has grown dramatically as a result of the increased awareness of the threat of global terror activity in the wake of the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. The letter attacks involved the delivery of mail contaminated with anthrax spores to government officials and members of the media in the United States. As a result of the letter attacks, 22 people became infected with anthrax, including 11 with inhalational anthrax, and five people died.

The U.S. government is the principal source of worldwide biodefense spending. Most U.S. government spending on biodefense programs results from procurement of countermeasures by HHS, the Centers for Disease Control and Prevention, or CDC, and the DoD and development funding from the National Institute of Allergy and Infectious Diseases of NIH, or NIAID, and the DoD. In 2004, the Project BioShield Act became law, providing \$5.6 billion in appropriations over ten years and authorizing the procurement of countermeasures for biological, chemical, radiological and nuclear attacks.

Biodefense product development. In addition to BioThrax, our biodefense product portfolio includes three biodefense product candidates in preclinical development. We are developing all of our biodefense product candidates to address category A biological agents, which are the class of biological agents that the CDC has identified as the greatest possible threat to public health. Our biodefense product candidates in preclinical development are:

- Anthrax immune globulin for post-exposure treatment of anthrax infection;
- Botulinum immune globulin for post-exposure treatment of illness caused by botulinum toxin, which we are developing based on a new botulinum toxoid vaccine that we are developing in collaboration with the U.K. Health Protection Agency, or HPA; and
- Recombinant bivalent botulinum vaccine a prophylaxis for illness caused by botulinum toxin, which we also are developing in collaboration with HPA.

We are evaluating several potential product candidates in connection with development of a next generation anthrax vaccine, featuring attributes such as self-administration and a longer shelf life.

Commercial market opportunity. Vaccines have long been recognized as a safe and cost-effective method for preventing infection caused by various bacteria and viruses. Because of an increased emphasis on preventative medicine in industrialized countries, vaccines are now well recognized as an important part of public health management strategies. According to Frost & Sullivan, a market research organization, from 2002 to 2005, annual worldwide vaccine sales increased from \$6.7 billion to \$9.9 billion, a compound annual growth rate of approximately 14%. Frost & Sullivan estimates that the worldwide sales of vaccines will grow at a compound annual rate of approximately 10.5% from 2005 through 2012.

Commercial product development. Our commercial product portfolio includes two product candidates in Phase II clinical development, one vaccine candidate in Phase I clinical development and two vaccine candidates in preclinical development. Our commercial product candidates in clinical development are:

- Typhoid vaccine a single dose, drinkable vaccine, for which we have completed a Phase I clinical program, including trials in the United States, the United Kingdom and Vietnam, and expect to initiate a Phase II clinical trial in Vietnam in the fourth quarter of 2006;
- Hepatitis B therapeutic vaccine a multiple dose, drinkable vaccine for treatment of chronic carriers of hepatitis B infection, for which we have completed a Phase I clinical trial in the United Kingdom and expect to initiate a Phase II clinical trial in the United Kingdom in the second half of 2006; and
- Group B streptococcus vaccine a multiple dose injectable vaccine for administration to women of childbearing age for protection of the fetus and

newborn babies, for which we have completed a Phase I clinical trial in the United Kingdom.
Our commercial product candidates in preclinical development are a chlamydia vaccine and a meningitis B vaccine.

The Wellcome Trust provided funding for our Phase I clinical trial of our typhoid vaccine candidate in Vietnam and has agreed to provide funding for our Phase II clinical trial of this vaccine candidate in Vietnam. In May 2006, we entered into a license and co-development agreement with Sanofi Pasteur, the vaccines business of Sanofi-Aventis, under which we granted Sanofi Pasteur an exclusive, worldwide license under our proprietary technology to develop and commercialize a meningitis B vaccine candidate.

Our strategy. Our goal is to become a worldwide leader in developing, manufacturing and commercializing immunobiotics that target diseases with significant unmet or underserved medical needs. Key elements of our strategy to achieve this goal are:

- Maximize the commercial potential of BioThrax. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market
  for BioThrax to other customers and pursuing label expansions and improvements for BioThrax. The potential label expansions and improvements for
  BioThrax include an extension of shelf life, reductions in the number of required doses, addition of another method of administration and use as a postexposure prophylaxis for anthrax infection in combination with antibiotic therapy.
- Continue to develop a balanced portfolio of immunobiotic products. We seek to maintain a balanced product portfolio that includes both biodefense and
  commercial immunobiotic product candidates and both vaccines and therapeutics to diversify product development and commercialization risk. We
  expect that biodefense product candidates may generate revenues from product sales sooner than commercial product candidates because of Project
  BioShield, which allows the U.S. government to purchase biodefense products for the strategic national stockpile before they are approved by the FDA.
- Focus on core capabilities in product development and manufacturing. We focus our efforts on immunobiotic product development and manufacturing, which we believe are our core capabilities. We seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties.
- Build large scale manufacturing infrastructure. To augment our existing manufacturing capabilities, we are constructing a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus. We anticipate that we will initiate large scale manufacturing of BioThrax at our new Lansing facility in 2008. We also own two buildings in Frederick, Maryland that we plan to build out as future manufacturing facilities.
- Selectively establish collaborations. For each of our product candidates, we plan to evaluate the merits of retaining commercialization rights or entering into collaboration arrangements with leading pharmaceutical or biotechnology companies or non-governmental organizations. We currently have collaborations with HPA and Sanofi Pasteur.
- Seek governmental and other third party grants and support. To date, the CDC, the NIH and the Wellcome Trust have provided product development support or funding. We plan to encourage government entities and non-government and philanthropic organizations to continue to conduct studies of, and pursue other development efforts and provide development funding for, BioThrax and our product candidates.

Our history. We commenced operations in September 1998 through an acquisition from the Michigan Biologic Products Institute of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how. We acquired our pipeline of commercial vaccine candidates through our acquisition of Microscience Limited in 2005 and our acquisition of substantially all of the assets of Antex Biologics, Inc. in 2003.

#### Risks associated with our business

Our business is subject to numerous risks, as more fully described in the section entitled "Risk factors" immediately following this prospectus summary. We have derived substantially all of our revenue from sales of BioThrax under contracts with the DoD and HHS. Our ongoing U.S. government contracts do not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government. We expect that a significant portion of the business that we will seek in the near future, in particular for BioThrax, will be under government contracts that present a number of risks that are not typically present in the commercial contracting process. Our U.S. government contracts for BioThrax require annual funding decisions by the government and are subject to unilateral termination by the government. We may fail to achieve significant sales of BioThrax to customers in addition to the U.S. government, which would harm our growth opportunities. We may not be able to sustain or increase profitability. We are spending significant amounts for the expansion of our manufacturing facilities. We may not be able to manufacture BioThrax consistently in accordance with FDA specifications. Other than BioThrax, all of our product candidates are undergoing clinical trials or are in early stages of development, and failure is common and can occur at any stage of development. None of our product candidates other than BioThrax has received regulatory approval.

#### Our corporate information

We were incorporated as BioPort Corporation under the laws of Michigan in May 1998. In June 2004, we completed a corporate reorganization in which Emergent BioSolutions Inc., a Delaware corporation formed in December 2003, issued shares of class A common stock to stockholders of BioPort in exchange for an equal number of outstanding shares of common stock of BioPort. As a result of this reorganization, BioPort became a wholly owned subsidiary of Emergent.

Our principal executive offices are located at 300 Professional Drive, Suite 250, Gaithersburg, Maryland 20879, and our telephone number is (301) 944-0290. Our website address is www.emergentbiosolutions.com. We have included our website address as an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of this prospectus.

In this prospectus, unless otherwise stated or the context otherwise requires, references to "Emergent," "we," "us," "our" and similar references refer to Emergent BioSolutions Inc. BioThrax® and *spi*-Vec® are our registered trademarks. Other trademarks, trade names or service marks appearing in this prospectus are the property of their respective owners.

# The offering

Common stock offered by us

Common stock offered by the selling stockholders

Common stock to be outstanding after this offering

Use of proceeds

Risk factors

shares

shares if the underwriters exercise their over-allotment option in full

shares

We expect to use the net proceeds from this offering, together with our existing cash and cash equivalents, revenues from BioThrax product sales and other committed sources of funds, to fund clinical trials, preclinical testing and other development activities and the balance for working capital, capital expenditures and other general corporate purposes. See "Use of proceeds."

We will not receive any proceeds from the sale of shares of common stock by the selling stockholders as a result of the exercise by the underwriters of their over-allotment option.

See "Risk factors" and other information in this prospectus for a discussion of factors you should

carefully consider before deciding to invest in shares of our common stock.

Proposed NASDAQ Global Market symbol

The number of shares of our common stock to be outstanding immediately after this offering is based on 7,782,016 shares outstanding as of July 31, 2006, and excludes:

- 1,062,779 shares of common stock issuable upon the exercise of stock options outstanding as of July 31, 2006 at a weighted average exercise price of \$6.38 per share;
- 157,206 additional shares of common stock reserved for issuance under our employee stock option plan as of July 31, 2006; and

**EBSI** 

175,000 additional shares of common stock that will be reserved for issuance under our 2006 stock incentive plan immediately prior to completion of this
offering.

Except in our financial statements included in this prospectus, in the table set forth under "Capitalization," in "Certain relationships and related party transactions" or where otherwise expressly indicated, all information in this prospectus assumes that, prior to the completion of this offering, our previously existing class A common stock has been reclassified as common stock, all previously outstanding shares of class B common stock have been converted into shares of common stock and each outstanding option to purchase class B common stock has become an option to purchase common stock.

Unless otherwise indicated, all information in this prospectus assumes:

- · no exercise of the outstanding options described above; and
- · no exercise by the underwriters of their option to purchase up to

shares of common stock from the selling stockholders to cover over-allotments.

# Summary consolidated financial data

You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Management's discussion and analysis of financial condition and results of operations" section of this prospectus.

The summary consolidated financial data for the years ended December 31, 2003, 2004 and 2005 have been derived from our historical audited consolidated financial statements. The summary consolidated financial data for the three-month periods ended March 31, 2005 and 2006 and as of March 31, 2006 have been derived from our unaudited consolidated financial statements. The unaudited summary consolidated financial data include, in the opinion of our management, all adjustments, consisting only of normal recurring adjustments, that are necessary for a fair presentation of our financial position and results of operations for these periods. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results for a full fiscal year. The as adjusted consolidated balance sheet data set forth below give effect to the sale by us of shares of common stock in this offering at an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and offering expenses payable by us.

		Year ended December 31,					Three months ended March 31,				
(in thousands, except share and per share data)		2003		2004		2005	2005		2006		
							(unau	dited	)		
Statements of operations data:											
Revenues:											
Product sales	\$	55,536	\$	81,014	\$	127,271	\$ 14,782	\$	12,196		
Milestones and grants		233		2,480		3,417	480		27		
Total revenues		55,769		83,494		130,688	15,262		12,223		
Operating expenses (income):											
Cost of product sales		22,342		30,102		31,603	4,136		2,861		
Research and development		6,327		10,117		18,381	1,852		8,173		
Selling, general & administrative		19,547		30,323		42,793	8,849		10,587		
Purchased in-process research and development		1,824		_		26,575	_				
Settlement of State of Michigan obligation		_		(3,819)		_	_		_		
Litigation settlement						(10,000)					
Total operating expenses		50,040		66,723		109,352	14,837		21,621		
Income (loss) from operations	_	5,729		16,771		21,336	425		(9,398)		
Other income (expense):											
Interest income		100		65		485	77		203		
Interest expense		(293)		(241)		(767)	(189)		(170)		
Other income (expense), net		168		6		55	(13)		7		
Total other income (expense)		(25)		(170)		(227)	(125)		40		
Net income (loss)	\$	4,454	\$	11,472	\$	15,784	\$ 224	\$	(4,636)		
Earnings (loss) per share — basic	\$	0.68	\$	1.74	\$	2.21	\$ 0.03	\$	(0.60)		
Earnings (loss) per share — diluted	\$	0.63	\$	1.61	\$	2.00	\$ 0.03	\$	(0.60)		
Weighted average number of shares — basic		6,570,856		6,576,019		7,136,866	6,494,604		7,767,859		
Weighted average number of shares — diluted		7,061,537		7,104,172		7,908,023	7,102,822		7,767,859		

		As of March 31, 2006				
(in thousands)	Actual	As adjusted				
	(una	(unaudited)				
Balance sheet data:						
Cash and cash equivalents	\$ 14,774	\$				
Working capital .	20,048					
Total assets	90,573					
Total long-term liabilities	10,225					
Total stockholders' equity	54,905					

The balance sheet data above do not reflect the incurrence of \$8.5 million of indebtedness under a mortgage loan from HSBC Realty Credit Corporation that we entered into in April 2006 in connection with the purchase of a building in Frederick, Maryland.

### **Risk factors**

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information included in this prospectus, including the financial statements and related notes appearing at the end of this prospectus, before deciding to invest in our common stock. If any of the following risks actually occurs, our business, prospects, financial condition and operating results could be materially harmed. In that event, the market price of our common stock could decline and you could lose part or all of your investment.

#### Risks related to our dependence on U.S. government contracts for BioThrax

We have derived substantially all of our revenue from sales of our BioThrax anthrax vaccine under contracts with the U.S. Department of Defense and the U.S. Department of Health and Human Services. If we are unable to obtain new contracts with and deliver BioThrax to these customers, our business, financial condition and operating results could be materially harmed.

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales of BioThrax, our FDA approved anthrax vaccine. We currently supply BioThrax to the DoD for immunization of military personnel and to HHS for placement into the strategic national stockpile. In 2005, we derived substantially all of our revenue from our BioThrax contracts with the DoD and HHS. Our current contract with the DoD expires on September 30, 2006. Although the DoD issued a notice that it intends to pursue a sole source fixed price contract to purchase up to an additional 11 million doses of BioThrax over one base contract year plus four option years, we may not be awarded a follow-on contract on favorable terms or at all. We have delivered all of the five million doses of BioThrax that HHS agreed to purchase under a contract that we entered into with HHS in May 2005. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007. Our ongoing contracts do not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government. The success of our business and our operating results for the foreseeable future are substantially dependent on the number of doses of BioThrax that the U.S. government purchases from us.

The results of ongoing legal proceedings could reduce demand for BioThrax by the U.S. government. Prior to the issuance of an order in December 2005 by the FDA and an appellate court ruling in February 2006, the DoD had been enjoined by a court order from administering BioThrax without informed consent of the recipient or a Presidential waiver. Although we are not a party to this lawsuit, if further proceedings result in another injunction or otherwise restrict the administration of BioThrax by the DoD, the amount of future purchases of BioThrax by the DoD could be limited.

Our business may be harmed as a result of the government contracting process, which is a competitive bidding process that involves risks not present in the commercial contracting process.

We expect that a significant portion of the business that we will seek in the near future will be under government contracts or subcontracts awarded through competitive bidding. Competitive bidding for government contracts presents a number of risks that are not typically present in the commercial contracting process, including:

• the need to devote substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us:

- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded; and
- the expenses that we might incur and the delays that we might suffer if our competitors protest or challenge contract awards made to us pursuant to
  competitive bidding, and the risk that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in
  termination, reduction or modification of the awarded contract.

The U.S. government may choose to award future contracts for the supply of anthrax vaccines and other biodefense product candidates that we are developing to our competitors instead of to us. If we are unable to win particular contracts, we may not be able to operate in the market for products that are provided under those contracts for a number of years. For example, in November 2004, HHS awarded VaxGen, Inc., one of our competitors in the anthrax vaccine market, a contract for the supply of 75 million doses of a recombinant protective antigen anthrax vaccine for inclusion in the strategic national stockpile. If VaxGen is able to deliver product under its contract, HHS may eliminate or reduce future orders for other anthrax vaccines, including BioThrax.

If we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition, and operating results could be materially adversely affected.

Our U.S. government contracts for BioThrax require annual funding decisions by the government and are subject to unilateral termination by the government. The failure to fund or termination of one or more of these contracts could cause our financial condition and operating results to suffer materially.

Our principal customer for BioThrax, our only marketed product, is the U.S. government. We sell to the U.S. government under contracts with the DoD and HHS. In addition, we anticipate that the U.S. government will be the principal customer for any other biodefense products that we successfully develop. Accordingly, we are subject to a range of risks arising out of being a contractor to the U.S. government under U.S. government programs.

Over its lifetime, a U.S. government program may be implemented through the award of many different individual contracts and subcontracts. The funding of government programs is subject to Congressional appropriations. Congress generally appropriates funds on a fiscal year basis even though a program may continue for several years. For example, our DoD contracts for BioThrax have been structured with one base year during which the DoD agrees to purchase a minimum number of doses of BioThrax with options for the DoD to purchase further quantities in future years. Government programs are often only partially funded initially, and additional funds are committed only as Congress makes further appropriations. The termination of a program or failure to commit funds to a program would result in a loss of anticipated future revenues attributable to that program, which could materially harm our business. Our government customers are subject to stringent budgetary constraints and political considerations. If annual levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, our business, revenues and operating results may suffer.

Generally, government contracts, including our U.S. government contracts for BioThrax, contain provisions permitting unilateral termination, in whole or in part, at the government's convenience. Under general principles of government contracting law, if the government terminates a contract for convenience, the terminated company may recover only its incurred or committed costs, settlement

expenses and profit on work completed prior to the termination. If the government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. One or more of our government contracts could be terminated under these circumstances.

Our business with the U.S. government is also subject to specific procurement regulations and a variety of other legal compliance obligations. These obligations include those related to:

- · procurement integrity;
- · export control;
- · government security regulations;
- · employment practices;
- · protection of the environment;
- · accuracy of records and the recording of costs; and
- · foreign corrupt practices.

Compliance with these obligations increases our performance and compliance costs. Failure to comply with these regulations and requirements could lead to suspension or debarment, for cause, from government contracting or subcontracting for a period of time. The termination of a government contract or relationship as a result of our failure to satisfy any of these obligations would have a negative impact on our operations and harm our reputation and ability to procure other government contracts in the future.

The pricing under our fixed price government contracts is based on estimates of the time, resources and expenses required to deliver the specified doses of BioThrax. If our estimates are not accurate, we may not be able to earn an adequate return under these contracts.

Our current contracts for the supply of BioThrax with the DoD and HHS are fixed price contracts. In addition, we expect that our future contracts with the U.S. government for biodefense product candidates that we successfully develop may be fixed price contracts. Under a fixed price contract, we are required to deliver our products at a fixed price regardless of the actual costs we incur and absorb any costs in excess of the fixed price. Estimating costs that are related to performance in accordance with contract specifications is difficult. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of a fixed price contract or cause a loss.

#### Unfavorable provisions in government contracts may harm our business, financial condition and operating results.

Government contracts customarily contain provisions that give the government rights and remedies that are not typically found in commercial contracts, including provisions that allow the government to:

- · terminate existing contracts, in whole or in part, for any reason or no reason;
- · reduce or modify contracts or subcontracts;

- · cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- · decline to exercise an option to renew a contract;
- · claim rights in products, including intellectual property, produced under the contract;
- · suspend or debar the contractor from doing business with the government or a specific government agency;
- · pursue criminal or civil remedies under the False Claims Act and False Statements Act; and
- · control or prohibit the export of products.

Some government contracts grant the government the right to use, for or on behalf of the U.S. government, any technologies developed by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the government.

#### Risks related to our financial position and need for additional financing

#### We have a limited operating history and may not maintain profitability in future periods or on a consistent basis.

We have a limited operating history. We commenced operations in 1998, and the FDA approved the manufacture of BioThrax at our renovated facilities in Lansing, Michigan in December 2001. Although we were profitable for each of the last three fiscal years, we have not been profitable for every quarter during that time. In particular, we were not profitable for the three months ended March 31, 2006. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis. If we are unable to maintain profitability on a consistent basis, the market price of our common stock may decline, and you could lose part or all of your investment.

#### Our indebtedness may limit cash flow available to invest in the ongoing needs of our business.

As of July 31, 2006, we had \$19.5 million principal amount of debt outstanding. We also have a revolving line of credit for up to \$10.0 million. We can borrow under the line of credit through October 1, 2006.

Our leverage could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of any cash flow from operations to the payment of interest on, and principal of, our debt, which will reduce
  the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- · increasing the amount of interest that we have to pay on debt with variable interest rates if market rates of interest increase;
- · increasing our vulnerability to general adverse economic and industry conditions;
- · limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt.

We may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. Because of the covenants under our existing debt instruments and the pledge of our existing assets as collateral, we have a limited ability to obtain additional debt financing.

# We may need additional funding and may be unable to raise capital when needed, which would harm our business, financial condition and operating results.

We expect our development expenses to increase in connection with our ongoing activities, particularly as we conduct additional and later stage clinical trials for our product candidates. In addition, we incur significant commercialization expenses for BioThrax product sales, marketing and manufacturing. We expect these commercialization expenses to increase in the future as we seek to broaden the market for BioThrax and if we receive marketing approval for additional products. We also are committed to substantial capital expenditures in connection with the expansion of our Lansing, Michigan facility. In addition, we expect to incur substantial capital expenditures in connection with our planned build out of two buildings in Frederick, Maryland as future manufacturing facilities. We expect to rely on cash from product sales to fund development and commercialization costs for our product candidates. If we do not obtain future contracts with, and deliver BioThrax to, the DoD and HHS, we may be forced to find additional sources of funding and to do so earlier than we currently anticipate. We may be unable to raise capital when needed or on attractive terms, which would force us to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

As of July 31, 2006, we had \$6.0 million of cash and cash equivalents. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, revenues from BioThrax product sales and other committed sources of funds, will be sufficient to enable us to fund our anticipated operating expenses and capital expenditure and debt service requirements for at least the next 24 months. Our future capital requirements will depend on many factors, including:

- the level of BioThrax product sales and cost of product sales;
- the timing of, and the costs involved in, constructing our new manufacturing facility in Lansing, Michigan and the build out of our manufacturing facilities in Frederick, Maryland;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- · the costs, timing and outcome of regulatory review of our product candidates;
- · the number of, and development requirements for, other product candidates that we may pursue;
- · the costs of commercialization activities, including product marketing, sales and distribution;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- · the extent to which we acquire or invest in businesses, products and technologies; and
- · our ability to establish and maintain collaborations, such as our collaboration with Sanofi Pasteur.

To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Our only committed external sources of funds are remaining borrowing availability under our revolving line of credit, development funding under our collaboration agreement with Sanofi Pasteur and funding from the Wellcome Trust for our Phase II clinical trial of our

typhoid vaccine candidate in Vietnam. Our ability to borrow additional amounts under our loan agreements is subject to our satisfaction of specified conditions. Additional equity or debt financing, grants, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

#### Risks related to manufacturing and manufacturing facilities

We have initiated a manufacturing facility expansion program. Delays in completing and receiving regulatory approvals for these manufacturing facility projects could limit our potential revenues and growth.

We are spending significant amounts for the construction of a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus, which is being designed to enable us to manufacture BioThrax on a large scale for our existing and potential future customers. We are also constructing this new facility to accommodate large scale commercial manufacturing of multiple vaccine products, subject to complying with appropriate change-over procedures. In addition, we own two buildings in Frederick, Maryland that we plan to build out as future manufacturing facilities. Constructing and preparing a facility for commercial vaccine manufacturing is a significant project. For example, constructing the new Lansing facility with increased manufacturing capacity requires that we scale up both fermentation and downstream processing compared to levels at our existing production facility. These projects may result in unanticipated delays and cost more than expected due to a number of factors, including regulatory requirements. The FDA must approve our new manufacturing facilities before they can be used to commercially manufacture our products. For example, we are required to show that the product we manufacture in our new Lansing facility is comparable to BioThrax manufactured in our existing production facility. The costs and time required to comply with the FDA's current Good Manufacturing Practice, or cGMP, regulations, or similar regulatory requirements for sales of our products outside the United States, may be significant. If construction or regulatory approval of our new facility in Lansing is delayed, we may not be able to manufacture sufficient quantities of BioThrax to allow us to increase sales of BioThrax to the U.S. government and other customers, which would limit our opportunities for growth. If construction or regulatory approval of our new manufacturing facilities at our Frederick site is delayed, we may not be able to independently manufacture our commercial product candidates for clinical trials or comm

BioThrax and our immunobiotic product candidates are difficult to manufacture on a large scale commercial basis, which could cause us to delay product launches or experience shortages of products.

BioThrax and all our product candidates are biologics. Manufacturing biologic products, especially in large quantities, is complex. The products must be made consistently and in substantial compliance with a

clearly defined manufacturing process. Accordingly, it is essential to be able to validate and control the manufacturing process to assure that it is reproducible. Slight deviations anywhere in the manufacturing process, including filling, labeling and packaging and quality control and testing, may result in lot failures or product recalls. From time to time, we experience deviations during the manufacturing process of BioThrax that can affect our release of the production lot according to our release protocols and other acceptance criteria. Lot failures or product recalls could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

For example, in late 2005, our standard product release testing identified BioThrax production lots for which follow up testing was required to determine whether we can submit these lots to the FDA for release for sale. We waited to conduct final release testing of these lots pending FDA review of an application that we submitted to amend the BioThrax release specifications. The FDA approved our amendment to the release specifications in May 2006, and we subsequently reinitiated release testing of these BioThrax lots. We will not be able to sell any lots that fail to satisfy the amended release testing specifications or that are not released for sale by the FDA.

# Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture BioThrax, which would harm our business, financial condition and operating results.

We currently rely on our manufacturing facilities at a single location in Lansing, Michigan for the production of BioThrax. Any interruption in manufacturing operations at this location could result in our inability to satisfy the product demands of our customers. A number of factors could cause interruptions, including:

- · equipment malfunctions or failures;
- · technology malfunctions;
- · work stoppages;
- · damage to or destruction of the facility due to natural disasters;
- · regional power shortages;
- product tampering; or
- · terrorist activities

Any disruption that impedes our ability to manufacture and ship BioThrax in a timely manner could reduce our revenues and materially harm our business, financial condition and operating results.

#### Our business may be harmed if we do not adequately forecast customer demand.

The timing and amount of customer demand is difficult to predict. We may not be able to scale up our production quickly enough to fill any new customer orders on a timely basis. This could cause us to lose new business and possibly existing business. In addition, we may not be able to scale up manufacturing processes for our product candidates to allow production of commercial quantities at a reasonable cost or at all. Furthermore, if we overestimate customer demand, we could incur significant unrecoverable costs from creating excess capacity. For example, if we do not maintain and increase sales of BioThrax to the U.S. government and other customers, we may not be able to generate an adequate return on the significant amounts that we are spending for construction of our new manufacturing facility in Lansing.

In addition, if we do not successfully develop and commercialize any of our product candidates, we may never require the production capacity that we expect to have available at our Frederick site.

If third parties do not manufacture our product candidates in sufficient quantities and at an acceptable cost or in compliance with regulatory requirements and specifications, the development and commercialization of our product candidates could be delayed, prevented or impaired.

We currently rely on third parties to manufacture the supplies of our immunobiotic product candidates that we require for preclinical and clinical development. Any significant delay in obtaining adequate supplies of our product candidates could adversely affect our ability to develop or commercialize these product candidates. Although we recently commissioned a new pilot plant manufacturing facility on our Lansing campus and plan to construct a pilot plant in Maryland for production of preclinical and clinical supplies of our product candidates, we expect that we will continue to use third parties for these purposes. In addition, we expect that we will rely on third parties for a portion of the manufacturing process for commercial supplies of product candidates that we successfully develop, including fermentation for some of our vaccine product candidates, plasma fractionation and purification for our immune globulin product candidates and contract fill and finish operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our ability to develop product candidates and commercialize any products that receive regulatory approval on a timely and competitive basis.

Other than our agreement with a third party for purification and fractionation of plasma for our anthrax immune globulin candidate, we do not have any long-term manufacturing agreements with third parties, and manufacturers under our short-term supply agreements are not obligated to accept any purchase orders we may submit. If any third party terminates its agreement with us, based on its own business priorities, or otherwise fails to fulfill our purchase orders, we would need to rely on alternative sources to satisfy our requirements. If these alternative suppliers are not available or are delayed in fulfilling our requirements, we may not be able to obtain adequate supplies of our product candidates on a timely basis. A change of manufacturers may require review from the FDA and satisfaction of comparable foreign requirements. This review may be costly and time consuming. There are a limited number of manufacturers that operate under the FDA's cGMP requirements and that are both capable of manufacturing for us and willing to do so.

We currently rely on third parties for regulatory compliance and quality assurance with respect to the supplies of our product candidates that they produce for us. We also will rely for these purposes on any third party that we use for production of commercial supplies of product candidates that we successfully develop. Manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP regulations and other governmental regulations and corresponding foreign standards. We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the United States. We do not control compliance by manufacturers with these regulations and standards. If we or these third parties fail to comply with applicable regulations, sanctions could be imposed on us, which could significantly and adversely affect supplies of our product candidates. The sanctions that might be imposed include:

- · fines, injunctions and civil penalties;
- · refusal by regulatory authorities to grant marketing approval of our product candidates;
- · delays, suspension or withdrawal of regulatory approvals, including license revocation;

- · seizures or recalls of product candidates or products;
- · operating restrictions; and
- · criminal prosecutions.

If as a result of regulatory requirements or otherwise we or third parties are unable to manufacture our product candidates at an acceptable cost, our product candidates may not be commercially viable.

# Our use of hazardous materials, chemicals, bacteria and viruses requires us to comply with regulatory requirements and exposes us to significant potential liabilities.

Our development and manufacturing processes involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we are subject to federal, state, local and foreign laws and regulations governing the use, manufacture, distribution, storage, handling, disposal and recordkeeping of these materials. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS and the DoD.

The Public Health Security and Bioterrorism Preparedness and Response Act and the Agricultural Protection Act require us to register with the CDC and the Department of Agriculture our possession, use or transfer of select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires increased safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel, and establishes a comprehensive national database of registered entities.

We also are subject to export control regulations governing the export of BioThrax and technology and materials used to develop and manufacture BioThrax and our product candidates. If we fail to comply with environmental, occupational health and safety, biosafety and export control laws, we could be held liable for fines, penalties and damages that result, and any such liability could exceed our assets and resources. In addition, we could be required to cease immediately all use of a select agent or toxin, and we could be prohibited from exporting our products, technology and materials.

### If the company on whom we rely for filling BioThrax vials is unable to perform these services for us, our business may suffer.

We have outsourced the operation for filling BioThrax into vials to a single company, Hollister-Stier Laboratories LLC. Our contract with Hollister-Stier expires on December 31, 2007. We have not established internal redundancy for our filling functions and currently have no substitute provider that can handle our filling needs. If Hollister-Stier is unable to perform filling services for us or we are unable to enter into a new contract with Hollister-Stier, we would need to identify and engage an alternative filling company. Any new contract filling company will need to obtain FDA approval for filling BioThrax at its facilities. Identifying and engaging a new contract filling company and obtaining FDA approval could involve significant cost and delay. As a result, we might not be able to deliver BioThrax orders on a timely basis and our revenues could decrease.

#### Risks related to product development

Our business depends significantly on our success in completing development and commercializing product candidates that are still under development. If we are unable to commercialize these product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of our immunobiotic product candidates. In addition to BioThrax product sales, our ability to generate near term revenue is particularly dependent on the success of our anthrax immune globulin candidate and our botulinum development programs. All of these product candidates are currently in preclinical development. The commercial success of our product candidates will depend on many factors, including:

- · successful completion of preclinical development;
- · successful completion of clinical trials;
- · receipt of marketing approvals from the FDA and similar foreign regulatory authorities;
- a determination by the Secretary of HHS that our biodefense product candidates should be purchased for the strategic national stockpile prior to FDA approval;
- · establishing commercial manufacturing processes or arrangements;
- · launching commercial sales of the product, whether alone or in collaboration with others; and
- acceptance of the product by potential government customers, physicians, patients, healthcare payors and others in the medical community.

We expect to rely on FDA regulations known as the animal rule to obtain approval for our biodefense product candidates. The animal rule permits the use of animal efficacy studies together with human clinical safety and immunogenicity trials to support an application for marketing approval. These regulations are relatively new, and we have limited experience in the application of these rules to the product candidates that we are developing. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our immunobiotic product candidates in humans. In addition, our development plans for our botulinum immune globulin candidate require the development of a new botulinum toxoid vaccine that we would use to vaccinate individuals who would then donate plasma for use in our botulinum immune globulin candidate. If the development of this new botulinum toxoid vaccine is delayed or not completed, for regulatory or other reasons, we may not be able to successfully develop our botulinum immune globulin candidate.

If we are not successful in completing the development and commercialization of our immunobiotic product candidates, or if we are significantly delayed in doing so, our business will be materially harmed.

We will not be able to commercialize our product candidates if our preclinical development efforts are not successful, our clinical trials do not demonstrate safety or our clinical or animal trials do not demonstrate efficacy.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive preclinical development, clinical trials to demonstrate the safety of our product candidates and clinical or animal trials to demonstrate the efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or

animal efficacy trials will be successful, and interim results of a clinical trial or animal efficacy trial do not necessarily predict final results. A failure of one or more of our clinical trials or animal efficacy trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical or animal efficacy trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- · regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy trials produce negative or inconclusive results;
- · we might have to suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we currently anticipate;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing or if the results of these trials or tests are not positive, we may:

- · be delayed in obtaining marketing approval for our product candidates;
- · not be able to obtain marketing approval; or
- obtain approval for indications that are not as broad as intended.

For example, the FDA could require us to conduct additional clinical development in our botulinum immune globulin program that we currently do not plan to conduct. We expect to rely on safety and immunogenicity data from a pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan in the development of a new bivalent botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin candidate. Following our completion of a planned Phase I clinical trial to evaluate the safety of the botulinum toxoid vaccine, we anticipate that the FDA will not require us to conduct a Phase II clinical trial for the botulinum toxoid vaccine stimulation program for our botulinum immune globulin candidate. If the FDA requires us to conduct a Phase II clinical trial for the botulinum toxoid vaccine, the development plans for our botulinum immune globulin candidate will be delayed.

Our product development costs will also increase if we experience delays in testing or approvals. Significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

Under Project BioShield, the Secretary of HHS can contract to purchase countermeasures for the strategic national stockpile prior to FDA approval of the countermeasure in specified circumstances. Project

BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA. However, our product candidates may not be selected by the Secretary under this authority. Moreover, this authority could result in increased competition for our products and product candidates, as has occurred in the case of the HHS procurement contract for VaxGen's anthrax vaccine candidate and as discussed below under "— Risks related to commercialization — We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do."

#### Risks related to commercialization

#### If we fail to achieve significant sales of BioThrax to customers in addition to the U.S. government, our opportunities for growth could be harmed.

An element of our business strategy is to establish a market for sales of BioThrax to customers in addition to the U.S. government. The market for sales of BioThrax to customers other than the U.S. government is new and undeveloped, and we may not be successful in generating meaningful sales of BioThrax to these potential customers. In 2005, our sales of BioThrax to customers other than the U.S. government represented only one percent of our revenue. If we fail to significantly increase our sales of BioThrax to these customers, our business and opportunities for growth could be materially harmed.

Government regulations and the terms of our U.S. government contracts may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of BioThrax, the U.S. government may decide, particularly in the current environment of elevated concerns about global terrorism, to increase the scope of export prohibitions. These controls could limit our sales of BioThrax to foreign governments and other foreign customers.

In addition, the DoD has contractual and statutory rights that could interfere with sales of BioThrax to customers other than the U.S. government. For example, our efforts to develop domestic commercial and international sales may be impeded by the DoD's right under the Defense Production Act to require us to deliver more doses than are otherwise specified in our contract with the DoD. If the DoD required delivery of these additional doses, it could affect our production schedule and deplete BioThrax supplies that would otherwise be available for commercial sales. In addition, the DoD could either sell BioThrax directly to foreign governments at a lower price than we may offer or donate BioThrax to foreign governments under the DoD's Foreign Military Sales program.

Our ability to meet any increased demand that develops for sales of BioThrax to customers other than the U.S. government depends on our available production capacity. We use substantially all of our current production capacity at our facility in Lansing, Michigan to manufacture BioThrax for sale to U.S. government customers. Until our new manufacturing facility in Lansing is available for commercial use, we will not have sufficient available production capacity to allow us to significantly increase sales of BioThrax to customers other than the U.S. government.

The commercial success of BioThrax and any products that we may develop will depend upon the degree of market acceptance by the government, physicians, patients, healthcare payors and others in the medical community.

Any products that we bring to the market may not gain or maintain market acceptance by potential government customers, physicians, patients, healthcare payors and others in the medical community. In particular, our biodefense immunobiotic products and product candidates are subject to the product criteria that may be specified by potential U.S. government customers. The product specifications in any

government procurement request may prohibit or preclude us from participating in the government program if our products or product candidates do not satisfy the stated criteria. For example, in 2004, HHS issued a request for proposals for the supply of anthrax vaccine for the strategic national stockpile. The HHS request was limited to a recombinant anthrax vaccine. Because BioThrax is not a recombinant vaccine, BioThrax was precluded from consideration under that procurement program.

In May 2006, an HHS official stated in Congressional testimony that HHS maintains a commitment to develop a next generation recombinant protective antigen anthrax vaccine. A significant portion of future government anthrax vaccine procurement requests may specify a recombinant anthrax vaccine, which would limit, possibly significantly, the market for BioThrax. In May 2006, NIAID issued a notice seeking statements of capability for the advanced development and testing of next generation anthrax vaccine candidates with specified properties, including the ability to generate protective immune response in one or two doses, the ability to be self administered or rapidly inoculated into large numbers of people and a superior safety profile to BioThrax. Although we are evaluating several potential product candidates in connection with development of a next generation anthrax vaccine with these properties, we may not be successful in our development efforts.

In addition, notwithstanding favorable findings regarding the safety and efficacy of BioThrax by the FDA in its final ruling in December 2005, the U.S. Government Accountability Office reiterated concerns regarding BioThrax in Congressional testimony in May 2006 that it had previously identified beginning in 1999. These concerns include the need for a six dose regimen and annual booster doses, questions about the long-term and short-term safety of the vaccine, including how safety is affected by gender differences, and uncertainty about the vaccine's efficacy.

If any products that we develop do not achieve an adequate level of acceptance, we may not generate material revenues with respect to these products. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects;
- · the efficacy and potential advantages over alternative treatments;
- · the ability to offer our product candidates for sale at competitive prices;
- · relative convenience and ease of administration;
- the willingness of the target patient population to try new products and of physicians to prescribe these products;
- · the strength of marketing and distribution support; and
- · sufficient third party coverage or reimbursement.

Political or social factors may delay or impair our ability to market BioThrax and our biodefense product candidates and may require us to spend time and money to address these issues.

Products developed to treat diseases caused by or to combat the threat of bioterrorism will be subject to changing political and social environments. The political and social responses to bioterrorism have been highly charged and unpredictable. Political or social pressures or changes in the perception of the risk that military personnel or civilians could be exposed to biological agents as weapons of bioterrorism may delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, which would harm our business. In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Furthermore, lawsuits brought against us by third parties

or activists, even if not successful, require us to spend time and money defending the related litigation. The need to address political and social issues may divert our management's time and attention from other business concerns.

For example, between 2001 and 2004, members of the military and various activist groups filed a citizen's petition with the FDA and various lawsuits seeking the revocation of the license for BioThrax and the termination of the DoD program for the mandatory administration of BioThrax to military personnel. In October 2004, a federal court ruled that the FDA, as part of its review of all biological products approved prior to 1972, had not properly issued a final order determining that BioThrax is safe and effective and not misbranded. As a result, the court issued an injunction prohibiting the DoD from administering BioThrax to military personnel without informed consent of the recipient or a Presidential waiver. Although the FDA issued a final order in December 2005 determining that BioThrax is safe and effective and not misbranded and, as a result, an appellate court ruled in February 2006 that the injunction was dissolved, these actions created negative publicity about BioThrax. Similar or other such lawsuits or publicity campaigns could harm our future husiness

We have a small marketing and sales group. If we are unable to expand our sales and marketing capabilities or enter into sales and marketing agreements with third parties, we may be unable to generate product sales revenue from sales to customers other than the U.S. government.

To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We currently market and sell BioThrax directly to the DoD and HHS through a small, targeted marketing and sales group. We plan to continue to do so and expect that we will use a similar approach for sales to the U.S. government of any other biodefense product candidates that we successfully develop. However, to increase our sales of BioThrax to state and local governments and foreign governments and create an infrastructure for future sales of other biodefense products to these customers, we plan to expand our sales and marketing organization. In addition, we expect to establish a separate internal organization to market and sell commercial products for which we retain commercialization or co-commercialization rights.

We may not be able to attract, hire, train and retain qualified sales and marketing personnel to build a significant or effective marketing and sales force for sales of biodefense product candidates to customers other than the U.S. government or for sales of our commercial product candidates. If we are not successful in our efforts to expand our internal sales and marketing capability, our ability to independently market and sell BioThrax and any other product candidates that we successfully develop will be impaired. Expanding our internal sales and marketing capability will be expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed as a result of FDA requirements or other reasons, we would incur related expenses too early relative to the product launch. This may be costly, and our investment would be lost if we cannot retain our sales and marketing personnel.

#### We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.

The development and commercialization of new immunobiotics is highly competitive. We face competition with respect to BioThrax, our current product candidates and any products we may seek to develop or commercialize in the future from major pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research institutions that conduct research, seek patent protection and establish collaborative

arrangements for research, development, manufacturing and commercialization. Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. We believe that our most significant competitors in the area of immunobiotics are a number of pharmaceutical companies that have vaccine programs, including GlaxoSmithKline, Sanofi-Aventis, Wyeth, Merck and Novartis, as well as smaller more focused companies engaged in immunobiotic development, such as VaxGen, Cangene, Human Genome Sciences, Acambis, Avant Immunotherapeutics and Avecia Group.

Any immunobiotic product candidate that we successfully develop and commercialize is likely to compete with currently marketed products, such as vaccines and therapeutics, including antibiotics, and with other product candidates that are in development for the same indications. In many cases, the currently marketed products have well known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. In addition, we are aware of product candidates of third parties that are in development, which, if approved, would compete against product candidates for which we receive marketing approval.

BioThrax. Although BioThrax is the only anthrax vaccine approved by the FDA for the prevention of anthrax infection, we face significant competition for the supply of this vaccine to the U.S. government. The Biodefense Research Agenda for CDC Category A Agents published by NIAID includes the development of an anthrax vaccine based on recombinant protective antigen. In September 2003, NIAID awarded joint three-year contracts totaling \$151.6 million to VaxGen and Avecia to fund development of a recombinant protective antigen anthrax vaccine. In November 2004, HHS awarded VaxGen a contract with a value of \$877.5 million to supply 75 million doses of recombinant protective antigen vaccine for the strategic national stockpile. VaxGen has not yet delivered any vaccine doses under its contract with HHS. If VaxGen is ultimately successful in completing the development of its vaccine and delivering product under its contract, the demand for BioThrax by HHS could diminish significantly.

HPA manufactures an anthrax vaccine for use by the government of the United Kingdom. In addition, other countries may have anthrax vaccines for use by or in development for their own internal purposes.

Other biodefense products. The competition for our biodefense immunobiotic product candidates includes the following:

- Anthrax immune globulin. Cangene, in collaboration with the CDC, is currently developing an anthrax immune globulin product using plasma collected
  from military personnel vaccinated with BioThrax. In July 2006, HHS exercised an option under a modification to an existing development and supply
  contract for Cangene to supply 10,000 doses of anthrax immune globulin for the strategic national stockpile. This contract modification has a total value
  of approximately \$143 million. Human Genome Sciences is developing a monoclonal antibody to Bacillus anthracis as a post-exposure therapeutic for
  anthrax infection. In June 2006, HHS awarded a contract with a value of \$165 million to Human Genome Sciences to supply 20,000 treatment courses of
  the monoclonal antibody, referred to as ABthrax®, for the strategic national stockpile.
- Recombinant bivalent botulinum vaccine. DynPort Vaccine Company has a recombinant bivalent botulinum vaccine in Phase I clinical development with funding from the DoD and NIAID. AlphaVax and DOR BioPharma currently have botulinum vaccines in preclinical development.
- Botulinum immune globulin. The current recommended therapy for clinical symptoms of botulism following exposure consists of passive immunization with an immune globulin derived from equine plasma. In June 2006, HHS awarded a five-year development and supply contract with a base value of

\$362 million to Cangene for a heptavalent botulinum immune globulin derived from equine plasma. The contract provides for the supply of 200,000 doses of a botulinum immune globulin for the strategic national stockpile.

BioThrax and our biodefense product candidates also face competition for BioShield funding from other defensive measures, including protective gear such as bio-suits and gas masks.

Commercial products. The competition for our commercial immunobiotic product candidates includes the following:

- Typhoid vaccine. One oral typhoid vaccine, Vivotif® from Berna Biotech, and one injectable typhoid vaccine, sold as Typhim-Vi® by Sanofi Pasteur and Typherix® by GlaxoSmithKline, are currently approved and administered in the United States and Europe. Avant Immunotherapeutics is also developing an oral typhoid vaccine candidate. Antibiotics typically are used to treat typhoid after infection.
- Hepatitis B therapeutic vaccine. There is no vaccine currently on the market that is licensed for therapeutic use for hepatitis B infection. Currently available therapies for this patient population consist mainly of antiviral drugs, such as an immunotherapy with interferons, including Epivir® from GlaxoSmithKline and Hepsera® from Gilead Sciences. Several other companies have vaccine candidates in clinical development.
- Group B streptococcus vaccine. The existing method of prevention of group B streptococcus infection in neonates is the targeted administration of intravenous antibiotics to women during labor. A number of competitors have passive immune vaccines in preclinical development.
- Chlamydia vaccine. There is no vaccine currently on the market for chlamydia, and we are not aware of any competing chlamydia vaccine candidate in clinical development. Several competitors may have chlamydia vaccine candidates in preclinical development.
- Meningitis B vaccine. Currently, there is no meningitis vaccine on the market that is protective against group B meningococcal infection. Novartis
  markets a meningitis B vaccine in New Zealand to people under the age of 20 and is also developing a broad coverage protein subunit vaccine
  candidate. Current meningitis B treatment strategies include antibiotics and clinical support.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring products, product candidates and technologies complementary to, or necessary for, our programs or advantageous to our business.

Legislation and contractual provisions limiting or restricting liability of manufacturers, such as us, may not be adequate to protect us from all liabilities associated with the manufacture, sale and use of our products.

Provisions of our BioThrax contracts with the DoD and HHS and federal legislation enacted to protect manufacturers of biodefense and anti-terrorism countermeasures may limit our potential liability related to the manufacture, sale and use of BioThrax and our biodefense product candidates. However, these contractual provisions and legislation may not fully protect us from all related liabilities.

The Public Readiness and Emergency Preparedness Act, which was signed into law in December 2005, creates general immunity for manufacturers of biodefense countermeasures, including security countermeasures, when the Secretary of HHS issues a declaration for their manufacture, administration or use. The declaration is meant to provide general immunity from all claims under state or federal law for loss arising out of the administration or use of a covered countermeasure. Manufacturers are not entitled to this protection in cases of willful misconduct.

Upon a declaration by the Secretary, a compensation fund is created to provide "timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." The "covered injuries" to which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer only after they have exhausted their remedies under the compensation program. However, a willful misconduct action could be brought against us if any individuals exhausted their remedies under the compensation program and thereby expose us to liability. Although we may petition the Secretary to make such a declaration with respect to anthrax generally and BioThrax specifically, we do not know if any such petition would be successful or that, if successful, the Act will provide adequate coverage or survive anticipated legal challenges to its validity.

We have applied to the Department of Homeland Security under the Safety Act enacted by the U.S. Congress in 2002 for liability protection for sales of BioThrax. The Safety Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. In addition, the Safety Act provides a process by which an anti-terrorism technology may be certified as an "approved product" by the Department of Homeland Security and therefore entitled to a rebuttable presumption that the government contractor defense applies to sales of the product. The government contractor defense, under specified circumstances, extends the sovereign immunity of the United States to government contractors who manufacture a product for the government. Specifically, for the government contractor defense to apply, the government must approve reasonably precise specifications, the product must conform to those specifications and the supplier must warn the government about known dangers arising from the use of the Department of Homeland Security does not designate BioThrax as a qualifying anti-terrorism technology, we would not be entitled to the benefits of the Safety Act. Even if we are entitled to the benefits of the Safety Act, it may not provide adequate protection from any claims made against us.

In addition, although our existing contracts with the DoD and HHS provide that the government will indemnify us for any damages resulting from product liability claims, we cannot be certain that we will be able to continue to negotiate similar rights in future contracts or that the U.S. government will honor this obligation. For example, although we have notified the DoD of the lawsuits filed against us by current and former members of the U.S. military claiming damages as the result of personal injuries allegedly suffered from vaccination with BioThrax, the DoD has not yet acted on our claim for indemnification pending resolution of our claims under our product liability insurance.

In addition, members of Congress have proposed and may in the future propose legislation that reduces or eliminates these and other liability protections for manufacturers of biodefense countermeasures.

# Product liability lawsuits could cause us to incur substantial liabilities and require us to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the sale of BioThrax and any other products that we successfully develop and the testing of our product candidates in clinical trials. We currently are a defendant in three federal lawsuits filed on behalf of three individuals vaccinated with BioThrax by the U.S. Army that claim damages resulting from personal injuries allegedly suffered because

of the vaccination. If we cannot successfully defend ourselves against claims that our product or product candidates caused injuries and we are not entitled to indemnity by the U.S. government, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- · injury to our reputation;
- · withdrawal of clinical trial participants;
- · withdrawal of a product from the market;
- · costs to defend the related litigation;
- · substantial monetary awards to trial participants or patients;
- loss of revenue: and
- · the inability to commercialize any products that we may develop.

We have product liability insurance for coverage up to a \$10 million annual aggregate limit with a deductible of \$75,000 per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. For example, from 2002 through February 2006, we were unable to obtain product liability insurance for sales of BioThrax on commercially reasonable terms. We do not believe that the amount of insurance we have been able to obtain for BioThrax is sufficient to manage the risk associated with the potential deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on contractual indemnification provisions and statutory protections to limit our liability for BioThrax.

If we are unable to obtain adequate reimbursement from governments or third party payors for any products that we may develop or to obtain acceptable prices for those products, our revenues will suffer.

Our revenues and profits from any products that we successfully develop, other than with respect to sales of our biodefense products under government contracts, will depend heavily upon the availability of adequate reimbursement for the use of such products from governmental and other third party payors, both in the United States and in other markets. Reimbursement by a third party payor may depend upon a number of factors, including the third party payor's determination that use of a product is:

- · a covered benefit under its health plan;
- · safe, effective and medically necessary;
- · appropriate for the specific patient;
- · cost-effective; and
- · neither experimental nor investigational.

Obtaining a determination that a product is covered is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to gain coverage. Even when a payor determines that a product is covered, the payor may impose limitations that preclude payment for some

uses that are approved by the FDA or comparable authorities but are determined by the payor to not be medically reasonable and necessary. Moreover, eligibility for coverage does not imply that any product will be covered in all cases or that reimbursement will be available at a rate that permits the health care provider to cover its costs of using the product. We expect that the success of some of our commercial vaccine candidates for which we obtain marketing approval will depend on inclusion of those product candidates in government immunization programs.

Most non-pediatric commercial vaccines are purchased and paid for, or reimbursed by, managed care organizations, other private health plans or public insurers or paid for directly by patients. In the United States, pediatric vaccines are funded by a variety of federal entitlements and grants, as well as state appropriations. Foreign governments also commonly fund pediatric vaccination programs through national health programs. In addition, with respect to some diseases affecting the public health generally, particularly in developing countries, public health authorities or nongovernmental, charitable or philanthropic organizations fund the cost of vaccines.

Federal legislation, enacted in December 2003, has altered the way in which physician-administered drugs and biologics covered by Medicare are reimbursed. Under the new reimbursement methodology, physicians are reimbursed based on a product's "average sales price." This new reimbursement methodology has generally led to lower reimbursement levels. The new federal legislation also has added an outpatient prescription drug benefit to Medicare, which went into effect January 2006. These benefits will be provided primarily through private entities, which we expect will attempt to negotiate price concessions from pharmaceutical manufacturers.

Any products we may develop may also be eligible for reimbursement under Medicaid. If the state-specific Medicaid programs do not provide adequate coverage and reimbursement for any products we may develop, it may have a negative impact on our operations.

The scope of coverage and payment policies varies among third party private payors, including indemnity insurers, employer group health insurance programs and managed care plans. These third party carriers may base their coverage and reimbursement on the coverage and reimbursement rate paid by carriers for Medicare beneficiaries. Furthermore, many such payors are investigating or implementing methods for reducing health care costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by health care providers. If third party payors do not provide adequate coverage or reimbursement for any products we may develop, it could have a negative effect on revenues and results of operations.

#### Foreign governments tend to impose strict price controls, which may adversely affect our revenues.

In some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Legislation has been introduced into Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the United States, which may include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. Such

legislation, or similar regulatory changes, could decrease the price we receive for any approved products which, in turn, could adversely affect our operating results and our overall financial condition.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully sustain or expand our BioThrax operations or develop or commercialize our product candidates.

Our success depends on our continued ability to attract, retain and motivate highly qualified managerial and key scientific personnel. We consider Fuad El-Hibri, our president, chief executive officer and chairman of our board of directors, Steven N. Chatfield, our chief scientific officer and president of Emergent Product Development UK Limited, Edward J. Arcuri, our executive vice president and chief operating officer, and Robert G. Kramer, president and chief executive officer of BioPort, to be key to our BioThrax operations and our efforts to develop and commercialize our product candidates. All of these key employees, other than Dr. Chatfield, are at will employees and can terminate their employment at any time. Our employment agreement with Dr. Chatfield is terminable by him on short notice. We do not maintain "key person" insurance on any of our employees.

In addition, our growth will require us to hire a significant number of qualified scientific and commercial personnel, including clinical development, regulatory, marketing and sales executives and field sales personnel, as well as additional administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

### Additional risks related to sales of biodefense products to the U.S. government

#### Our business could be adversely affected by a negative audit by the U.S. government.

U.S. government agencies such as the Defense Contract Audit Agency, or the DCAA, routinely audit and investigate government contractors. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. The DCAA also reviews the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- · termination of contracts;
- forfeiture of profits;
- · suspension of payments;
- · fines: and
- · suspension or prohibition from doing business with the U.S. government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us.

#### Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business.

We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under these contracts. These laws and regulations affect how we do business with federal, state and local government agencies. Among the most significant government contracting regulations that affect our business are:

- the Federal Acquisition Regulations, and agency-specific regulations supplemental to the Federal Acquisition Regulations, which comprehensively
  regulate the procurement, formation, administration and performance of government contracts;
- the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act and Foreign Corrupt Practices Act;
- · export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

In addition, qui tam lawsuits have been brought against us in which the plaintiffs argued that we defrauded the U.S. government by distributing non-compliant doses of BioThrax. This litigation was brought against us under a provision of the False Claims Act that allows a private citizen to file a suit in the name of the U.S. government charging fraud by government contractors and other entities who receive or use government funds and share in any money recovered. Although a federal district court dismissed the litigation, and a federal appeals court subsequently upheld that decision, we spent significant time and money defending the litigation.

The states, many municipalities and foreign governments typically also have laws and regulations governing contracts with their respective agencies. These domestic and foreign laws and regulations affect how we and our customers can do business and, in some instances, impose added costs on our business. Any changes in applicable laws and regulations could restrict our ability to maintain our existing contracts and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our revenues and results of operations.

### We rely on property and equipment owned by the Department of Defense in the manufacturing process for BioThrax.

Our BioThrax supply contract with the DoD grants us the right to use property and equipment owned by the DoD in the manufacture of BioThrax. This property and equipment, referred to as government furnished equipment, is in service at our Lansing site. Some of this government furnished equipment is important to our business. We pay the DoD a fee for the use of the government furnished equipment based on the number of doses of BioThrax that we produce for sale to customers other than the U.S. government. We have the option to purchase all or part of the government furnished equipment at any time during the contract period for approximately \$21 million. If the DOD modifies the terms under which we use the government furnished equipment in a manner unfavorable to us, including raising the usage fee, our business could be harmed. If DoD terminated our contract, we could be required to rent or purchase all or a part of the government furnished equipment to continue production of BioThrax in our current facility.

#### Risks related to regulatory approvals

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have only limited experience in preparing, filing and prosecuting the applications necessary to gain regulatory approvals and expect to rely on third party contract research organizations and consultants to assist us in this process. Securing FDA approval requires the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA to establish the product candidate's safety and efficacy. Our future products may not be effective, may be only moderately effective or may prove to have significant side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

In the United States, BioThrax, our biodefense product candidates and our commercial product candidates are regulated by the FDA as biologics. To obtain approval from the FDA to market these product candidates, other than biodefense products purchased by HHS for the strategic national stockpile, we will be required to submit to the FDA a biologics license application, or BLA. Ordinarily, the FDA requires a sponsor to support a BLA application with substantial evidence of the product's safety and effectiveness in treating the targeted indication based on data derived from adequate and well controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted.

Because humans are rarely exposed to anthrax or botulinum toxins under natural conditions, and cannot be intentionally exposed, statistically significant effectiveness of our biodefense product candidates cannot be demonstrated in humans, but instead must be demonstrated, in part, by utilizing animal models before they can be approved for marketing. We believe that, according to the FDA's current BLA requirements for biologics that cannot be ethically or feasibly tested in humans in Phase III efficacy trials, we may instead be able to obtain BLA approval based on clinical data from Phase III and Phase III trials in healthy subjects that demonstrate adequate safety and immune response and effectiveness data from studies in animals. Specifically, we intend to pursue FDA approval of our immune globulin candidates and our recombinant bivalent botulinum vaccine candidate under the FDA animal rule. Under the animal rule, if human efficacy trials are not ethical or feasible, the FDA can approve drugs or biologics used to treat or prevent serious or life threatening conditions caused by exposure to lethal or permanently disabling toxic chemical, biological, radiological or nuclear substances based on human clinical data demonstrating safety and immunogenicity and evidence of efficacy from appropriate non-clinical animal studies and any additional supporting data. Products approved under the animal rule are subject to additional regulation not normally required of other products. Additional regulation may include post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

Based on an interim analysis of data from an ongoing clinical trial of BioThrax being conducted by the CDC, we have applied to the FDA to reduce the number of required doses of BioThrax for pre-exposure prophylaxis from six to five, with an annual booster dose thereafter. In April 2006, the FDA issued a complete response letter to our application, requesting clarification and requiring additional analysis of the data that we submitted. We are in the process of responding to this letter and amending our

application. If the FDA does not find our response to be adequate, we might be required to conduct additional independent testing to continue to pursue the development of this dosing regimen. Responding to the FDA's complete response letter will delay potential approval of our application. If we are unable ultimately to respond satisfactorily to the FDA, our application will not be approved.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

# Our products could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any immunobiotic product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies, including through inspections of our facilities. As an approved product, BioThrax is subject to these requirements and ongoing review. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. The FDA enforces its cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect manufacturing facilities without a warrant at reasonable times and in a reasonable manner.

After we acquired BioThrax and related vaccine manufacturing facilities in Lansing, Michigan in 1998 from the Michigan Biologic Products Institute, we spent significant amounts of time and money renovating those facilities before the FDA approved a supplement to our manufacturing facility license in December 2001. The State of Michigan had initiated renovations after the FDA issued a notice of intent to revoke the FDA license to manufacture BioThrax in 1997. The notice of intent to revoke cited significant deviations by the Michigan Biologic Products Institute from cGMP requirements, including quality control failures. After approving the renovated Lansing facilities in December 2001, the FDA conducted routine, biannual inspections of the Lansing facilities in September 2002, May 2004 and May 2006. Following each of these inspections, the FDA issued inspectional observations on Form FDA 483. We responded to the FDA regarding the inspectional observations relating to each inspection and, where necessary, implemented corrective action. In December 2005, the FDA stated in its final order on BioThrax that at that time we were in compliance with all regulatory requirements related to the manufacture of BioThrax and that the FDA would continue to evaluate the production of BioThrax to assure compliance with federal standards and regulations. Although we have filed with the FDA our response to the inspectional observations relating to the May 2006 inspection, the FDA may not find our response to be adequate. If the FDA finds that we are not in substantial compliance with cGMP requirements, the FDA may undertake enforcement action against us.

Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain

requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products or manufacturing processes, or failure to comply with regulatory requirements, may result in:

- · restrictions on the marketing or manufacturing of a product;
- warning letters:
- · withdrawal of the product from the market;
- · refusal to approve pending applications or supplements to approved applications;
- · voluntary or mandatory product recall;
- · fines or disgorgement of profits or revenue;
- · suspension or withdrawal of regulatory approvals, including license revocation;
- · refusal to permit the import or export of products;
- · product seizure; and
- · injunctions or the imposition of civil or criminal penalties.

We may not be able to obtain orphan drug exclusivity for our products. If our competitors are able to obtain orphan drug exclusivity for their products that are the same as our products, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug or biologic for that time period for the same indication. Orphan drug exclusivity in Europe lasts for ten years, but can be reduced to six years if a drug or biologic no longer meets the criteria for orphan drug designation or if the drug or biologic is sufficiently profitable so that market exclusivity is no longer justified. If a competitor obtains orphan drug exclusivity for an indication for a product that competes with one of the indications for one of our product candidates before we obtain orphan drug designation, and if the competitor's product is the same drug as ours, the FDA would be prohibited from approving our product candidate for the same orphan indication unless we demonstrate that our product is clinically superior. None of our product candidates have been designated as orphan drugs. Even if we obtain orphan drug exclusivity for one or more indications for one of our product candidates, we may not be able to maintain it. For example, if a competitive product that is the same drug or biologic as our product is shown to be clinically superior to our product, any orphan drug exclusivity we have obtained will not block the approval of that competitive product

#### Failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our products abroad.

We intend to have our products marketed outside the United States. To market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. With respect to some of our

product candidates, we expect that a future collaborator will have responsibility to obtain regulatory approvals outside the United States, and we will depend on our collaborators to obtain these approvals. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We and our collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

#### Risks related to our dependence on third parties

We may not be successful in maintaining and establishing collaborations, which could adversely affect our ability to develop and, particularly in international markets, commercialize our product candidates.

For each of our product candidates, we plan to evaluate the merits of retaining commercialization rights for ourselves or entering into collaboration arrangements with leading pharmaceutical or biotechnology companies or non-governmental organizations, such as our collaboration agreement with Sanofi Pasteur for our meningitis B vaccine candidate. We expect that we will selectively pursue collaboration arrangements in situations in which the collaborator has particular expertise or resources for the development or commercialization of our products and product candidates or to access particular markets. If we are unable to reach agreements with suitable collaborators, we may fail to meet our business objectives for the affected product or program. We face, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements. The terms of any collaborations or other arrangements that we establish may not be favorable to us.

Any collaboration that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. It is likely that our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations. In particular, the successful development of our meningitis B vaccine candidate will initially depend on the success of our research collaboration with Sanofi Pasteur and whether Sanofi Pasteur selects one or more viable candidates pursuant to the collaboration for development of a product. Thereafter, Sanofi Pasteur will have significant discretion in the development and commercialization of any such candidate. Sanofi Pasteur may choose not to pursue further development and commercialization of any candidate that it selects based on many factors outside our control. Sanofi Pasteur has the ability to suspend development of a candidate under the collaboration in various circumstances. The risks that we are subject to in our current collaborations, and anticipate being subject to in future collaborations, include the following:

- · our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach by us;
- our collaborators are likely to have the first right to maintain or defend our intellectual property rights and, although we would have the right to assume
  the maintenance and defense of our intellectual property rights if our collaborators do not, our ability to do so may be compromised by our collaborators'
  acts or omissions; and

our collaborators may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. For example, Sanofi Pasteur has the right to terminate our meningitis B vaccine collaboration at any time after April 1, 2007 upon six months' prior written notice. Sanofi Pasteur can also terminate the collaboration upon a change of control or insolvency event involving us or upon our uncured material breach. Those terminations or expirations would adversely affect us financially and could harm our business reputation.

If third parties on whom we rely for clinical trials do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our product candidates, and our business may suffer.

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our products. We depend on independent clinical investigators, contract research organizations and other third party service providers to conduct the clinical trials of our product candidates and expect to continue to do so.

We rely heavily on these third parties for successful execution of our clinical trials, but do not exercise day-to-day control over their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting and recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates.

In addition, we encourage government entities and non-government organizations to conduct studies of, and pursue other development efforts for, our product candidates. For example, the CDC is currently conducting an independent clinical trial to evaluate the administration of BioThrax in a regimen of fewer doses. We expect to rely on data from these development efforts in seeking marketing approval for our product candidates. However, these government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. In addition, government entities depend on annual Congressional appropriations to fund these development efforts. In prior years, there has been some uncertainty whether Congress would choose to fund the CDC trial. Although the trial has been funded to date, Congress may not continue to fund the trial.

We plan to expand our internal clinical development and regulatory capabilities. We will not be successful in doing so unless we are able to recruit appropriately trained personnel and add to our infrastructure.

# Risks related to our intellectual property

We may fail to protect our intellectual property rights, which would harm our business.

Our success, particularly with respect to our commercial business, will depend in large part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property

covering or incorporated into our technology and products. The patent situation in the field of immunobiotics and other pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our natent protection

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, patents generally expire, regardless of their date of issue, 20 years from the earliest claimed non-provisional filing date. As a result, the time required to obtain regulatory approval for a product candidate may consume part or all of the patent term. We are not able to accurately predict the remaining length of the applicable patent term following regulatory approval of any of our product candidates.

# If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a number of license agreements. We consider our licenses with HPA relating to our recombinant bivalent botulinum vaccine candidate and the botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin candidate to be material to our business. Under these license agreements, we obtained the exclusive, worldwide right to develop, manufacture and commercialize pharmaceutical products that consist of botulinum toxoid components or recombinant botulinum toxin components for the prevention or treatment of illness in humans caused by exposure to the botulinum toxin, subject to HPA's non-exclusive right to make, use or sell recombinant botulinum products to meet public health requirements in the United Kingdom. We expect to enter into additional licenses in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

# If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for BioThrax, the label expansions and improvements that we are pursuing for BioThrax or our anthrax immune globulin candidate, our only intellectual property protection for BioThrax and our anthrax immune globulin candidate is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and biological starting materials. However, these types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, with agreements with our employees, consultants and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise

become known or be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

# If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or patent applications under which we do not hold licenses or other rights. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, we or our collaborators may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology and pharmaceutical industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference and reexamination proceedings declared by the United States Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. We may also become a party to trademark invalidation and interference proceedings in foreign trademark offices. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

# Risks related to our acquisition strategy

# Our strategy of generating growth through acquisitions may not be successful.

We have pursued an acquisition strategy since our inception to build our business of developing, manufacturing and commercializing immunobiotics. We commenced operations in September 1998 through an acquisition of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how from the Michigan Biologic Products Institute. We acquired our pipeline of commercial vaccine candidates through our acquisition of Microscience in 2005 and our acquisition of substantially all of the assets of Antex in 2003.

In the future, we may be unable to license or acquire suitable products or product candidates from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical and biological products is a competitive area. A number of more established companies are also pursuing strategies to license or acquire products in the immunobiotics field. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable products and product candidates include the following:

- · we may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return on the product;
- · companies that perceive us to be their competitor may be unwilling to assign or license their product rights to us; or
- we may be unable to identify suitable products or product candidates within our areas of expertise.

In addition, we expect competition for acquisition candidates in the immunobiotic field to increase, which may mean fewer suitable acquisition opportunities for us as well as higher acquisition prices. If we are unable to successfully obtain rights to suitable products and product candidates, our business, financial condition and prospects for growth could suffer.

# If we fail to successfully manage any acquisitions, our ability to develop our product candidates and expand our product candidate pipeline may be harmed.

As part of our business strategy, we intend to continue to seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties. The failure to adequately address the financial, operational or legal risks of these transactions could harm our business. Financial aspects of these transactions that could alter our financial position, reported operating results or stock price include:

- · use of cash resources;
- · higher than anticipated acquisition costs and expenses;
- · potentially dilutive issuances of equity securities;
- the incurrence of debt and contingent liabilities, impairment losses or restructuring charges;
- large write-offs and difficulties in assessing the relative percentages of in-process research and development expense that can be immediately written off as compared to the amount that must be amortized over the appropriate life of the asset; and
- · amortization expenses related to other intangible assets.

Operational risks that could harm our existing operations or prevent realization of anticipated benefits from these transactions include:

- · challenges associated with managing an increasingly diversified business;
- disruption of our ongoing business;
- · difficulty and expense in assimilating the operations, products, technology, information systems or personnel of the acquired company;
- · diversion of management's time and attention from other business concerns;

- · inability to maintain uniform standards, controls, procedures and policies;
- · the assumption of known and unknown liabilities of the acquired company, including intellectual property claims; and
- · subsequent loss of key personnel.

If we are unable to successfully manage our acquisitions, our ability to develop new products and continue to expand our product pipeline may be limited.

# Risks related to the offering

Fuad El-Hibri, our president, chief executive officer and chairman of our board of directors, will continue to have substantial control over us after this offering and could delay or prevent a change of control.

Even after this offering, Mr. El-Hibri will be able to control the election of the members of our board of directors through his ownership interests and voting arrangements among our significant stockholders. Immediately prior to this offering, Mr. El-Hibri was the beneficial owner of 99.6% of our outstanding common stock. Immediately following this offering, Mr. El-Hibri will be the beneficial owner of % of our outstanding common stock, or % of our outstanding common stock if the underwriters exercise their over-allotment option in full.

Because Mr. El-Hibri will be able to control the election of the members of our board, and because of his substantial control of our capital stock, Mr. El-Hibri will likely have the ability to delay or prevent a change of control of our company that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

Provisions in our corporate charter documents, in our shareholder rights plan and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us.

Provisions of our certificate of incorporation and by-laws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions include:

- · the classification of our directors;
- · limitations on changing the number of directors then in office;
- · limitations on the removal of directors;
- · limitations on filling vacancies on the board;
- · limitations on the removal and appointment of the chairman of our board of directors;
- following the second anniversary of the completion of this offering, advance notice requirements for stockholder nominations for election of directors and other proposals;
- · the inability of stockholders to act by written consent;

- · the inability of stockholders to call special meetings; and
- · the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval.

Until the second anniversary of the completion of this offering, the affirmative vote of holders of our capital stock representing a majority of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. Following the second anniversary of the completion of this offering, the affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. Until the second anniversary of the completion of this offering, the affirmative vote of either at least 75% of the directors then in office or holders of our capital stock representing a majority of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws. Following the second anniversary of the completion of this offering, the affirmative vote of either a majority of the directors present at a meeting of our board of directors or holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal or by-laws.

In addition, our board of directors has adopted a shareholder rights plan intended to protect stockholders in the event of an unfair or coercive offer to acquire our company and to provide our board of directors with adequate time to evaluate unsolicited offers. Preferred stock purchase rights have been distributed to holders of our common stock pursuant to the rights plan. This rights plan may have anti-takeover effects. The rights plan will cause substantial dilution to a person or group that attempts to acquire us on terms that our board of directors does not believe are in our best interests and those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

Furthermore, Section 203 of the General Corporation Law of Delaware prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns or within the last three years has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of our company.

# If you purchase shares of our common stock in this offering, you will suffer immediate and substantial dilution of your investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, your interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the net tangible book value per share of our common stock after this offering. See "Dilution."

# An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters. Although we have applied to have our common stock listed on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult to sell shares you purchase in this offering without depressing the market price for the shares or at all.

# If our stock price is volatile, purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- · results of clinical trials of our product candidates or those of our competitors;
- · decisions and procurement policies by the U.S. government affecting BioThrax and our biodefense product candidates;
- · regulatory developments in the United States and foreign countries;
- · developments or disputes concerning patents or other proprietary rights;
- · the recruitment or departure of key personnel;
- · variations in our financial results or those of companies that are perceived to be similar to us;
- · market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- · general economic, industry and market conditions; and
- · the other factors described in this "Risk factors" section.

# We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our net proceeds from this offering in a manner that does not produce income or that loses value.

# We do not anticipate paying any cash dividends in the foreseeable future.

We currently intend to retain our future earnings, if any, to fund the development and growth of our business. Any future debt agreements that we enter into may limit our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. In particular, Mr. El-Hibri could direct the sale of all or part of the shares of our common stock as to

which he exercises dispositive control. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, after this offering, holders of an aggregate of 7,752,001 shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of our common stock that we may issue under our employee benefit plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements described in "Underwriting."

In addition, of the 1,062,779 shares of our common stock that may be issued upon the exercise of options outstanding as of July 31, 2006, approximately shares will be vested and eligible for sale within 180 days after the date of this prospectus. For a further description of the eligibility of shares for sale into the public market following this offering, see "Shares eligible for future sale."

# Special note regarding forward-looking statements

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- · our performance under existing BioThrax sales contracts with HHS and DoD, including the timing of deliveries under these contracts;
- · our plans for future sales of BioThrax:
- our plans to pursue label expansions and improvements for BioThrax;
- · our plans to expand our manufacturing facilities and capabilities;
- the rate and degree of market acceptance and clinical utility of our products;
- our ongoing and planned development programs, preclinical studies and clinical trials;
- · our ability to identify and acquire or in license products and product candidates that satisfy our selection criteria;
- · the potential benefits of our existing collaboration agreements and our ability to enter into selective additional collaboration arrangements;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- · our commercialization, marketing and manufacturing capabilities and strategy;
- · our intellectual property portfolio; and
- · our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the "Risk factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

# Use of proceeds

We estimate that the net proceeds to us from this offering will be approximately \$\) million, assuming an initial public offering price of \$\) per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and offering expenses payable by us. A \$1.00 increase (decrease) in the assumed initial public offering price of \$\) per share would increase (decrease) our net proceeds from this offering by approximately \$\) million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. We will not receive any proceeds from the sale of shares of common stock by the selling stockholders as a result of the exercise by the underwriters of their over-allotment option.

We expect to use the net proceeds from this offering, together with our existing cash and cash equivalents, revenues from BioThrax product sales and other committed sources of funds, to fund clinical trials, preclinical testing and other development activities, for the construction of our new manufacturing facility in Lansing, Michigan and the initial build out of our manufacturing facilities in Frederick, Maryland and the balance for working capital, capital expenditures and other general corporate purposes, which may include the acquisition or in license of technologies, products or businesses.

This expected use of proceeds from this offering represents our intentions based upon our current plans and business conditions. The amounts and timing of our actual expenditures may vary significantly depending upon numerous factors, including the progress of our development and commercialization efforts, the progress of our clinical trials and our operating costs and capital expenditures, including the timing of, and the costs involved in, constructing our new manufacturing facilities in Lansing, Michigan and the build out of our manufacturing facilities in Frederick, Maryland. As a result, we will retain broad discretion in the allocation of the net proceeds from this offering. We have no current understandings, commitments or agreements to acquire or in license any technologies, products or businesses.

Pending use of the proceeds from this offering, we intend to invest the proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments.

# **Dividend policy**

We currently intend to retain all of our future earnings to finance the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future.

On June 15, 2005, our board of directors declared a special cash dividend to the holders of our outstanding shares of common stock in an aggregate amount of approximately \$5.4 million. Our board of directors declared this special dividend in order to distribute the net proceeds of a payment that we received as a result of the settlement of litigation that we initiated against Elan Pharmaceuticals, Inc., Athena Neurosciences, Inc. and Solstice Neurosciences, Inc. We paid the special cash dividend on July 13, 2005 to stockholders of record as of June 15, 2005. Prior to this special cash dividend, we had never declared or paid any cash dividends on our common stock.

# Capitalization

The following table sets forth our capitalization as of March 31, 2006:

- · on an actual basis; and
- · on an as adjusted basis to give effect to:
  - the reclassification of our class A common stock as common stock and the conversion of each outstanding share of our class B common stock into
    one share of common stock prior to the completion of this offering; and
  - the sale of shares of common stock that we are offering at an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and offering expenses payable by us.

Our capitalization following this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our financial statements and the related notes appearing at the end of this prospectus and the "Management's discussion and analysis of financial condition and results of operations" section of this prospectus.

		As of March 31, 2006
(in thousands, except share and per share data)	Actual	As adjusted(1)
	(	unaudited)
Long-term indebtedness, including current portion	\$ 11,198	\$
Notes payable to employees	520	
Stockholders' equity:		
Common stock, class A, \$0.01 par value per share; 10,000,000 shares authorized and 7,752,001 shares issued and		
outstanding, actual; no shares authorized, issued or outstanding, as adjusted	78	
Common stock, class B, \$0.01 par value per share; 2,000,000 shares authorized and 16,800 shares issued and		
outstanding, actual; no shares authorized, issued or outstanding, as adjusted	_	
Common stock, \$0.01 par value per share; no shares authorized, issued or outstanding, actual; shares		
authorized and shares issued and outstanding, as adjusted	_	
Additional paid-in capital	34,637	
Accumulated other comprehensive loss	(370)	
Retained earnings	20,560	
Total stockholders' equity	54,905	
Total capitalization	\$ 66,623	\$

(1) A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) each of additional paid-in capital, total stockholders' equity and total capitalization by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions.

The table above does not include:

- the incurrence of \$8.5 million of indebtedness under a mortgage loan from HSBC Realty Credit Corporation that we entered into in April 2006 in connection with the purchase of a building in Frederick, Maryland;
- 1,064,679 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2006 at a weighted average exercise price of \$5.16 per share;
- 168,521 additional shares of common stock reserved for issuance under our employee stock option plan as of March 31, 2006; and
- 175,000 additional shares of common stock that will be reserved for issuance under our 2006 stock incentive plan immediately prior to completion of this offering.

# **Dilution**

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the public offering price per share of our common stock and the net tangible book value per share of our common stock after this offering.

Our actual net tangible book value as of March 31, 2006 was \$54.9 million or \$7.07 per share of our common stock. Net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the number of shares of common stock outstanding.

After giving effect to the issuance and sale by us of shares of common stock in this offering, at an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, less estimated underwriting discounts and commissions and offering expenses payable by us, our net tangible book value as of March 31, 2006 would have been \$ million, or \$ per share of common stock. This represents an immediate increase in net tangible book value per share of \$ to existing stockholders and immediate dilution of \$ per share to new investors. Dilution per share to new investors is determined by subtracting the net tangible book value per share after this offering from the initial public offering price per share paid by a new investor. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share of common stock		\$
Actual net tangible book value per share as of March 31, 2006	\$ 7.07	
Increase in net tangible book value per share attributable to new investors		
Adjusted net tangible book value per share after this offering		
Dilution per share to new investors		\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) our adjusted net tangible book value per share after this offering by approximately \$ and dilution per share to new investors by approximately \$ , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions.

If any shares are issued in connection with outstanding options, you will experience further dilution.

The following table summarizes as of March 31, 2006 the number of shares of common stock purchased from us, the total consideration paid and the average price per share paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of \$\\$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and offering expenses payable by us.

		Shares purchased		Average price	
	Number	Percentage	Amount	Percentage	per share
Existing stockholders	7,768,801	%	\$ 34,715,125	%	\$ 4.47
New investors					
Total		100%	\$	100%	\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) the total consideration paid by new investors by \$ million and increase (decrease) the percentage of total consideration paid by new investors by approximately %, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

The table above is based on shares outstanding as of March 31, 2006 and excludes:

- 1,064,679 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2006 at a weighted average exercise price
  of \$5.16 per share;
- · 168,521 additional shares of common stock reserved for issuance under our employee stock option plan as of March 31, 2006; and
- 175,000 additional shares of common stock that will be reserved for issuance under our 2006 stock incentive plan immediately prior to completion of this offering.

If the underwriters exercise their over-allotment option in full, the following will occur:

- the number of shares of common stock held by existing stockholders will decrease to common stock outstanding after this offering; and
   , or approximately % of the total number of shares of our common stock outstanding after this offering; and
- the number of shares of common stock held by new investors will increase to stock outstanding after this offering.
   , or approximately % of the total number of shares of our common

# Selected consolidated financial data

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the "Management's discussion and analysis of financial condition and results of operations" section of this prospectus.

We have derived the consolidated statement of operations data for the years ended December 31, 2003, 2004 and 2005 and the consolidated balance sheet data as of December 31, 2004 and 2005 from our audited consolidated financial statements, which are included in this prospectus. We have derived the consolidated statements of operations data for the years ended December 31, 2001 and 2002 and the consolidated balance sheets data as of December 31, 2001, 2002 and 2003 from our audited consolidated financial statements, which are not included in this prospectus. We have derived the consolidated statement of operations data for the three-month periods ended March 31, 2005 and 2006 and the consolidated balance sheet data as of March 31, 2006 from our unaudited consolidated financial statements, which are included in this prospectus. The unaudited consolidated financial data include, in the opinion of our management, all adjustments, consisting only of normal recurring adjustments, that are necessary for a fair presentation of our financial position and results of operations for these periods. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results for a full fiscal year.

										Year ended December 31,				Three months ended March 31,			
(in thousands, except share and per share data)	_	2001		2002		2003		2004		2005		2005		2006			
												(unau	dited	)			
Statements of operations data:																	
Revenues:																	
Product sales	\$	45,309	\$	78,541	\$	55,536	\$	81,014	\$	127,271	\$	14,782	\$	12,196			
Milestones and grants				_		233		2,480		3,417		480		27			
Total revenues		45,309		78,541		55,769		83,494		130,688		15,262		12,223			
Operating expenses (income):																	
Cost of product sales		34,367		24,569		22,342		30,102		31,603		4,136		2,861			
Research and development		382		2,808		6,327		10,117		18,381		1,852		8,173			
Selling, general & administrative		10,924		13,397		19,547		30,323		42,793		8,849		10,587			
Purchased in-process research and development		_		_		1,824		_		26,575		_		_			
Settlement of State of Michigan Obligation		_		_		_		(3,819)		_		_		_			
Litigation settlement				_		_		_		(10,000)		_					
Total operating expenses		45,673		40,774		50,040		66,723		109,352		14,837		21,621			
Income (loss) from operations	_	(364)		37,767		5,729		16,771		21,336		425		(9,398			
Other income (expense):																	
Interest income		122		80		100		65		485		77		203			
Interest expense		(193)		(451)		(293)		(241)		(767)		(189)		(170			
Other income (expense), net		(119)		(271)		`168´		6		55		(13)		7			
Total other income (expense)		(190)		(642)		(25)		(170)		(227)		(125)		40			
Income (loss) before provision for income taxes		(554)		37,125		5,704		16,601		21,109		300		(9,358			
Provision for (benefit from) income taxes		· —		733		1,250		5,129		5,325		76		(4,722			
Net income (loss)	\$	(554)	\$	36,392	\$	4,454	\$	11,472	\$	15,784	\$	224	\$	(4,636			
Earnings (loss) per share — basic	\$	(0.10)	\$	5.68	\$	0.68	S	1.74	\$	2.21	\$	0.03	\$	(0.60			
Earnings (loss) per share — diluted	\$	(0.10)	\$	5.05	\$	0.63	\$	1.61	\$	2.00	\$	0.03	\$	(0.60			
Weighted average number of shares — basic	·	5,651,192		6,409,661		6,570,856		6,576,019		7,136,866		6,494,604	- 1	7,767,859			
Weighted average number of shares — diluted		5,561,192		7,212,903		7,061,537		7,104,172		7.908.023		7,102,822		7,767,859			

						-	As of		
(in thousands)	2001	2001		2003	2003 20		2004		March 31, 2006
									(unaudited)
Balance sheet data:									
Cash and cash equivalents	\$ 5,854	\$	4,891	\$ 7,119	\$	6,821	\$	36,294	\$ 14,774
Working capital	(35,299)		1,130	(3,147)		7,509		29,023	20,048
Total assets	25,423		22,790	37,127		69,056		100,332	90,573
Total long-term liabilities	4,857		4,592	1,228		11,921		10,502	10,225
Total stockholders' equity (deficit)	(32,295)		4,155	8,448		22,949		59,737	54,905

The balance sheet data above do not reflect the incurrence of \$8.5 million of indebtedness under a mortgage loan from HSBC Realty Credit Corporation that we entered into in April 2006 in connection with the purchase of a building in Frederick, Maryland.

# Management's discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

#### Overview

We are a biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics. We operate in two business segments: biodefense and commercial. We commenced operations as BioPort Corporation in September 1998 through an acquisition from the Michigan Biologic Products Institute of rights to our marketed product, BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how. Following this acquisition, we completed renovations at the Lansing facilities that had been initiated by the State of Michigan. In December 2001, the FDA approved a supplement to our manufacturing facility license for the manufacture of BioThrax at the renovated facilities.

In June 2004, we completed a corporate reorganization in which we:

- issued 6,487,950 shares of class A common stock in exchange for 6,262,554 shares of BioPort class A common stock and 225,396 shares of BioPort class B common stock;
- · repurchased and retired all other issued and outstanding shares of BioPort class B common stock; and
- assumed all outstanding stock options to purchase BioPort class B common stock and granted option holders replacement stock options to purchase an
  equal number of shares of our class B common stock.

As a result of the reorganization, BioPort became a wholly owned subsidiary of Emergent. We acquired our portfolio of commercial vaccine candidates through our acquisition of Microscience in a share exchange in June 2005 and our acquisition of substantially all of the assets of Antex for cash in May 2003. We subsequently renamed Microscience as Emergent Product Development UK. We expect to continue to seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties.

Our biodefense business has generated net income for each of the last three fiscal years. However, in our commercial business, we have not received approval to market any of our product candidates and, to date, have received no product sales revenues. Our only sources of revenue in our commercial business are development grant funding and an upfront license fee and additional payments for development work under a collaboration agreement with Sanofi Pasteur. As a result, our commercial business has incurred a net loss for each of the last three fiscal years.

#### Biodefense

In our biodefense business, we develop and commercialize immunobiotics for use against biological agents that are potential weapons of bioterrorism. Our marketed product, BioThrax, is the only vaccine approved by the FDA for the prevention of anthrax infection. In addition to BioThrax, our biodefense product portfolio includes three biodefense product candidates in preclinical development. The DoD and HHS have been the principal customers for BioThrax. In addition, we have supplied small amounts of BioThrax directly to several foreign governments. Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we have supplied over eight million doses of BioThrax through July 2006 for immunization of military personnel. Under a contract that we entered into with HHS in May 2005, we have supplied five million doses of BioThrax to HHS for placement into the strategic national stockpile for a fixed price of \$123 million. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007 for a fixed price of \$120 million.

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales of BioThrax. Our total revenues from BioThrax sales were \$55.5 million in 2003, \$81.0 million in 2004 and \$127.3 million in 2005. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers and pursuing label expansions and improvements for BioThrax.

We are collaborating with HPA in the development of a recombinant bivalent botulinum vaccine candidate and a new botulinum toxoid vaccine that we plan to use as the basis for a botulinum immune globulin candidate. We are independently developing an anthrax immune globulin candidate. We also are evaluating several potential product candidates in connection with development of a next generation anthrax vaccine, featuring attributes such as self-administration and a longer shelf life. We are actively pursuing government sponsored development grants and working with various government agencies to encourage them to conduct studies relating to BioThrax and our biodefense product candidates.

# Commercial

In our commercial business, we develop immunobiotics for use against infectious diseases with significant unmet or underserved medical needs. Our commercial product portfolio includes a typhoid vaccine candidate and a hepatitis B therapeutic vaccine candidate, both of which are in Phase II clinical development, a group B streptococcus vaccine candidate in Phase I clinical development and a chlamydia vaccine candidate and a meningitis B vaccine candidate, both of which are in preclinical development. In May 2006, we entered into a license and co-development agreement with Sanofi Pasteur under which we granted Sanofi Pasteur an exclusive, worldwide license under our proprietary technology to develop and commercialize a meningitis B vaccine

We plan to encourage government entities and non-government and philanthropic organizations to provide development funding for, or to conduct clinical studies of, one or more of our commercial product candidates. For example, the Wellcome Trust provided funding for our Phase I clinical trial of our typhoid vaccine candidate in Vietnam and has agreed to provide funding for our Phase II clinical trial of this vaccine candidate in Vietnam.

# Manufacturing infrastructure

To augment our existing manufacturing capabilities, we are constructing a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus. We expect the construction of the facility to cost approximately \$75 million, including approximately \$55 million for the building and associated

capital equipment, with the balance related to validation activities required for regulatory approval and initiation of manufacturing. We anticipate that we will incur approximately \$42 million of these capital expenditures during 2006. We expect to complete construction of this facility in 2007. We are constructing this new facility as a large scale manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures. We anticipate that we will initiate large scale manufacturing of BioThrax at the new facility in 2008. We also own two buildings in Frederick, Maryland that we plan to build out as new manufacturing facilities. We anticipate that we will incur up to \$5 million during 2006 related to initial engineering design and preliminary utility build out for this facility. Because we are in the preliminary planning stages for our Frederick build out, we cannot reasonably estimate the timing and estimated costs that will be necessary to complete this project.

# Critical accounting policies and estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, fair valuation of stock related to stock-based compensation and income taxes. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

## Revenue recognition

We recognize revenues from product sales in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition, or SAB 104. SAB 104 requires recognition of revenues from product sales that require no continuing performance on our part if four basic criteria have been met:

- · there is persuasive evidence of an arrangement;
- · delivery has occurred or title has passed to our customer based on contract terms;
- the fee is fixed and determinable and no further obligation exists; and
- · collectibility is reasonably assured.

We have generated BioThrax sales revenues under U.S. government contracts with the DoD and HHS. Under our DoD contract, we invoice the DoD for progress payments upon reaching contractually specified stages in the manufacture of BioThrax. We record as deferred revenue the full amount of each progress payment invoice that we submit to the DoD. Title to the product passes to the DoD upon submission of the first invoice. Delivery occurs upon FDA release of the product for sale and distribution. Following FDA release of the product, we segregate the product for later shipment and recognize as period revenue all deferred revenue related to the released product in accordance with the "bill and hold" sale requirements under SAB 104. At that time, we also invoice the DoD for the final progress payment and recognize the amount of that invoice as period revenue. Our contract with HHS does not provide for progress

payments. We invoice HHS and recognize the related revenue upon delivery of the product to the government carrier, at which time title to the product passes to HHS.

Under the collaboration agreement that we entered into with Sanofi Pasteur in May 2006 for our meningitis B vaccine candidate, we received an upfront license fee and are entitled to additional payments for development work under the collaboration and upon achieving contractually defined development and commercialization milestones. We also will be entitled to royalty payments on net sales of this product. Under the collaboration agreement, we have contracted to perform development work for Sanofi Pasteur for which we are entitled to payments up to specified levels. We invoice Sanofi Pasteur in the beginning of each quarter for the estimated work to occur in that quarter. We record the invoice amount as deferred revenue. As services are completed, we recognize the amount of the related deferred revenue as period revenue. We evaluate the various components of a collaboration in accordance with Emerging Issues Task Force, or EITF, Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, or EITF No. 00-21, which addresses whether, for revenue recognition purposes, there is one or several elements in an arrangement. We concluded that under EITF No. 00-21, the milestone payments under our contract with Sanofi Pasteur should be accounted for as multiple units of accounting because the milestones have predetermined independent deliverables with a specific payment associated with each deliverable. We recognize revenue from milestone payments upon achievement of pre-defined scientific events that require substantive effort, if achievement of the milestone was not readily assured at the inception of the agreement. We recognize revenue immediately from readily assured achievements.

From time to time, we are awarded development grant contracts with government entities and non-government and philanthropic organizations. Under these contracts, we typically are reimbursed for our costs in connection with specific development activities and may also be entitled to additional fees. We record the reimbursement of our costs and any associated fees as grant revenue and the associated costs as research and development expense. We issue invoices under these contracts after we incur the reimbursable costs. We recognize revenue upon invoicing the sponsoring organization.

#### Accounts receivable

Accounts receivable are stated at invoice amounts and consist primarily of amounts due from the DoD and HHS as well as amounts due under reimbursement contracts with other government entities and non-government and philanthropic organizations. Because the prior collection history for receivables from these entities indicate that collection is likely, we do not currently record an allowance for doubtful accounts.

# Inventories

Inventories are stated at the lower of cost or market, with cost being determined using a standard cost method, which approximates average cost. Average cost consists primarily of material, labor and manufacturing overhead expenses and includes the services and products of third party suppliers. We analyze our inventory levels quarterly and write down in the applicable period inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand. We also write off in the applicable period the costs related to expired inventory.

# Accrued expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level

of service performed and the associated cost incurred for such service where we have not yet been invoiced or otherwise notified of actual cost. We make these estimates as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include:

- · fees payable to contract research organizations in conjunction with clinical trials;
- · fees payable to third party manufacturers in conjunction with the production of clinical trial materials; and
- · professional service fees.

In accruing service fees, we estimate the time period over which services were provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify costs that have begun to be incurred or we underestimate or overestimate the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. We make judgments based upon the facts and circumstances known to us.

# Purchased in-process research and development

We account for purchased in-process research and development in accordance with Statement of Financial Accounting Standards, or SFAS, No. 2, Accounting for Research and Development Costs along with Financial Accounting Standards Board, or FASB, Interpretation No. 4, Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method.

Under these standards, we are required to determine whether the technology relating to a particular research and development project we acquire has an alternative future use. If we determine that the technology has no alternative future use, we expense the value of the research and development project not directly attributed to fixed assets. Otherwise, we capitalize the value of the research and development project not attributable to fixed assets as an intangible asset and conduct an impairment analysis at least annually. In connection with our acquisition of Microscience and our acquisition of substantially all of the assets of Antex, we allocated the value of the purchase consideration to current assets, current liabilities, fixed assets and development programs. Because we determined that the development programs at Microscience and Antex had no future alternative use, we charged the value attributable to the development programs as in-process research and development. For the Microscience acquisition, which was a share exchange, our board of directors determined the fair value of our shares issued in the exchange for financial statement purposes after taking into account the recommendations of management and the assessments provided by a third party valuation specialist. For the Antex acquisition, which was a cash transaction, no fair value determination was necessary.

#### Stock-based compensation

Through December 31, 2005, in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, or SFAS No. 123, we elected to account for our employee stock-based compensation using the intrinsic value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, or APB No. 25, rather than the alternative fair value accounting method provided for under SFAS No. 123. Accordingly, we did not record compensation expense on employee stock options granted in fixed amounts and with fixed exercise prices when the exercise prices of the options were equal to the fair value of the underlying

common stock on the date of grant. Pro forma information regarding net loss and loss per share is required by SFAS No. 123 and has been determined as if we had accounted for employee stock option grants under the fair value method prescribed by that statement. We provide this pro forma disclosure in our financial statements. We account for transactions in which services are received in exchange for equity instruments based on the fair value of the services received from non-employees or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS No. 123 and EITF Issue No. 96-18, Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, or EITF No. 96-18. In accordance with EITF No. 96-18, we periodically remeasure stock-based compensation for options granted to non-employees as the underlying options vest. As of March 31, 2006, we had no outstanding options that had been granted to non-employees other than our directors.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123(R), which is a revision of SFAS No. 123. SFAS No. 123(R) supersedes APB No. 25 and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their estimated fair values. Pro forma disclosure is no longer an alternative. We adopted SFAS No. 123(R) on January 1, 2006 using the modified prospective method. We will continue to value our share-based payment transactions using a Black-Scholes valuation model. Under the modified prospective method, we recognize compensation cost in our financial statements for all awards granted after January 1, 2006 and for all awards outstanding as of January 1, 2006 for which the requisite service had not been rendered as of the date of adoption. Prior period operating results have not been restated. We measure the amount of compensation cost based on the fair value of the underlying common stock on the date of grant. We recognize compensation cost over the period that an employee provides service in exchange for the award.

As a result of our adoption of SFAS No. 123(R) effective January 1, 2006, we recorded stock-based compensation expense of \$96,000, after tax, for the three months ended March 31, 2006. This expense related to stock options that were outstanding as of January 1, 2006. During the three months ended March 31, 2006, we did not grant any stock options and, consequently, did not record any additional related stock-based compensation expense. Both basic and diluted loss per share for the three months ended March 31, 2006 are \$.02 less than if we had continued to account for stock-based compensation under APB No. 25. The effect of adopting SFAS No. 123(R) on net loss and net loss per share is not necessarily representative of the effects in future years due to, among other things, the vesting period of the stock options and the fair value of additional stock option grants in future years. Based on options granted to employees as of March 31, 2006, total compensation expense not yet recognized related to unvested options is approximately \$612,000. We expect to recognize that expense over a weighted average period of 3.5 years. We expect to recognize amortization of stock-based compensation, after tax, of approximately \$281,000 during the remainder of 2006, \$279,000 in 2007, \$36,000 in 2008 and \$16,000 in 2009.

The factors that most affect charges or credits to operations related to stock-based compensation are the fair value of the common stock underlying stock options for which stock-based compensation is recorded, the volatility of fair value of the common stock, the expected life of the instrument and the assumed risk free rate of return. Because shares of our common stock have not been publicly traded, our board of directors has determined the fair value of our common stock for accounting purposes. There is

no certainty that the results of our board's determination would be the value at which the shares would be traded for cash. In determining the fair value of our common stock, our board of directors considered:

- · the history and nature of our business and our growth opportunities, including our contracts for BioThrax product sales;
- prior determinations of the fair value of the common stock underlying stock options granted and the effect of corporate developments, including the
  progress of our product candidates, that have occurred between the time of the grants;
- · rights and preferences of the security being granted compared to the rights and preferences of our other outstanding equity;
- · values of public companies that we believe are comparable to us, adjusted for the risk and limited liquidity provided for in the shares we are issuing;
- · the assessments provided by independent valuation specialists;
- · business developments involving our direct competitors; and
- · general economic trends and the economic outlook for our industry.

If our estimates of the fair value of these equity instruments are too high or too low, it would have the effect of overstating or understating expenses.

Our board of directors considered the assessments of independent valuation specialists in determining the fair value of our class B common stock underlying stock options granted during 2003, 2004 and 2005. The assessments of these valuation specialists were based upon the application of the income and market approaches consistent with the practice aid issued by the American Institute of Certified Public Accountants entitled Valuation of Privately Held Company Equity Securities Issued as Compensation. Under the income approach, the valuation specialists used a discounted cash flow analysis based on projections of future cash flow to determine an estimated value. Under the market approach, the valuation specialists analyzed comparable public companies and developed an estimated value for the class B common stock based on revenues, earnings and enterprise values. The values derived by each of these methods were adjusted for lack of voting rights, minority interest and lack of marketability of the class B common stock.

In 2004, in connection with our reorganization, we recorded stock-based compensation expense as a result of the issuance of stock options to purchase our class B common stock to replace the outstanding stock options to purchase BioPort class B common stock. The exercise period of these replacement options was extended to June 2007. Based upon the guidance in APB No. 25, because the stock options granted for our class B common stock provided for an extended term over that of the cancelled BioPort options, a new measurement date was created and we recorded as stock-based compensation expense the excess of the intrinsic value of the modified options over the intrinsic value of the BioPort options when originally issued. This resulted in stock-based compensation expense of \$4.3 million for 2004. We did not record any stock-based compensation expense for options granted during 2003 or 2005.

#### Income taxes

Our deferred tax assets include the unamortized portion of in-process research and development expenses, the anticipated future benefit of the net operating losses that we have incurred and other timing differences between financial reporting basis of assets and liabilities. We have historically incurred net operating losses for income tax purposes in some states and in some foreign jurisdictions, primarily

the United Kingdom. The amount of the deferred tax assets on our balance sheet reflects our expectations regarding our ability to use our net operating losses to offset future taxable income. The applicable tax rules in particular jurisdictions limit our ability to use net operating losses as a result of ownership changes. In particular, we believe that these rules will significantly limit our ability to use net operating losses generated by Microscience and Antex prior to our acquisition of Microscience in June 2005 and our acquisition of substantially all of the assets of Antex in May 2003.

We review our deferred tax assets on a quarterly basis to assess our ability to realize the benefit from these deferred tax assets. If we determine that it is more likely than not that the amount of our expected future taxable income will not be sufficient to allow us to fully utilize our deferred tax assets, we increase our valuation allowance against deferred tax assets by recording a provision for income taxes on our income statement, which reduces net income, or increases net loss, for that period and reduces our deferred tax assets on our balance sheet. If we determine that the amount of our expected future taxable income will allow us to utilize net operating losses in excess of our net deferred tax assets, we reduce our valuation allowance by recording a benefit from income taxes on our income statement, which increases net income, or reduces net loss, for that period and increases our deferred tax assets on our balance sheet

# Financial operations overview

#### Revenues

We have generated substantially all of our revenues from sales of BioThrax. In 2005, BioThrax product sales accounted for 97% of our total revenues. The DoD and HHS have been the principal customers for BioThrax. We also have had limited sales of BioThrax to foreign governments and private industry. In addition, we periodically realize revenues from grants from government entities and non-government and philanthropic organizations and from licensing fees, milestone payments and development reimbursement. In 2005, these items accounted for 3% of our total revenues. If our ongoing development efforts are successful, we would expect to generate revenues from sales of additional products and milestone payments, development payments and royalties on sales of products that we license to third parties.

In May 2005, we entered into an agreement to supply five million doses of BioThrax to HHS for placement into the strategic national stockpile for a fixed price of \$123 million. We completed delivery of all five million doses by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007 for a fixed price of \$120 million. Immediately following the contract modification, we delivered to and invoiced HHS for approximately 250,000 doses of BioThrax. We expect to deliver to HHS between 1.0 million and 1.5 million doses of BioThrax in August 2006 and between 1.25 million and 1.75 million doses in each of October 2006 and December 2006, with the balance, if any, to be delivered in the first quarter of 2007.

In January 2004, we entered into our current contract with the DoD for the delivery of a minimum number of doses of BioThrax over one base contract year plus two option periods for a minimum fixed price of approximately \$91 million. Under this contract, we were required to deliver a minimum of approximately 2.8 million total doses in 2004 and 2005. We delivered approximately 4.0 million total doses in 2004 and 2005 under DoD purchase orders. We are required to deliver approximately an additional 1.0 million doses of BioThrax between January 1, 2006 and September 30, 2006. As of March 31, 2006, we had not begun delivery of these additional required doses before expiration of this contract in September 2006. We have invoiced the DoD, as contemplated under this contract, for progress payments as doses of BioThrax are

manufactured for sale to the DoD. In accordance with our revenue recognition policy, we record deferred revenue for invoiced amounts until the FDA releases the product for sale and delivery. As of March 31, 2006, the amount of our deferred revenue for DoD sales was \$7.3 million. In April 2006, the DoD issued a notice that it intends to negotiate a sole source fixed price contract for the purchase of up to an additional 11 million doses of BioThrax over one base year plus four option years. Although we are in discussions with the DoD, we have not yet entered into an agreement with the DoD for this procurement.

In May 2006, we entered into a collaboration agreement with Sanofi Pasteur relating to the development and commercialization of our meningitis B vaccine candidate and received a \$3.8 million upfront license fee. This agreement also provides for a series of milestone payments upon the achievement of specified development and commercialization objectives, payments for development work under the collaboration and royalties on net sales of this product. We will recognize milestone payments and development payments under this agreement as revenue in accordance with our revenue recognition policies.

Our revenue, operating results and profitability have varied, and we expect that they will continue to vary, on a quarterly basis primarily because of the timing of fulfilling orders for BioThrax. We expect milestone and grant revenues to increase in 2006 as we receive reimbursement for development expenses under our meningitis B collaboration with Sanofi Pasteur and funding from the Wellcome Trust for costs associated with our completed Phase I clinical trial and planned Phase II clinical trial of our typhoid vaccine candidate in Vietnam.

# Cost of product sales

The primary expense that we incur to deliver BioThrax to our customers is manufacturing costs, which are primarily fixed costs. These fixed manufacturing costs consist of attributable facilities, utilities and salaries and personnel related expenses for indirect manufacturing support staff. Variable manufacturing costs for BioThrax consist primarily of costs for materials, direct labor and contract filling operations. In 2005, we improved manufacturing efficiencies for BioThrax by extending the hours of operation for our manufacturing facility. As a result, the cost of product sales per dose of BioThrax decreased in 2005 compared to 2004. We do not expect further significant improvements in manufacturing efficiencies for BioThrax until we complete our new manufacturing facility in Lansing, Michigan. We currently are producing BioThrax at close to the maximum capacity of our existing manufacturing facility. We expect our manufacturing costs to remain relatively stable for the remainder of 2006 and during 2007.

We determine the cost of product sales for doses sold for a period based on the average manufacturing cost per dose for that period. We calculate the average manufacturing cost per dose by dividing the actual costs of manufacturing in the applicable period by the number of units produced in that period. In addition to the fixed and variable manufacturing costs described above, the average manufacturing cost per dose depends on the efficiency of the manufacturing process, utilization of available manufacturing capacity and the production yield for any period.

# Research and development expenses

We expense research and development costs as incurred. Our research and development expenses consist primarily of:

- salaries and related expenses for personnel:
- fees to professional service providers for, among other things, independently monitoring our clinical trials and acquiring and evaluating data from our clinical trials;

- · costs of contract manufacturing services;
- · costs of materials used in clinical trials and research and development;
- · depreciation of capital assets used to develop our products; and
- · operating costs, such as the cost of facilities and the legal costs of pursuing patent protection of our intellectual property.

The successful development of our product candidates is highly uncertain. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to be in a position to realize the potential of our product candidates. We cannot reasonably estimate or know the nature, timing and projected costs of the efforts that will be necessary to complete the remainder of the development of, or the period, if any, in which material net cash inflows may commence from any of our product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- · the scope, rate of progress and expense of our clinical trials and other research and development activities;
- · the potential benefits of our product candidates over other products;
- our ability to market, commercialize and achieve market acceptance for any of our product candidates that we are developing or may develop in the future:
- · future clinical trial results;
- · the terms and timing of regulatory approvals; and
- · the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate.

We expect that development spending will increase for all of our biodefense product candidates as our product development activities continue and we prepare for regulatory submissions and other regulatory activities. We expect our development expenses in our commercial business to increase in connection with our ongoing activities, particularly as we conduct additional and later stage clinical trials for our product candidates.

We expect that the magnitude of any increase in our research and development spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, the size, structure and duration of any follow on clinical program that we may initiate, our ability to use data generated by government agencies, such as the ongoing CDC studies with BioThrax, and our ability to rely upon and utilize clinical and nonclinical data, such as the data generated by CDC from use of the pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan. Furthermore, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

# Selling, general and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, business development, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales or research and development expense and professional fees for legal and accounting services. We expect that our general and administrative expenses will increase as we add personnel to support the increased scale of our operations and become subject to the reporting obligations applicable to public companies. Our general and administrative expenses have increased as a result of preparing for this offering and supporting the overall growth of the company. We currently market and sell BioThrax directly to the DoD and HHS with a small, targeted marketing and sales group. Accordingly, our marketing and sales expense for these efforts has been limited. As we seek to broaden the market for BioThrax and if we receive marketing approval for additional products, we expect that we will increase our spending for marketing and sales activities.

#### Total other income (expense)

Total other income (expense) consists principally of interest income and interest expense. We earn interest on our cash, cash equivalents and short-term investments, and we incur interest expense on our indebtedness. Our net interest expense will increase in future periods as compared to prior periods as a result of the mortgage loan that we entered into in April 2006 and any borrowings under our revolving line of credit. In addition, some of our existing debt arrangements provide for increasing amortization of principal payments in future periods. See "Liquidity and capital resources — Debt financing" for additional information.

# Results of operations

# Three months ended March 31, 2006 compared to three months ended March 31, 2005

#### Revenues

Product sales revenues, which relate only to the biodefense segment, decreased by \$2.6 million, or 17%, to \$12.2 million for the three months ended March 31, 2006 from \$14.8 million for the three months ended March 31, 2005. This decrease in product sales revenues was due to the timing of fulfilling orders from the DoD and HHS. Product sales revenues in the three months ended March 31, 2006 consisted of BioThrax sales to HHS of \$11.6 million and sales to the Canadian government of \$630,000. We did not deliver any doses of BioThrax to the DoD in the three months ended March 31, 2006. As required by our current contract with the DoD, we anticipate delivering approximately 1.0 million doses of BioThrax to the DoD before expiration of this contract in September 2006. Product sales revenues in the three months ended March 31, 2005 consisted exclusively of BioThrax sales to the DoD. Because we did not enter into our supply contract with HHS until May 2005, we had no sales to HHS in the three months ended March 31, 2005. We began delivering BioThrax to HHS in May 2006 under our recent contract modification.

Milestone and grant revenues decreased by \$453,000, or 94%, to \$27,000 for the three months ended March 31, 2006 from \$480,000 for the three months ended March 31, 2005. Milestone and grant revenue for the three months ended March 31, 2005 resulted from reimbursement from the DoD for expenses related to production development and supply chain management improvements for BioThrax incurred in prior periods.

#### Cost of product sales

Cost of product sales, which relate only to the biodefense segment, consists of expenses incurred in the manufacture of BioThrax. Cost of product sales decreased by \$1.3 million, or 31%, to \$2.9 million for the three months ended March 31, 2006 from \$4.1 million for the three months ended March 31, 2005. This decrease was attributable to the delivery of 141,000 fewer doses of BioThrax in the three months ended March 31, 2006 and improved utilization of our manufacturing capacity for BioThrax as a result of extending the hours of operation for our manufacturing facility. The reduction in the number of doses delivered resulted in a cost savings of approximately \$2.00,000. Manufacturing efficiencies resulted in a cost savings of approximately \$1.0 million.

# Research and development expenses

Research and development expenses increased by \$6.3 million to \$8.2 million for the three months ended March 31, 2006 from \$1.9 million for the three months ended March 31, 2005. This increase reflects increased expenses of \$3.9 million in the biodefense segment and \$2.9 million in the commercial segment, offset by a reduction of \$407,000 in other research and development expenses.

The increase in biodefense spending was attributable to increased efforts on all our biodefense programs as we completed various studies and began subsequent studies and trials. The increase in spending for BioThrax enhancements related to preparing for animal efficacy studies to support applications for marketing approval of these enhancements, which we expect to submit to the FDA later in 2006 and in 2007. The increase in spending for immune globulin development related primarily to costs associated with our plasma donor stimulation program for our anthrax immune globulin candidate. The increase in spending for the recombinant botulinum vaccine and next generation anthrax vaccine programs, both of which are in preclinical development, resulted from advancing these programs to the process development stage and the manufacture of supplies of product candidates required for clinical development.

The increase in commercial spending was mainly attributable to spending on the commercial products listed in the table below following our acquisition of Microscience in June 2005. Research and development spending by Microscience is not included in our results for the three months ended March 31, 2005. The spending in the three months ended March 31, 2006 for our typhoid vaccine candidate resulted from ongoing work for the Phase I clinical trial in Vietnam that we recently completed and preparing for our Phase II clinical trial in Vietnam that we plan to initiate in the fourth quarter of 2006. The spending in the three months ended March 31, 2006 for our hepatitis B therapeutic vaccine candidate resulted from preparing for our Phase II clinical trial that we plan to initiate in the second half of 2006. The spending in the three months ended March 31, 2006 for our group B streptococcus vaccine candidate resulted from costs associated with our analysis of results from the Phase I clinical trial that we recently completed for one of the protein components of the vaccine candidate and preparation for Phase I clinical trials for the two other protein components of the vaccine candidate. Both our chlamydia vaccine and meningitis B vaccine candidates are in preclinical development.

The decrease in spending on other research and development expenses was attributable to our discontinuation of preclinical programs that we acquired from Antex and determined not to pursue.

Our principal research and development expenses for the three months ended March 31, 2005 and 2006 are shown in the following table:

		Three mo	nths ended March 31,
(in thousands)	2005		2006
Biodefense:			
BioThrax enhancements	\$ 432	\$	1,364
Immune globulin development	558		2,733
Recombinant bivalent botulinum vaccine	186		497
Next generation anthrax vaccine	47		497
Total biodefense	 1,223		5,091
Commercial:			
Typhoid vaccine	_		605
Hepatitis B therapeutic vaccine	_		638
Group B streptococcus vaccine	_		997
Chlamydia vaccine	91		442
Meningitis B vaccine	 _		269
Total commercial	91		2,951
Other	 538		131
Total	\$ 1,852	\$	8,173

# Selling, general and administrative expenses

Selling, general and administrative expenses increased by \$1.7 million, or 20%, to \$10.6 million for the three months ended March 31, 2006 from \$8.8 million for the three months ended March 31, 2005. Selling, general and administrative expenses related to the biodefense segment increased by \$1.5 million to \$8.9 million for the three months ended March 31, 2006 from \$7.4 million for the three months ended March 31, 2005. Selling, general and administrative expenses related to the commercial segment increased by \$237,000 to \$1.7 million for the three months ended March 31, 2006 from \$1.4 million for the three months ended March 31, 2005. The increase in the biodefense segment was attributable to an increase in general and administrative expenses of \$1.2 million resulting from the addition of personnel for our headquarters organization who devoted time to the biodefense segment and an increase in sales and marketing expenses of \$280,000. The increase in the commercial segment was primarily attributable to an increase in general and administrative expenses of \$232,000 resulting from the addition of personnel and facilities for Emergent Product Development UK.

# Total other income (expense)

Total other income increased by \$165,000 to \$40,000 for the three months ended March 31, 2006 from a loss of \$125,000 for the three months ended March 31, 2005. The increase resulted principally from an increase in interest income of \$126,000 as a result of increased average cash balances and a decrease in interest expense of \$19,000.

#### Income taxes

We recorded a benefit from income taxes of \$4.7 million for the three months ended March 31, 2006 compared to a provision for income taxes of \$76,000 for the three months ended March 31, 2005. The benefit from income taxes for the three months ended March 31, 2006 resulted primarily from our loss before benefit from income taxes of \$9.4 million and an estimated effective annual tax rate of 50%. The provision for income taxes for the three months ended March 31, 2005 resulted primarily from our income before provision for income taxes of \$300,000 and an estimated effective annual tax rate of 25%. The increase in the estimated effective annual tax rate by 25% is due primarily to an increase in the valuation allowance related to foreign and state net operating losses. While the net operating losses for foreign and state jurisdictions have been recorded as deferred tax assets, a full valuation allowance also has been recorded due to current uncertainty as to whether we will generate sufficient future taxable income in the applicable jurisdictions to fully utilize these net operating losses.

# Year ended December 31, 2005 compared to year ended December 31, 2004

#### Revenues

Product sales revenues increased by \$46.3 million, or 57%, to \$127.3 million for 2005 from \$81.0 million for 2004. Product sales revenues in 2005 consisted of BioThrax sales to HHS of \$111.2 million, sales to the DoD of \$14.5 million and aggregate sales to the governments of Canada and Taiwan of \$1.6 million. Product sales revenues in 2004 consisted of BioThrax sales to the DoD of \$80.6 million and sales to the Canadian government of \$360,000.

Milestone and grant revenues increased by \$937,000, or 38%, to \$3.4 million in 2005 from \$2.5 million in 2004 primarily as a result of additional work that we performed on a project basis for the DoD's Defense Advanced Research Projects Agency, or DARPA, to evaluate a new vaccine adjuvant for BioThrax.

# Cost of product sales

Cost of product sales increased by \$1.5 million, or 5%, to \$31.6 million for 2005 from \$30.1 million for 2004. This increase was attributable to the delivery of 1.8 million additional doses of BioThrax in 2005 and a decrease in production yield, resulting in a higher average manufacturing cost per dose in 2005, offset by improved utilization of our manufacturing capacity for BioThrax as a result of extending the hours of operation for our manufacturing facility. The increase in the number of doses delivered combined with the decrease in production yield resulted in additional costs of \$6.6 million. Manufacturing efficiencies resulted in a cost savings of \$5.1 million.

# Research and development expenses

Research and development expenses increased by \$8.3 million, or 82%, to \$18.4 million for 2005 from \$10.1 million for 2004. This increase reflects increased expenses of \$4.0 million in the biodefense segment and \$5.8 million in the commercial segment, offset by a reduction of \$1.6 million in other research and development expenses.

The increase in biodefense spending resulted from costs associated with our plasma donor stimulation program for our anthrax immune globulin candidate, process development related to our recombinant botulinum vaccine candidate and evaluation of third party technology related to our next generation anthrax vaccine program for potential acquisition or in-license, offset by decreased spending on BioThrax enhancements. In 2004, the immune globulin program was in initial studies and we had not yet begun work on the recombinant botulinum vaccine and next generation anthrax vaccine candidates. The

decrease in spending on BioThrax enhancements resulted from substantial completion during 2004 of research regarding manufacturing process development for BioThrax to improve the stability and consistency of production lots.

The increase in spending in the commercial segment was attributable to spending on the commercial programs listed in the table below following our acquisition of Microscience in June 2005. Research and development spending by Microscience is not included in our results prior to the acquisition date. The commercial spending in 2005 resulted from the Phase I clinical trial in Vietnam for our typhoid vaccine candidate, preparation for a planned Phase II clinical trial for our hepatitis B therapeutic vaccine candidate, including the manufacture of clinical trial material, preparation for one of three planned Phase I clinical trials related to one of the protein components of our group B streptococcus vaccine candidate and preclinical work for our chlamydia vaccine and meningitis B vaccine candidates.

The decrease in spending on other research and development expenses was attributable to our discontinuation of preclinical programs that we acquired from Antex and determined not to pursue.

Our principal research and development expenses for 2004 and 2005 are shown in the following table:

		Year ended December 31,
(in thousands)	2004	2005
Biodefense:		
BioThrax enhancements	\$ 5,929	\$ 2,883
Immune globulin development	350	5,309
Recombinant bivalent botulinum vaccine	_	1,708
Next generation anthrax vaccine	_	427
Total biodefense	6,279	10,327
Commercial:		
Typhoid vaccine	_	1,477
Hepatitis B therapeutic vaccine	_	1,558
Group B streptococcus vaccine	_	2,433
Chlamydia vaccine	1,136	837
Meningitis B vaccine	_	656
Total commercial	 1,136	6,961
Other	2,702	1,093
Total	\$ 10,117	\$ 18,381

# Selling, general and administrative expenses

Selling, general and administrative expenses increased by \$12.5 million, or 41%, to \$42.8 million for 2005 from \$30.3 million for 2004. Selling, general and administrative expenses related to our biodefense segment increased by \$6.4 million to \$35.4 million for 2005 from \$29.0 million for 2004. Selling, general and administrative expenses related to our commercial segment increased by \$6.0 million to \$7.3 million for 2005 from \$1.3 million for 2004. The increase in the biodefense segment was attributable to an increase in general and administrative expenses of \$5.5 million resulting from the addition of personnel

for our headquarters organization who devoted time to the biodefense segment and an increase in sales and marketing expenses of \$1.0 million resulting from the addition of sales personnel to investigate potential other markets for BioThrax. The increase in the commercial segment was attributable to an increase in general and administrative expenses of \$5.3 million resulting from the addition of personnel for our European subsidiary and legal expenses associated with reorganizing our corporate structure following our acquisition of Microscience in June 2005.

#### Purchased in-process research and development

In 2005, we recorded a non-cash charge of \$26.6 million associated with our acquisition of Microscience. We valued the 1,264,051 shares of class A common stock that we issued in the acquisition at \$28.2 million after the inclusion of acquisition costs. Of this amount, we identified \$1.4 million as current assets, \$0.9 million as fixed assets, \$0.7 million as current liabilities and \$26.6 million as the value attributable to development programs. Because we determined that the development programs had no future alternative use, we charged the value attributable to the development programs as purchased in-process research and development. We will amortize this charge for tax purposes over 15 years.

# Litigation settlement

In 2005, we recorded a gain of \$10.0 million relating to a settlement of a litigation matter that we initiated to resolve a contract and intellectual property dispute. There were no settlements in 2004.

#### Total other income (expense)

Total other expense increased by \$57,000 to \$227,000 for 2005 from \$170,000 for 2004. This increase resulted primarily from an increase in interest expense associated with our financing of the acquisition costs for one building at our Frederick facility.

#### Income taxes

Provision for income taxes increased by \$196,000, or 4%, to \$5.3 million for 2005 from \$5.1 million for 2004. The provision for income taxes for 2005 resulted primarily from our income before provision for income taxes of \$21.1 million and an effective annual tax rate of 25%. The provision for income taxes for 2004 resulted primarily from our income before provision for income taxes of \$16.6 million and an effective annual tax rate of 31%. The provision for income taxes also reflects research and development tax credits of \$474,000 for 2005 and \$492,000 for 2004 and small amounts of permanent tax differences in each year.

# Year ended December 31, 2004 compared to year ended December 31, 2003

#### Revenues

Product sales revenues increased by \$25.5 million, or 46%, to \$81.0 million for 2004 from \$55.5 million for 2003. Product sales revenues in 2004 consisted of BioThrax sales to the DoD of \$80.6 million and sales to the Canadian government of \$360,000. Product sales revenues in 2003 consisted of BioThrax sales to the DoD of \$55.2 million and sales to the Canadian government of \$270,000.

Milestones and grant revenues increased to \$2.5 million in 2004 from \$233,000 in 2003 primarily as a result of additional work that we performed on a project basis for DARPA to evaluate a new vaccine adjuvant for BioThrax.

#### Cost of product sales

Cost of product sales increased by \$7.8 million, or 35%, to \$30.1 million for 2004 from \$22.3 million for 2003. This increase was attributable to the delivery of 1.0 million additional doses of BioThrax in 2004. We were able to deliver these additional doses as a result of increasing our manufacturing capacity at our Lansing facility in 2004 by extending the hours of operation of the facility. The increase in the number of doses delivered resulted in additional costs of \$3.5 million. Increasing manufacturing capacity resulted in additional costs of \$4.3 million, primarily for the training of new personnel. Our increase in manufacturing capacity allowed us to spread our fixed manufacturing costs over a greater number of doses, which resulted in a decrease in the cost of product sales per dose of BioThrax in 2004 compared to 2003.

#### Research and development expenses

Research and development expenses increased by \$3.8 million, or 60%, to \$10.1 million for 2004 from \$6.3 million for 2003. This increase reflects increased expenses of \$1.9 million in the biodefense segment and \$1.8 million in the commercial segment. The increase in the biodefense segment was attributable to work on the initiation of programs for BioThrax enhancements. The increase in the commercial segment was attributable to spending on commercial product candidates acquired from Antex in May 2003. Research and development spending by Antex is not included in our results prior to the acquisition date.

#### Selling, general and administrative expenses

Selling, general and administrative expenses increased by \$10.8 million, or 55%, to \$30.3 million for 2004 from \$19.5 million for 2003. Selling, general and administrative expenses related to the biodefense segment increased by \$9.5 million to \$29.0 million for 2004 from \$19.5 million for 2003. This increase was attributable to growth in corporate staff to support expanding business activity. Selling, general and administrative expenses related to the commercial segment increased by \$1.3 million for 2004 from an immaterial amount for 2003 as we hired additional employees to support the newly acquired Antex operations. The overall increase in selling, general and administrative expenses was primarily attributable to an increase of \$7.0 million in general and administrative expenditures as a result of our corporate reorganization in June 2004 and the formation of our headquarters organization, including a non-cash stock-based compensation charge of \$4.3 million. In addition, general and administrative expenses increased \$1.1 million as a result of our acquisition of assets from Antex. Selling and marketing expense increased to \$843,000 for 2004 from an immaterial amount for 2003. This increase in spending resulted from the addition of personnel and outside consulting fees.

### Purchased in-process research and development

In 2003, we recorded a non-cash charge of \$1.8 million associated with our acquisition of assets from Antex. The purchase consideration was \$3.4 million in cash. We valued the transaction at \$3.8 million after the inclusion of acquisition costs. Of this amount, we identified \$300,000 as current assets, \$1.7 million as fixed assets and \$1.8 million as the value attributable to development programs. Because we determined that the development programs had no future alternative use, we charged the value attributable to the development programs as purchased in-process research and development. We will amortize this charge for tax purposes over 15 years.

# Settlement of State of Michigan obligation

In 2004, we recorded a gain of \$3.8 million from the satisfaction for less than originally estimated of an obligation to the State of Michigan related to our acquisition of assets from the Michigan Biologic Products Institute in 1998. We have no ongoing obligations to the State of Michigan related to our acquisition of assets from the Michigan Biologic Products Institute. There was no settlement of obligations in 2003.

#### Total other income (expense)

Total other expense, net, increased to \$170,000 for 2004 from \$25,000 for 2003. The increase resulted principally from a decrease in other income of \$162,000.

#### Income taxes

Provision for income taxes increased by \$3.9 million to \$5.1 million for 2004 from \$1.3 million for 2003. The provision for income taxes for 2004 resulted primarily from our income before provision for income taxes of \$16.6 million and an effective annual tax rate of 31%. The provision for income taxes for 2003 resulted primarily from our income before provision for income taxes of \$5.7 million and an effective annual tax rate of 22%. The provision for income taxes also reflects research and development tax credits of \$492,000 for 2004 and \$441,000 for 2003 and small amounts of permanent tax differences in each year.

# Liquidity and capital resources

# Sources of liquidity

We require cash to meet our operating expenses and for capital expenditures, acquisitions and principal and interest payments on our debt. We have funded our cash requirements from inception through March 31, 2006 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases and, to a lesser extent, from the sale of our class B common stock upon exercise of stock options. We have operated profitably for each of the years in the three year period ended December 31, 2005 and incurred a loss in the three months ended March 31, 2006. As of March 31, 2006, we had cash and cash equivalents of \$14.8 million.

#### Cash flows

The following table provides information regarding our cash flows for the years ended December 31, 2003, 2004 and 2005 and the three months ended March 31, 2005 and March 31, 2006.

			Year end	ded Dec	ember 31,	Three months ended March 3				
(in thousands)	·	2003	2004		2005		2005		2006	
Net cash provided by (used in):										
Operating activities(1)	\$	11,072	\$ 9,196	\$	41,974	\$	(1,313)	\$	(18,277)	
Investing activities		(7,917)	(18,175)		(5,841)		(379)		(2,853)	
Financing activities		(927)	8,681		(6,660)		(138)		(390)	
Total net cash provided (used)	\$	2,228	\$ (298)	\$	29,473	\$	(1,830)	\$	(21,520)	

<sup>(1)</sup> Includes the effect of exchange rate changes on cash and cash equivalents.

Net cash used in operating activities of \$18.2 million in the three months ended March 31, 2006 resulted principally from our net loss of \$4.6 million, an increase in inventories of \$4.7 million, reflecting the value of work in process for BioThrax lots being manufactured or awaiting delivery, and a non-cash benefit from income taxes of \$6.6 million, reflecting our net loss before provision for income taxes for the period.

Net cash used in operating activities of \$1.3 million in the three months ended March 31, 2005 resulted principally from a reduction in deferred revenue of \$10.9 million, reflecting the delivery to the DoD of BioThrax lots for which we had previously invoiced the DoD for progress payments, and an increase in inventories of \$4.3 million, reflecting the value of work in process for BioThrax lots being manufactured or awaiting delivery, offset by a decrease in accounts receivable of \$13.6 million as a result of the collection of amounts due from the DoD for invoices previously issued for progress in the manufacture of BioThrax lots.

Net cash provided by operating activities of \$42.3 million in 2005 resulted principally from our net income of \$15.8 million, a non-cash charge for purchased in-process research and development relating to the Microscience acquisition, which reduced net income by \$26.6 million, and a reduction of accounts receivable of \$16.1 million as a result of the collection of amounts due from the DoD during 2005 for invoices issued at the end of 2004 for progress in the manufacture of BioThrax lots, offset by a reduction of deferred revenue of \$10.9 million, reflecting the delivery to the DoD in the first quarter of 2005 of BioThrax lots for which we had previously invoiced the DoD for progress payments and an increase in deferred tax assets of \$11.0 million, reflecting the purchased in-process research and development expense related to the Microscience acquisition.

Net cash provided by operating activities of \$9.2 million in 2004 resulted principally from our net income of \$11.5 million, a non-cash stock based compensation charge that we incurred as a result of our issuance of new stock options in our corporate reorganization in June 2004, which reduced net income by \$4.3 million, a provision for income taxes of \$5.8 million, reflecting our net income before provision for income taxes for the year, and an increase in deferred revenue of \$3.9 million, reflecting invoices to the DoD for progress payments for the manufacture of BioThrax lots, offset by an increase in accounts receivable of \$15.7 million, reflecting invoices for amounts due from the DoD for progress in the manufacture of BioThrax lots, and a one-time non-cash gain of \$3.8 million resulting from the satisfaction of an obligation to the State of Michigan for less than originally estimated.

Net cash provided by operating activities of \$11.1 million in 2003 resulted principally from our net income of \$4.5 million and an increase of \$11.9 million in deferred revenue reflecting invoices to the DoD for progress payments for the manufacture of BioThrax lots, offset by an increase in inventories of \$4.7 million reflecting the timing of deliveries to the DoD.

Net cash used in investing activities in the three months ended March 31, 2006 and 2005 and in 2005, 2004 and 2003 resulted principally from the purchase of property, plant and equipment. Capital expenditures in the three months ended March 31, 2006 relate primarily to costs for construction of our new building in Lansing, Michigan. Capital expenditures in 2005 were primarily attributable to investments in information technology upgrades and miscellaneous facility enhancements. Capital expenditures in 2004 include infrastructure investments in our facilities in Lansing and an enterprise resource planning system totaling \$8.5 million and cash used to purchase one of our facilities in Frederick, Maryland totaling \$9.7 million. Capital expenditures in 2003 include infrastructure investments in our Lansing facilities. Net cash used in investing activities in 2003 also includes cash of \$3.8 million used for the acquisition of assets from Antex.

Net cash used in financing activities of \$390,000 in the three months ended March 31, 2006 and \$138,000 in the three months ended March 31, 2005 resulted principally from the repayment of notes payable to employees and the repurchase of class B common stock.

Net cash used in financing activities of \$6.7 million in 2005 resulted principally from the payment of a special dividend of \$5.4 million from a portion of the proceeds of a litigation settlement and the repayment of notes payable to employees.

Net cash provided by financing activities of \$8.7 million in 2004 resulted principally from an increase in notes payable as a result of \$11.0 million of total debt incurred to finance the purchase of one of our facilities in Frederick, Maryland and to finance the purchase of an enterprise resource planning system, offset by the repayment of non-recurring royalty and product supply obligations to the State of Michigan of \$2.4 million.

Net cash used in financing activities of \$927,000 in 2003 resulted primarily from the repayment of royalty and product supply obligations to the State of Michigan.

# Contractual obligations

The following table summarizes our contractual obligations at March 31, 2006.

						Pa	ymen	ts due by period
(in thousands)	 Total	2006	2007	2008	2009	2010		After 2010
Contractual obligations(1):								
Short and long-term debt(2)	\$ 13,844	\$ 1,587	\$ 1,479	\$ 349	\$ 816	\$ 815	\$	8,798
Operating lease obligations	3,785	1,292	1,249	1,188	56	_		_
Contractual settlement liabilities	 200	100	100	_	_	_		
Total contractual obligations	\$ 17,829	\$ 2,979	\$ 2,828	\$ 1,537	\$ 872	\$ 815	\$	8,798

- (1) Does not include contingent royalties and milestone payments.
- (2) Includes scheduled interest payments, net of capitalization of interest estimates related to construction in progress on long term construction of fixed assets.

#### Debt financing

As of July 31, 2006, we had \$19.5 million principal amount of debt outstanding, comprised primarily of the following:

- \$2.5 million outstanding under a forgivable loan from the Department of Business and Economic Development of the State of Maryland used to finance eligible costs incurred to purchase one of our facilities in Frederick, Maryland;
- \$7.0 million outstanding under a mortgage loan from Mercantile Potomac Bank used to finance the remaining portion of the purchase price for the Frederick facility;
- \$8.5 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance the purchase price for a second facility on the Frederick site; and
- \$1.4 million outstanding under a term loan from Fifth Third Bank used to finance the purchase of an enterprise resource planning system.

We also have a revolving line of credit for up to \$10.0 million with Fifth Third Bank. We can borrow under the line of credit through October 1, 2006.

Some of these debt instruments contain financial and operating covenants. In particular:

- Under our mortgage loan from Mercantile Potomac Bank for our Frederick facility, we are required to maintain at all times a minimum tangible net worth, on a consolidated basis, of not less than \$5.0 million and a ratio of earnings before interest, taxes, depreciation and amortization to the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable within the following 12 months, of not less than 1.1 to 1.0.
- Under our forgivable loan from the State of Maryland, we are not required to repay the principal amount of the loan if beginning December 31, 2009 and
  through 2012 we maintain a specified number of employees at the Frederick site, by December 31, 2009 we have invested at least \$42.9 million in total
  funds toward financing the purchase of the buildings on the site and for related improvements and operation of the facility and we occupy the facility
  through 2012.
- Under our line of credit with Fifth Third Bank, we are required to maintain at all times a ratio of total liabilities to tangible net worth of not more than 2.5 to 1.0.

Our debt instruments also contain negative covenants restricting our activities. In particular, our line of credit with Fifth Third Bank limits our ability to incur indebtedness and liens, sell assets, make loans or advances, enter into transactions with affiliates and amend the terms of any government contract.

The facilities and software and other equipment that we purchased with the proceeds of our loans from Mercantile Potomac Bank, the State of Maryland, HSBC Realty Credit Corporation and Fifth Third Bank serve as collateral for these loans. Our line of credit with Fifth Third Bank is secured by accounts receivable under our DoD and HHS contracts. The covenants under our existing debt instruments and the pledge of our existing assets as collateral limit our ability to obtain additional debt financing.

Under our mortgage loan from Mercantile Potomac Bank, we are required to make monthly principal payments beginning in November 2006. A residual principal repayment of approximately \$5.0 million is due in October 2011. Under our HSBC mortgage loan, we are required to make monthly principal payments. A residual principal repayment of approximately \$7.5 million is due in April 2011. Under our loan from Fifth Third Bank, we make monthly principal payments through September 2007.

#### Tax benefits

In connection with our facility expansion in Lansing, the State of Michigan and the City of Lansing have provided us a variety of tax credits and abatements. We estimate that the total value of these tax benefits may be up to \$18.5 million over a period of up to 15 years. These tax benefits are based on our \$75 million planned additional investment in our Lansing facilities. In addition, we must maintain a specified number of employees in Lansing to continue to qualify for these tax benefits.

## Funding requirements

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, revenues from BioThrax product sales and other committed sources of funds, will be sufficient to enable us to fund our anticipated operating expenses and capital expenditure and debt service requirements for at least the next 24 months. We have based this estimate on assumptions that may prove to be wrong. There are numerous risks and uncertainties associated with BioThrax product sales and with the development and commercialization of our product candidates. Our only committed external sources of funds are remaining borrowing availability under our revolving line of credit with Fifth Third Bank, development funding under our collaboration agreement with Sanofi Pasteur and funding from the Wellcome Trust for our Phase II clinical trial of our typhoid vaccine candidate in Vietnam. Our ability to

borrow additional amounts under our loan agreements is subject to our satisfaction of specified conditions. Our future capital requirements will depend on many factors, including:

- the level of BioThrax product sales and cost of product sales;
- · the timing of, and the costs involved in, constructing our new manufacturing facility in Lansing, Michigan and the build out of our manufacturing facilities in Frederick, Maryland;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, other product candidates that we may pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- · the extent to which we acquire or invest in businesses, products and technologies; and
- our ability to establish and maintain collaborations, such as our collaboration with Sanofi Pasteur.

We may require additional sources of funds for future acquisitions that we may make or, depending on the size of the obligation, to meet balloon payments upon maturity of our current borrowings. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements.

Additional equity or debt financing, grants, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to

# Quantitative and qualitative disclosures about market risk

Our exposure to market risk is currently confined to our cash and cash equivalents and restricted cash that have maturities of less than three months. We currently do not hedge interest rate exposure. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments, but may increase the interest expense associated with our debt.

## Effects of inflation

Our most liquid assets are cash, cash equivalents and short-term investments. Because of their liquidity, these assets are not directly affected by inflation. We also believe that we have intangible assets in the

value of our intellectual property. In accordance with generally accepted accounting principles, we have not capitalized the value of this intellectual property on our balance sheet. Due to the nature of this intellectual property, we believe that these intangible assets are not affected by inflation. Because we intend to retain and continue to use our equipment, furniture and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

# Recent accounting pronouncements

In June 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections, a replacement of APB Opinion No. 20, Accounting Changes, and FASB Statement No. 3, Reporting Accounting Changes in Interim Financial Statements, or SFAS No. 154. SFAS No. 154 requires retrospective application to prior periods' financial statements for all voluntary changes in accounting principle, unless impracticable. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. SFAS No. 154 will have no immediate impact on our consolidated financial statements, though it would impact our presentation of future voluntary accounting changes, should such changes occur.

In June 2005, the EITF reached consensus on EITF Issue 05-06, *Determining the Amortization Period for Leasehold Improvements Purchased after Lease Inception or Acquired in a Business Combination*, or EITF 05-06. EITF 05-06 provides that leasehold improvements acquired in a business combination should be amortized over the lesser of the useful life of the assets or a term that includes renewals that are reasonably assured at the date of acquisition. The EITF also concluded that leasehold improvements placed in service significantly after and not contemplated at or near the beginning of the lease term should be amortized over the lesser of the useful life of the assets or a term that includes renewals that are reasonably assured at the date the leasehold improvements are purchased. EITF 05-06 is effective prospectively for leasehold improvements purchased or acquired in periods beginning after June 29, 2005. We do not believe that the adoption of this new standard will have a material impact on our financial position.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*, an amendment of Accounting Research Bulletin No. 43, Chapter 4, or SFAS No. 151. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not believe the adoption of SFAS No. 151 will have a material impact on our financial position for the year ending December 31, 2005. We have adopted this policy effective January 1, 2006.

In June 2006, the FASB also issued FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB Statement No. 109, *Accounting for Income Taxes*, or FIN 48. FIN 48 clarifies the accounting for uncertainty in income taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 requires that we recognize in the financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. We are currently evaluating the impact of adopting FIN 48 on our financial statements.

# **Business**

## Overview

We are a biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics. Immunobiotics are pharmaceutical products, such as vaccines and immune globulins that induce or assist the body's immune system to prevent or treat disease. We operate in two business segments: biodefense and commercial. In our biodefense business, we develop and commercialize immunobiotics for use against biological agents that are potential weapons of bioterrorism. In our commercial business, we develop immunobiotics for use against infectious diseases with significant unmet or underserved medical needs. Our marketed product, BioThrax, is the only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. In addition to BioThrax, our biodefense product portfolio includes three biodefense product candidates in preclinical development. Our commercial product portfolio includes a typhoid vaccine candidate and a hepatitis B therapeutic vaccine candidate, both of which are in Phase II clinical development, one vaccine candidate in Phase I clinical development and two vaccine candidates in preclinical development.

We manufacture and market BioThrax, also referred to as anthrax vaccine adsorbed, the only FDA approved anthrax vaccine. BioThrax was originally approved in the United States in 1970. There have been more than 20 published studies of the use of BioThrax in humans. In December 2005, based on a review of the human efficacy data used to support the approval of BioThrax and other studies of BioThrax, the FDA reaffirmed that BioThrax is safe and effective for the prevention of anthrax infection by all routes of exposure, including inhalation. Our total revenues from BioThrax sales were \$55.5 million in 2003, \$81.0 million in 2004 and \$127.3 million in 2005. The U.S. Department of Defense, or DoD, and the U.S. Department of Health and Human Services, or HHS, have been the principal customers for BioThrax. Under two contracts with the DoD, we have supplied over eight million doses of BioThrax through July 2006 for immunization of military personnel. Since March 1998, the DoD has vaccinated more than 1.5 million military personnel with more than 5.5 million doses of BioThrax. In April 2006, the DoD issued a notice that it intends to negotiate a sole source fixed price contract for the purchase of up to an additional 11 million doses of BioThrax over one base contract year plus four option years. Under a contract that we entered into with HHS in May 2005, we supplied five million doses of BioThrax to HHS for placement into the strategic national stockpile for a fixed price of \$123 million. In May 2006, we entered into a contract modification with HHS by May 2007 for a fixed price of \$120 million.

The September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks significantly affected political and budgetary attitudes toward the threat of bioterrorism. Following these attacks, the U.S. government enacted measures to provide incentives for private industry to develop and manufacture biodefense products. In particular, in 2004, the Project BioShield Act became law, providing \$5.6 billion in appropriations over ten years and authorizing the procurement of countermeasures for biological, chemical, radiological and nuclear attacks. Project BioShield provides for the procurement of countermeasures for anthrax and botulism, which are two of the biological agents that the Centers for Disease Control and Prevention, or CDC, has identified as the greatest possible threat to public health. The U.S. government procures most biodefense countermeasures through HHS, the CDC and the DoD and provides biodefense research and development funding through the National Institute of Allergy and Infectious Diseases, or NIAID, of the National Institutes of Health, or NIH, and the DoD.

In addition to BioThrax, we are developing three other biodefense immunobiotic product candidates, all of which are in preclinical development. These product candidates are:

· Anthrax immune globulin — for post-exposure treatment of anthrax infection;

- Botulinum immune globulin for post-exposure treatment of illness caused by botulinum toxin, which we are developing based on a new botulinum toxoid vaccine that we are developing in collaboration with the U.K. Health Protection Agency, or HPA; and
- · Recombinant bivalent botulinum vaccine a prophylaxis for illness caused by botulinum toxin, which we also are developing in collaboration with HPA.

We also are evaluating several potential product candidates in connection with development of a next generation anthrax vaccine, featuring attributes such as self-administration and a longer shelf life.

In our commercial business, we are developing a range of immunobiotic product candidates for use against infectious diseases with significant unmet or underserved medical needs. Our commercial product candidates in clinical development are:

- Typhoid vaccine a single dose, drinkable vaccine, for which we have completed a Phase I clinical program, including trials in the United States, the
  United Kingdom and Vietnam, and expect to initiate a Phase II clinical trial in Vietnam in the fourth quarter of 2006;
- Hepatitis B therapeutic vaccine a multiple dose, drinkable vaccine for treatment of chronic carriers of hepatitis B infection, for which we have completed a Phase I clinical trial in the United Kingdom and expect to initiate a Phase II clinical trial in the United Kingdom in the second half of 2006: and
- Group B streptococcus vaccine a multiple dose, injectable vaccine for administration to women of childbearing age for protection of the fetus and newborn babies, for which we have completed a Phase I clinical trial in the United Kingdom.

In addition, we are developing a chlamydia vaccine and a meningitis B vaccine, each of which is currently in preclinical development.

The Wellcome Trust provided funding for our Phase I clinical trial of our typhoid vaccine candidate in Vietnam and has agreed to provide funding for our Phase II clinical trial of this vaccine candidate in Vietnam. In May 2006, we entered into a license and co-development agreement with Sanofi Pasteur, the vaccines business of Sanofi-Aventis, under which we granted Sanofi Pasteur an exclusive, worldwide license under our proprietary technology to develop and commercialize a meningitis B vaccine candidate.

# Our strategy

Our goal is to become a worldwide leader in developing, manufacturing and commercializing immunobiotics that target diseases with significant unmet or underserved medical needs. Key elements of our strategy to achieve this goal are:

Maximize the commercial potential of BioThrax. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers and pursuing label expansions and improvements for BioThrax. The potential label expansions and improvements for BioThrax include an extension of shelf life, reductions in the number of required doses, addition of another method of administration and use as a post-exposure prophylaxis for anthrax infection in combination with antibiotic therapy.

Continue to develop a balanced portfolio of immunobiotic products. We seek to maintain a balanced product portfolio that includes both biodefense and commercial immunobiotic product candidates and both vaccines and therapeutics to diversify product development and commercialization risk. We use multiple technologies in our development programs, which we believe significantly reduces our risk in these activities. We expect that biodefense product candidates may generate revenues from product sales

sooner than commercial product candidates because of Project BioShield, which allows the U.S. government to purchase biodefense products for the strategic national stockpile before they are approved by the FDA.

Focus on core capabilities in product development and manufacturing. We focus our efforts on immunobiotic product development and manufacturing, which we believe are our core capabilities. This approach enables us to avoid the expense and time entailed in early stage research activities and, we believe, reduces product development and commercialization risk. We seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties. We believe that we have secured, and will be able to continue to secure, rights to a diverse product pipeline that targets diseases with significant unmet or underserved medical needs. We also believe that this approach may enable us to accelerate product development timelines through our preclinical and clinical development and regulatory expertise and manufacturing capabilities.

Build large scale manufacturing infrastructure. To augment our existing manufacturing capabilities, we are constructing a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus. We also own two buildings in Frederick, Maryland that we plan to build out as future manufacturing facilities. We are constructing our new facility in Lansing as a large scale commercial manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures. We anticipate that we will initiate large scale manufacturing of BioThrax at our new Lansing facility in 2008. We are constructing this facility to accommodate production of up to 40 million doses of BioThrax per year on a single production line, which we could expand for production of up to 80 million doses per year through the addition of a second production line. In comparison, our current facility has a maximum production capacity of approximately nine million doses of BioThrax per year.

Selectively establish collaborations. For each of our product candidates, we plan to evaluate the merits of retaining commercialization rights for ourselves or entering into collaboration arrangements with leading pharmaceutical or biotechnology companies or non-governmental organizations. We expect that we will selectively pursue collaboration arrangements in situations in which the collaborator has particular expertise or resources for the development or commercialization of our products and product candidates or to access particular markets. We recently entered into a collaboration with Sanofi Pasteur for our meningitis B vaccine candidate as we believe that the value of this vaccine candidate may be maximized if it is sold in combination with other vaccines offered by Sanofi Pasteur. We are currently collaborating with HPA for the development of both a new botulinum toxoid vaccine, which we plan to use to develop our botulinum immune globulin candidate, and our recombinant bivalent botulinum vaccine candidate, which has given us access to HPA's technology and manufacturing capabilities.

Seek governmental and other third party grants and support. The biodefense immunobiotic product candidates that we are developing are of significant interest to the U.S. and potentially other governments. The CDC currently is independently conducting a clinical trial to evaluate the administration of BioThrax in a regimen of fewer doses. In addition, the NIH has completed an independent animal efficacy study of BioThrax in combination with antibiotics as a post-exposure prophylaxis for anthrax infection. We believe that some of our commercial immunobiotic product candidates that may benefit people in the developing world are of interest to charitable and philanthropic organizations. The Wellcome Trust provided funding for our Phase I clinical trial of our typhoid vaccine candidate in Vietnam and has agreed to provide funding for our Phase II clinical trial of this vaccine candidate in Vietnam. We plan to encourage government entities and non-government and philanthropic organizations to continue to conduct studies of, and pursue other development efforts and provide development funding for, BioThrax and our product candidates.

## Market opportunity

We focus on the biodefense and commercial markets for immunobiotics.

#### The biodefense market

The biodefense market for immunobiotics has grown dramatically as a result of the increased awareness of the threat of global terror activity in the wake of the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. The letter attacks involved the delivery of mail contaminated with anthrax spores to government officials and members of the media in the United States. As a result of the letter attacks, 22 people became infected with anthrax, including 11 with inhalational anthrax, and five people died.

The U.S. government is the principal source of worldwide biodefense spending. Most U.S. government spending on biodefense programs results from procurement of countermeasures by HHS, the CDC and the DoD and development funding from NIAID and the DoD. The U.S. government is now the largest source of funding for academic institutions and biotechnology companies conducting biodefense basic research or developing novel vaccines and other immunobiotic therapeutics.

Department of Health and Human Services. In 2004, the Project BioShield Act became law. This statute provides \$5.6 billion in appropriations over ten years and authorizes the procurement of countermeasures for biological, chemical, radiological and nuclear attacks. Pursuant to Project BioShield, HHS has begun to procure vaccines and other products for a strategic national stockpile. The strategic national stockpile is a national repository of medical assets and countermeasures designed to provide state and local public health agencies with medical supplies needed to treat those affected by terrorist attacks, natural disasters, industrial accidents and other public health emergencies, such as a flu epidemic. Materials from the strategic national stockpile were deployed following both the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. We expect that HHS will procure supplies of vaccines for the strategic national stockpile on an ongoing basis and replenish the stockpile as the existing inventories reach the end of their shelf lives.

Pursuant to Project BioShield, the CDC has categorized bioterrorism agents into three categories from A to C based on the perceived risk of the agent to national security. The highest risk category is category A. The six agents that the CDC has classified as category A are anthrax, botulism, plague, smallpox, tularemia and viral hemorrhagic fevers. The Secretary of HHS has directed most of the BioShield procurement efforts and funding to date to category A agents. Under Project BioShield, the Secretary of HHS can contract to purchase countermeasures for the strategic national stockpile prior to FDA approval of the countermeasure in specified circumstances. To be eligible for purchase under these provisions, the Secretary of HHS must determine that there is sufficient and satisfactory clinical results or research data, including data, if available, from preclinical and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years, even though the product has not completed clinical trials and has not yet been approved by the FDA. Project BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA.

Members of Congress have proposed and may in the future propose legislation that expands the funding and coverage of Project BioShield. We believe that continued assessments of the threat that bioterrorism poses to the public health are likely to advance these legislative initiatives.

Centers for Disease Control. The U.S. Congress provides annual funding to the CDC for the procurement of medical assets and countermeasures for the strategic national stockpile. This appropriation funding supplements amounts available under Project BioShield for procurement of countermeasures. Congress provided funding to CDC of \$525 million in fiscal year 2006 and \$467 million in fiscal year 2005 for this purpose.

Department of Defense. The DoD procures biodefense immunobiotics that it administers primarily through the Military Vaccine Agency, or MilVax. MilVax administers various vaccination programs for military personnel, including vaccines for common infectious diseases, such as influenza, and vaccines to protect against specific bioterrorism threats, such as anthrax and smallpox. The DoD has included anthrax at the top of its biological threat list. The level of spending by the DoD for MilVax is a function of the size of the U.S. military and the approach of the DoD with respect to vaccine stockpile and use, particularly whether the DoD mandates that members of the military participate in vaccination programs. Absent a Presidential waiver or the informed consent of the recipient, the DoD is required to use FDA approved products, if available, and not investigational products under development, in MilVax vaccination programs. The DoD provides development funding for biodefense vaccines through its Joint Vaccine Acquisition Program.

National Institute of Allergy and Infectious Diseases. Beginning with fiscal year 2003, the U.S. Congress added approximately \$1.5 billion per year to the biodefense research funding budget for NIAID. In fiscal year 2004, NIAID awarded more than 700 research project grants for biodefense research. In fiscal year 2004, biodefense funding by NIAID totaled \$1.6 billion, which was more than one-third of NIAID's total budget.

There are also a number of potential additional customers for biodefense immunobiotics. These include:

- the U.S. Postal Service;
- foreign governments;
- state and local governments, which we expect will be interested in these products to protect first responders, such as police, fire and emergency medical personnel;
- multinational companies and non-governmental organizations; and
- hospitals

Although there have been minimal sales to these customers to date, we believe that they may comprise an important component of the overall biodefense market in the future.

#### The commercial market

Vaccines have long been recognized as a safe and cost-effective method for preventing infection caused by various bacteria and viruses. Because of an increased emphasis on preventative medicine in industrialized countries, vaccines are now well recognized as an important part of public health management strategies. According to Frost & Sullivan, a market research organization, from 2002 to 2005, annual worldwide vaccine sales increased from \$6.7 billion to \$9.9 billion, a compound annual growth rate of approximately 14%. Frost & Sullivan estimates that the worldwide sales of vaccines will grow at a compound annual rate of approximately 10.5% from 2005 through 2012. As of 2005, Frost & Sullivan estimates that approximately two-thirds of global vaccine sales were attributable to pediatric vaccines. In addition, vaccines sold in developed markets represented approximately 80% of worldwide

vaccine revenues. New vaccine technologies and a greater understanding of how disease-causing organisms, or pathogens, cause disease are leading to the introduction of new vaccine products. Moreover, while existing marketed vaccines generally are designed to prevent infections, new vaccine technologies have also led to a focus on the development of vaccines for therapeutic purposes. Potential therapeutic vaccines extend beyond infectious diseases to cancer, autoimmune diseases and allergies.

Most non-pediatric commercial vaccines are purchased and paid for, or reimbursed by, managed care organizations, other private health plans or public insurers or paid for directly by patients. With respect to some diseases affecting the public health generally, particularly in developing countries, public health authorities or nongovernmental, charitable or philanthropic organizations fund the cost of vaccines. According to Frost & Sullivan, public purchases of vaccines, including for immunization programs and government stockpiles, account for approximately 90% of the total volume of worldwide vaccine sales. Although accounting for only 10% of the total volume of worldwide vaccine sales, private market purchases of vaccines accounted for approximately 60% of total worldwide vaccine sales revenues in 2005.

## Scientific background

# The immune system

The immune system provides protection against pathogens, such as bacteria and viruses, through immune responses that are generated by a type of white blood cells known as lymphocytes. Immune responses that depend on lymphocyte recognition of components of pathogens, called antigens, have two important characteristics. First, these immune responses are specific, which means that lymphocytes recognize particular antigens on pathogens. Second, these immune responses induce memory so that when the antigen is encountered again, the immune response is enhanced. Generally, there are two types of specific immunity: humoral immunity and cell mediated immunity. Humoral immunity is provided by proteins, known as antibodies or immune globulins, that are produced by lymphocytes. Antibodies are effective in dealing with pathogens before the pathogens enter cells. Cell mediated immunity is provided by lymphocytes that generally deal with threats from cells that are already infected with pathogens by directly killing infected cells or interacting with other immune cells to initiate the production of antibodies or activate cells that kill and eliminate infected cells.

#### **Vaccines**

A vaccine is normally given to a healthy person as a prophylaxis in order to generate immune responses that will protect against future infection and disease caused by pathogens. Following vaccination, the immune system's memory of antigens presented by a vaccine allows for an immune response to be generated to a pathogen to provide protection against disease. Therapeutic vaccines also are being developed to strengthen or modify the immune response in patients already infected with bacterial and viral pathogens to clear the pathogens from their bodies. Without treatment, these patients can be subject to recurring bouts of the disease.

There are three basic types of vaccines: live attenuated vaccines, inactivated whole cell vaccines and subunit vaccines. Live attenuated vaccines are made from weakened, or attenuated, viruses or bacteria that are designed to mimic some of the early stages of infection without causing disease. Inactivated whole cell vaccines are made by growing the infectious organism in culture media or mammalian cells and then inactivating the organisms. Subunit vaccines are derived from individual antigens that can be purified and used as vaccines. Culture filtrate vaccines are a type of subunit vaccine. These vaccines are

based on components that are secreted by pathogens grown in a culture media and then purified by filtration of the culture media.

Live attenuated vaccines can produce stronger, longer lasting immunity than inactivated whole cell vaccines and often are effective after only a single dose. However, live attenuated vaccines are subject to safety concerns related to the risk that they may revert to the virulent form or cause disease in patients with weakened immune systems. Inactivated whole cell vaccines have been successfully developed for some pathogens, but large quantities of the infectious organism have to be grown to make the vaccine. This poses a safety risk for people involved in the manufacturing process and requires high levels of containment. Subunit vaccines generally produce fewer side effects than vaccines the whole organism, but often are not as immunogenic as inactivated whole cell or live attenuated vaccines. Adjuvants, which augment or enhance the immune responses to vaccine antiqens, are often used in combination with weaker antiqens, such as subunit vaccines.

Scientists have applied recombinant technology, which allows for the manipulation of the genetic material of pathogens, in the development of new live attenuated and subunit vaccines. For live attenuated vaccines, genes involved in virulence can be completely deleted from a pathogen so that the organism can no longer cause disease or revert to the virulent form. For subunit vaccines, the gene coding for the antigen can be isolated and moved into a harmless organism where it can be expressed at high levels and purified. In addition, scientists have used recombinant technology to develop vector systems to deliver multiple vaccine antigens from different disease-causing organisms in a single live attenuated vaccine by inserting genes coding for these antigens into the genetic material of the vector. Currently, the only recombinant vaccines approved by the FDA are those for the prevention of hepatitis B infection, including both stand-alone vaccines and combination vaccines that include the recombinant hepatitis B component. The only recombinant vaccines currently licensed by the European Medicines Agency for marketing in the European Union member states are several vaccines that contain recombinant hepatitis B and one vaccine that includes a recombinant cholera toxin B subunit. We believe that the primary application for recombinant technology in the vaccine field will be for the development of vaccines in situations in which other vaccine technologies have not been successful or in which recombinant technology permits vaccine production with a lower level of safety containment.

#### Immune globulins

Immune globulins are normally made by collecting plasma from individuals who have contracted or been vaccinated for a particular disease and whose plasma contains protective antibodies, known as IgG, generated by a humoral immune response to pathogen exposure or vaccination. These antibodies are isolated by fractionation of the plasma, purified and then administered intravenously to patients, providing an immediate protective effect. Because it normally takes several weeks to generate antibodies after vaccination, immune globulins are used in situations in which it is not possible to wait for active immunization to generate the protective immune response.

# **Products**

The following table summarizes key information about our marketed product, BioThrax, and our biodefense and commercial immunobiotic product candidates. We utilize a wide array of technologies to develop and manufacture our marketed product and product candidates, including conventional and recombinant technologies. For each development program, we select and apply the technology that we believe is best suited to address the particular disease based on our evaluation of factors such as safety, efficacy, manufacturing requirements, regulatory pathway and cost. We currently hold all commercial rights to BioThrax and all of our immunobiotic product candidates, other than our recombinant bivalent botulinum vaccine, for which HPA has the non-exclusive right to make, use and sell to meet public health requirements in the United Kingdom, and our meningitis B vaccine candidate that we are developing in collaboration with Sanofi Pasteur.

Immunobiotic	Therapeutic/ prophylactic	Stage of development	Status	Collaboration/external relationship
Illinunobiotic	propriyiactic	development	Status	relationship
<u>Biodefense</u>				
Anthrax				
BioThrax (anthrax vaccine adsorbed)	Prophylactic	FDA approved	Commercially marketed six dose regimen	
	Prophylactic	Post-approval label expansion	BLA supplement submitted for five dose regimen and intramuscular injection; CDC	CDC — independent clinical trial
			clinical trial ongoing	
	Prophylactic	Post-approval label	Single dose syringe development program	
	1 Tophlylactic	expansion	initiated	
DioThray (anthray vaccine absorbed)*	Post-exposure prophylactic	Post-approval label	Plan to file IND in 2006; two proof-of-concept	
BioThrax (anthrax vaccine absorbed)*	Post-exposure propriyiactic	expansion	animal studies completed	
	··		D	
Anthrax immune globulin*	Therapeutic	Preclinical	Plasma donor stimulation program ongoing; animal efficacy studies planned; plan to file	
			IND in late 2006 or early 2007	
Botulinum				
Recombinant bivalent botulinum vaccine*	Prophylactic	Preclinical	Proof-of-concept animal study completed	HPA — collaboration
vaccine				
Botulinum immune globulin*	Therapeutic	Preclinical	Proof-of-concept animal studies planned	HPA — collaboration for development of a new botulinum toxoid vaccine

<sup>\*</sup> We currently intend to rely on the FDA animal rule in seeking marketing approval for these product candidates. Under the animal rule, if human efficacy trials are not ethical or feasible, the FDA can approve drugs or biologics used to treat or prevent serious or life threatening conditions caused by exposure to lethal or permanently disabling toxic chemical, biological, radiological or nuclear substances based on human clinical data demonstrating safety and immunogenicity and evidence of efficacy from appropriate non-clinical animal studies and any additional supporting data. For more information about the FDA animal rule, see \*— Government regulation — Clinical trials.\*

Immunobiotic	Therapeutic/ prophylactic	Stage of development	Status	Collaboration/external relationship
Commercial				
<u>oommerciai</u>				
Typhoid vaccine	Prophylactic	Phase II	Phase I clinical trial in Vietnam completed; plan to initiate Phase II clinical trial in Vietnam in the fourth quarter of 2006	Wellcome Trust — funding for Phase I and Phase II clinical trials in Vietnam
Hepatitis B therapeutic vaccine	Therapeutic	Phase II	Phase I clinical trial in the United Kingdom completed; clinical trial application approved in the United Kingdom for a Phase II clinical trial	
Group B streptococcus vaccine	Prophylactic	Phase I	One Phase I clinical trial in the United Kingdom completed; two additional Phase I clinical trials planned	
Chlamydia vaccine	Prophylactic	Preclinical	Proof-of-concept animal study completed	
Meningitis B vaccine	Prophylactic	Preclinical	Antigen identification completed	Sanofi Pasteur — collaboration

## **Biodefense business**

In our biodefense business, we are developing and commercializing immunobiotics for use against biological agents that are potential weapons of bioterrorism. Our marketed product, BioThrax, is the only vaccine approved by the FDA for the prevention of anthrax infection. In addition to BioThrax, our biodefense product portfolio includes three product candidates in preclinical development. We are developing all of our biodefense product candidates to address category A biological agents, which are the class of biological agents that the CDC has identified as the greatest possible threat to public health.

# BioThrax (anthrax vaccine adsorbed)

Anthrax overview. Anthrax is a potentially fatal disease caused by the spore forming bacterium *Bacillus anthracis*. Anthrax bacteria are naturally occurring and spores are found in soil throughout the world. Anthrax spores can withstand extreme heat, cold and drought for long periods without nutrients or air. Anthrax infections occur if the spores enter the body through a cut, abrasion or open sore, referred to as cutaneous anthrax, or by ingestion or inhalation of the spores. Once inside the body, anthrax spores germinate into bacteria that then multiply. Anthrax bacteria secrete three toxin proteins, protective antigen, lethal factor and edema factor, which are individually non-toxic but can become highly toxic if allowed to interact on the surface of human or animal cells.

Cutaneous anthrax, although rare in the United States, is the most common type of naturally acquired anthrax. Cutaneous anthrax is typically acquired through contact with contaminated animals and animal products. The fatality rate for untreated cases of cutaneous anthrax is estimated to be approximately 20%.

Inhalational anthrax is the most lethal form of anthrax. We believe that aerosolized anthrax spores are the most likely method to be used in a potential anthrax bioterrorism attack. Inhalational anthrax has been reported to occur from one to 43 days after exposure to aerosolized spores. Initial symptoms of inhalational anthrax are non-specific and may include sore throat, mild fever, cough, achiness or weakness, lasting up to a few days. After a brief period of improvement, the release of anthrax toxins

may cause an abrupt deterioration of the infected person, with the sudden onset of symptoms, including fever, respiratory failure as the lungs fill with fluids and shock. Hemorrhagic meningitis is common. Death often occurs within 24 hours of the onset of advanced respiratory complications. The fatality rate for inhalational anthrax is estimated to be between 45% and 90%, depending on whether aggressive, early treatment is provided.

To date, the principal customer for anthrax vaccines has been the U.S. government. Because of concerns regarding the use of anthrax spores as a biological weapon during the first Persian Gulf War, the DoD began administering BioThrax to military personnel in 1990. Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we supplied over eight million doses of BioThrax through July 2006 to the DoD for immunization of military personnel. Since March 1998, the DoD has vaccinated more than 1.5 million military personnel with more than 5.5 million doses of BioThrax. The DoD currently administers BioThrax under its MilVax program on a voluntary basis.

In May 2005, we entered into an agreement to supply five million doses of BioThrax to HHS for placement into the strategic national stockpile for a fixed price of \$123 million. We completed delivery of all five million doses by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007 for a fixed price of \$120 million.

Following the October 2001 anthrax letter attacks, HHS provided BioThrax under an investigational new drug application, or IND, protocol for administration on a voluntary basis to Capitol Hill employees and others who may have been exposed to anthrax. In addition, we have supplied small amounts of BioThrax directly to several foreign governments. It is our understanding that the DoD has sold BioThrax to the governments of a number of other foreign countries for the protection of military personnel. We believe that state and local governments and several foreign governments are significant potential customers for BioThrax. Our total revenues from BioThrax sales were \$55.5 million in 2003, \$81.0 million in 2004 and \$127.3 million in 2005.

Current treatments. The only FDA approved product for pre-exposure prophylaxis of anthrax infection is BioThrax. The only FDA approved products for post-exposure prophylaxis of anthrax infection are antibiotics, which are typically administered over a 60-day period. Antibiotics prevent anthrax disease by killing the anthrax bacteria before the bacteria can release anthrax toxins into the body. However, antibiotics are not effective against anthrax toxins after the toxins have been released into the body and do not kill anthrax spores that may remain in the body for extended periods after exposure. Anthrax spores that remain in the body can potentially lead to infection following the end of antibiotic treatment. Infection also may occur if patients do not adhere to the prolonged course of antibiotic treatment or are not able to remain on antibiotics for extended periods of time. Because of these limitations, the CDC recommends administering BioThrax in combination with antibiotics under an IND with informed consent of the patient as a post-exposure prophylaxis for anthrax infection as an emergency public health intervention. While BioThrax is not currently approved by the FDA for post-exposure prophylaxis, as discussed below, we are actively pursuing a label expansion for this indication.

Description and benefits of BioThrax. BioThrax is the only FDA approved vaccine for the prevention of anthrax infection. It is approved by the FDA as a pre-exposure prophylaxis for use in adults who are at high risk of exposure to anthrax spores. BioThrax is manufactured from a culture filtrate, made from a non-virulent strain of Bacillus anthracis, and contains no dead or live bacteria. BioThrax is administered by subcutaneous injection in three initial doses followed by three additional doses, with an annual booster dose recommended thereafter. The initial three doses are given two weeks apart followed by three additional doses given at six, 12 and 18 months following first vaccination. BioThrax includes aluminum hydroxide, or alum, as an adjuvant.

The NIH originally approved the manufacture and sale of BioThrax by the Michigan Department of Public Health in 1970. In 1972, responsibility for approving biological products transferred from the NIH to the FDA. Following that transfer of responsibility, the FDA established procedures for reviewing the safety and efficacy of biological products, including BioThrax, that had been previously approved by the NIH. The FDA set out to categorize the products according to evidence of safety and effectiveness and determine if the products should remain approved and on the market. In December 1985, the FDA issued a proposed rule containing a finding that BioThrax was safe and effective. However, the FDA did not finalize that proposed rule pursuant to applicable notice and comment requirements. In December 2005, based on a review of data from the study used to support the original marketing approval of BioThrax and other studies of the use of BioThrax in humans, including studies by the CDC and the DoD, the FDA issued a final order regarding BioThrax. In the final order, the FDA affirmed the approval of BioThrax and found, among other things, that:

- · BioThrax is safe and effective;
- the study used to support the original marketing approval of BioThrax constituted a well controlled human efficacy study in which BioThrax was 92.5% effective in preventing inhalational and cutaneous anthrax;
- as reported by the National Academy of Science's Institute of Medicine, studies in humans and animal models support the conclusion that BioThrax is
  effective against anthrax strains that are dependent upon the anthrax toxin as a mechanism of virulence by all routes of exposure, including inhalation;
- periodic evaluations of reports in the vaccine adverse event reporting system database maintained by the CDC and the FDA confirm that BioThrax
  continues to be safe for its intended use; and
- as reported by an independent advisory panel to the FDA, CDC data suggest that BioThrax is fairly well tolerated with severe local reactions and systemic reactions being relatively rare.

In a study published in 2002, the Institute of Medicine, which is a component of The National Academy of Sciences and provides independent, unbiased, evidence-based advice on matters pertaining to public health, found that BioThrax is an effective vaccine for protection against anthrax, including inhalational anthrax, caused by any known or plausible engineered strains and that no convincing evidence exists that people face an increased risk of experiencing short-term life-threatening or permanently disabling adverse effects from BioThrax or developing any adverse effects from long-term use of RioThrax

BioThrax development activities. In its 2002 study, the Institute of Medicine recommended characteristics for the development of a new anthrax vaccine. Based on these recommendations, we are actively pursuing label expansions and improvements for BioThrax, including the following:

- Extend shelf life. In 2005, the FDA approved an extension of BioThrax shelf life from two to three years, which will allow BioThrax to be stockpiled for a longer period of time. We are conducting ongoing stability testing of BioThrax, and, depending on the outcome of these tests, we may apply for a further extension of BioThrax shelf life to five years in 2007.
- Reduce doses for pre-exposure prophylaxis. Based on an interim analysis of data from an ongoing clinical trial of BioThrax being conducted by the CDC, we have applied to the FDA to reduce the number of required doses of BioThrax for pre-exposure prophylaxis from six to five, with an annual booster dose thereafter. In April 2006, the FDA issued a complete response letter to our application, requesting clarification and requiring additional analysis of the data that we submitted. We are in the process of responding to this letter and amending our application.
- Add second route of administration. We have applied to the FDA to add a second route of administration of BioThrax to include intramuscular injection in addition to subcutaneous injection. We

believe that intramuscular injection will result in fewer injection site reactions than subcutaneous injection.

• Single dose syringe. We believe that products that are administered in a single dose syringe are of significant interest to HHS for inclusion in the strategic national stockpile. As a result, we have initiated a development program to make BioThrax available in single dose syringes.

Post-exposure prophylaxis. We also plan to seek approval of BioThrax in combination with antibiotic therapy as a post-exposure prophylaxis for anthrax infection. We expect that we will use three doses of BioThrax given two weeks apart for this indication. In 2005, the NIH completed a proof-of-concept study of BioThrax in which rabbits infected with anthrax were treated with the antibiotic levofloxacin or with levofloxacin in combination with two doses of BioThrax in one of three dose amounts. One of the dose amounts tested was a dilution of BioThrax designed to elicit an immune response that is proportional to the effect of an undiluted dose in humans. This is referred to as a humanized dose. Only 44% of the rabbits treated with antibiotics alone survived, while 100% of the rabbits treated with either humanized doses or undiluted human doses of BioThrax in combination with levofloxacin survived. In the trial, there were statistically significant increases in survival rates for rabbits treated with all dose amounts of BioThrax in combination with the antibiotic compared to rabbits treated with levofloxacin alone. These results were consistent with an earlier animal test conducted by the U.S. Army Medical Research Institute of Infectious Diseases, or USAMRIID, involving undiluted human doses of BioThrax in combination with an antibiotic administered to nonhuman primates infected with anthrax.

To advance the development of BioThrax for this additional indication, we plan to conduct three animal efficacy studies in accordance with the FDA animal rule. We plan to evaluate the effect of a humanized dose of BioThrax in combination with an antibiotic compared to the antibiotic alone in rabbits and nonhuman primates exposed by inhalation to anthrax spores. We plan to file an IND with the FDA in 2006 to initiate a human clinical trial of BioThrax for this indication using three doses of BioThrax given two weeks apart. The purpose of this trial will be to obtain additional immunogenicity data regarding BioThrax using the planned three dose regimen. We expect to conduct this clinical trial concurrently with our planned animal efficacy studies. Under the FDA animal rule, we believe that, if the results are favorable, the rabbit and nonhuman primate animal efficacy studies together with our planned human immungenicity clinical trial would be sufficient to support the filing with the FDA of a BLA supplement for marketing approval of BioThrax for this indication in the second half of 2007.

Next generation anthrax vaccine. We are evaluating several potential product candidates in connection with development of a next generation anthrax vaccine, featuring attributes such as self-administration and a longer shelf life. In June 2006, NIAID issued a request for proposals for the advanced development and testing of next generation anthrax vaccine candidates that have properties desirable for a biodefense vaccine to be stored in the strategic national stockpile, including the following:

- · shelf life of three years or longer at room temperature;
- the ability to generate protective immune response in one or two doses; and
- the ability to be safely self administered or rapidly inoculated into large numbers of people

The NIAID request stated that anthrax vaccine candidates should maintain a superior safety profile to BioThrax, contain a protective antigen that has been shown to be efficacious against anthrax spore challenge in animal models and have progressed through a proof-of-concept efficacy study in a relevant spore challenged animal model. The NIAID notice is not a request for proposals. NIAID is not obligated to make any award, and may decide not to make any award, for development funding pursuant to this request for proposals or otherwise.

#### Anthrax immune globulin

We are developing an anthrax immune globulin as a single dose intravenous therapeutic for treatment of patients with manifest symptoms of anthrax disease resulting from the release of anthrax toxins into the body. If successfully developed, we expect our anthrax immune globulin therapeutic to be prescribed for administration in these circumstances either as a monotherapy or in conjunction with an antibiotic.

There are no approved products for the effective treatment of anthrax disease after anthrax toxins have been released into the body. Cangene, in collaboration with the CDC, is currently developing an anthrax immune globulin for use in these circumstances based on plasma collected from military personnel who have been vaccinated with BioThrax. Pursuant to the first in a series of three anticipated requests for proposals, HHS awarded a contract to Cangene in 2005 to supply anthrax immune globulin for use in preliminary efficacy testing. In July 2006, HHS exercised an option under a modification to this contract for Cangene to supply 10,000 doses of anthrax immune globulin for the strategic national stockpile. This contract modification has a total value of approximately \$143 million. Cangene has announced that it expects to deliver these doses of anthrax immune globulin to the strategic national stockpile beginning in late 2007 through the end of 2009. HHS also awarded a contract to Human Genome Sciences in 2005 to supply a monoclonal antibody to Bacillus anthracis for evaluation of efficacy as a post-exposure therapeutic for anthrax infection. In June 2006, HHS awarded a development and supply agreement with a value of \$165 million to Human Genome Sciences for this monoclonal antibody, referred to as ABthrax. The contract provides for the supply of 20,000 treatment courses of ABthrax for the strategic national stockpile. Human Genome Sciences has announced that it expects to deliver ABthrax to the strategic national stockpile in 2008. The FDA has granted ABthrax an orphan drug designation for the treatment of inhalational anthrax.

Our plan is to develop our anthrax immune globulin therapeutic using antibodies that are produced by healthy donors immunized with BioThrax. We recently completed a plasma donor stimulation program in which we collected plasma from our employees and military personnel who had been vaccinated with BioThrax. We are currently designing a civilian donor stimulation program. We have collected a sufficient amount of plasma to initiate manufacturing of the anthrax immune globulin under current good manufacturing practice, or cGMP, requirements in a validated and approved process. The manufacturing process entails fractionating the plasma and purifying the immune globulin. We have engaged Talecris Biotherapeutics, Inc. to perform the plasma fractionation and purification processes and contract filling for our anthrax immune globulin candidate at its FDA approved facilities. We expect that the anthrax immune globulin that we manufacture will be acceptable under the FDA's rules for use in both preclinical studies and human clinical trials.

We plan to rely on the FDA animal rule in connection with the development of our anthrax immune globulin candidate. Specifically, we plan to conduct efficacy studies of this product candidate in infected rabbits and then infected nonhuman primates. Concurrently, we plan to file an IND for a Phase I clinical trial to evaluate the safety and pharmacokinetics of our anthrax immune globulin candidate in healthy volunteers. We currently anticipate filing such an IND in late 2006 or early 2007. We believe that favorable data from these animal efficacy studies and the safety and pharmacokinetic clinical trial would be sufficient to support an application to the FDA for marketing approval. We have applied to NIH for a grant to fund preclinical development and the production of clinical trial material. We believe that our anthrax immune globulin would be eligible to be procured by HHS under Project BioShield for inclusion in the strategic national stockpile after we file an IND and prior to receiving marketing approval.

## Recombinant bivalent botulinum vaccine

Disease overview. Botulism is a frequently fatal disease caused by botulinum toxins produced by the bacterium Clostridium botulinum. Clostridium botulinum is widely distributed in soil and aquatic

environments throughout the world. Botulinum bacteria produce seven distinct serotypes, each of which elicits a distinct antibody response. Naturally occurring outbreaks of botulism in humans have been reported from exposure to four of the seven serotypes: A, B, E and F. Botulism normally occurs when an individual consumes contaminated food containing botulinum toxin. Once consumed, the toxin rapidly attacks nerve cells, resulting in paralysis of peripheral muscles, including the muscles involved in respiration. Botulism can also be contracted if botulinum bacteria contaminate wounds or colonize in the intestine of infants, which is referred to as infant botulism.

Botulinum toxins are among the most potent and dangerous of potential biological weapons. Exposure to very small quantities of botulinum toxin can cause the rapid onset of life threatening paralytic disease syndrome. It has been estimated that a single gram of toxin evenly dispersed and inhaled could kill more than one million people.

Market opportunity and current treatment. Because botulinum toxin is stable when purified and extremely potent when administered in very small quantities, it has the potential to be used directly as a biological weapon, either through deliberate contamination of food or drinking water or as an aerosol. As with anthrax vaccines, we believe that the U.S. government will be the principal customer for a botulinum vaccine, particularly in the near term. We believe that state and local governments, which we expect will be interested in a botulinum vaccine to protect first responders to a bioterrorism attack, and several foreign governments are significant potential customers for a botulinum vaccine.

The Michigan Department of Public Health first developed a pentavalent botulinum toxoid vaccine in the late 1960s and began manufacturing the pentavalent vaccine for use under an IND in 1969. This vaccine is called pentavalent because it addresses five serotypes of botulinum neurotoxin. Since 1989, the CDC and the DoD have distributed the pentavalent botulinum toxoid vaccine under this IND for vaccination of a risk laboratory workers and military personnel as an adjunct to other measures of protection. The pentavalent botulinum toxoid vaccine exhibited an acceptable safety profile in connection with the immunization of over 5,000 individuals with more than 21,000 doses of the vaccine. Approximately 90% of injections were followed by no, or mild, local reactions. Only 0.3% of injections were followed by severe local reactions. A total of 5.1% of injections were followed by reported systemic reactions. In connection with our acquisition of assets from the Michigan Biologic Products Institute in 1998, we acquired rights to the pentavalent vaccine, know-how relating to the development of the pentavalent vaccine and rights to a master botulinum cell bank, which provides starting materials for the pentavalent vaccine.

After more than 15 years of use, the supplies of pentavalent botulinum toxoid vaccine are dwindling and in need of replacement. In August 2003, HHS issued a pre-solicitation notice for the acquisition of up to ten million doses of a recombinant trivalent botulinum vaccine, which would address botulinum serotypes A, B and E. HHS was seeking a trivalent vaccine because botulinum serotype F is more difficult to produce under cGMP conditions and does not appear to represent the same level of threat as other serotypes of botulinum neurotoxin. We also believe that botulinum serotype E does not represent the same level of threat as serotypes A and B. Botulinum serotypes A and B are responsible for approximately 85% of all cases of botulism.

In November 1997, the DoD, through its Joint Vaccine Acquisition Program, awarded a contract for \$322 million to DynPort Vaccine Company for the development of various biodefense vaccines. In April 2005, the DoD provided additional funding to DynPort for the continued development of a recombinant bivalent botulinum vaccine for protection against botulinum serotypes A and B.

Description and development status. We are developing a recombinant protein subunit bivalent botulinum vaccine for protection against botulinum serotypes A and B in collaboration with HPA. We hold an exclusive

license from HPA to the recombinant technology that we are using in the development of our vaccine candidate. HPA is also providing us with process development and toxicology expertise, access to its facilities and specialized manufacturing capabilities. We are designing our vaccine candidate to be administered by intramuscular injection with an alum adjuvant in a three dose regimen. Our recombinant vaccine candidate is based on a fragment of the botulinum toxin that we have selected as an antigen because we believe it to be non-toxic and immunogenic. We are producing this recombinant antigen in an E. coli expression system. We believe that our technology will allow us to develop a stable product with possible cross-protection against a range of toxin subtypes and ease of formulation into a multivalent vaccine.

We have completed initial proof-of-concept studies of this vaccine candidate in mice for botulinum serotypes A and B. In these studies, the vaccine elicited antibodies and provided protection against challenge with the botulinum toxin. We plan to initiate additional proof-of-concept animal studies in mice for botulinum serotype E and then to evaluate the toxicity of the vaccine in other animal studies so that we will be in a position, if we determine to do so, to develop a recombinant trivalent botulinum vaccine instead of a recombinant bivalent botulinum vaccine.

We have established a small scale production process for botulinum serotypes A and B. We anticipate that we will be able to manufacture our recombinant vaccine in a cGMP facility that will not require the high level of containment that is required for the production of conventional, non-recombinant toxoid vaccines that involve cultivation of the disease-causing organism. We plan to rely on the FDA animal rule in connection with the development of our recombinant bivalent botulinum vaccine candidate.

## Botulinum immune globulin

We are developing our botulinum immune globulin candidate in collaboration with HPA as an intravenous therapeutic for treatment of symptomatic botulinum exposure. Because of the rapid onset of symptoms following infection with botulinum toxin, prophylactic vaccines, which take several weeks to create an effective protective immune response, are not useful as post-exposure treatments for botulism. In addition, antibiotics are not effective post-exposure treatments since they work by killing the botulinum bacteria that produce the toxin, but do not act directly against the botulinum toxin.

We believe that an intravenous botulinum immune globulin has the potential to provide immediate protection from the effects of botulinum toxin. A third party's FDA approved botulinum immune globulin was tested in a five-year, randomized, double-blind, placebo controlled trial in 122 infants with infant botulism and a subsequent six-year, open-label study in 382 infants. In the placebo controlled trial, infants treated with the botulinum immune globulin had statistically significant reductions in the average length of hospital stay, duration of intensive care, duration of mechanical ventilation, duration of tube or intravenous feeding and hospital charges. In the open-label study, the early treatment of patients with infant botulism shortened the average length of stay significantly more than later treatment.

The only current recommended therapy for exposure to botulism consists of passive immunization with an immune globulin derived from equine plasma. The components of a previously approved trivalent equine immune globulin that contained antibodies against botulinum toxin types A, B, and E have been reformulated into an approved bivalent product and an investigational monovalent product. However, the equine immune globulin is subject to important shortcomings. First, because the human body recognizes the equine immune globulin as a foreign substance, its efficacy may be limited. In addition, the antibody immune response against the equine immune globulin can lead to potential severe side effects, including anaphylactic shock, if the equine immune globulin is administered more than once. To screen for sensitivity to the equine immune globulin, patients are given small challenge doses of the equine immune globulin before receiving a full dose.

In June 2006, HHS awarded a five-year development and supply contract with a base value of \$362 million to Cangene for a heptavalent botulinum immune globulin derived from equine plasma. The contract provides for the supply of 200,000 doses of a botulinum immune globulin for the strategic national stockpile. Cangene has announced that it expects to produce and deliver usable product to the strategic national stockpile from mid to late 2007. The contract also provides for optional task orders worth up to an extra \$234 million, which may be awarded at the sole discretion of HHS. Cangene previously began development work on the project under a research and development contract with the CDC.

We plan to rely on the FDA animal rule in connection with the development of our botulinum immune globulin candidate. Specifically, we plan to conduct efficacy studies of this product candidate in an infected rodent population and then infected nonhuman primates. Concurrently, we expect to file an IND for a Phase I clinical trial to evaluate the safety and pharmacokinetics of the botulinum immune globulin in healthy volunteers. We believe that favorable data from these animal efficacy studies and the safety and pharmacokinetic clinical trial would be sufficient to support an application to the FDA for marketing approval.

As the first step in the development of our botulinum immune globulin candidate, we are initiating production of a bivalent botulinum toxoid vaccine using botulinum serotypes A and B derived from the starting material for the pentavalent vaccine developed by the Michigan Department of Public Health. We are designing this botulinum toxoid vaccine to be administered by injection with an alum adjuvant. We anticipate that several doses will be needed to elicit a strong immune response. We are performing development activities at existing HPA facilities, which we expect may expedite production of clinical material for the vaccine. HPA is also providing us with process development and specialized manufacturing capabilities for the vaccine.

We plan to conduct a preclinical proof-of-concept study of this vaccine candidate in mice and then file an IND to initiate a Phase I clinical trial to evaluate the safety of this vaccine in healthy volunteers. If the results of the Phase I clinical trial are favorable, we intend to initiate a donor stimulation program in which we will immunize healthy volunteers with the vaccine and collect plasma for fractionation for the manufacture of our botulinum immune globulin candidate. We expect to rely on safety and immunogenicity data from the pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan in the development of this bivalent botulinum toxoid vaccine. As a result, we anticipate that the FDA will not require us to conduct a Phase II clinical trial for the bivalent botulinum toxoid vaccine before permitting us to initiate the donor stimulation program.

Our current plan is to develop the botulinum toxoid vaccine that we are using in the development of our botulinum immune globulin candidate through Phase I clinical trials. At that point, we expect to assess our future development plans based on the U.S. government's interest in providing funding for the further development or procurement of this toxoid vaccine, either instead of or in addition to a recombinant botulinum vaccine, as a pre-exposure prophylaxis for botulinum toxin. We believe that this type of government funding may become available as there is currently no botulinum vaccine available for the military or the strategic national stockpile. Moreover, we believe that the well-established nature of the manufacturing process for a toxoid vaccine, the availability of safety data from the pentavalent botulinum vaccine, our access to know-how from the development and manufacturing of the pentavalent botulinum vaccine by the State of Michigan and access to HPA technology would all facilitate our development of a bivalent botulinum toxoid vaccine.

#### Commercial business

In our commercial business, we are developing a range of commercial immunobiotic product candidates for use against infectious diseases with significant unmet or underserved medical needs.

# Typhoid vaccine

Disease overview. Typhoid, also known as typhoid fever, is caused by infection with the bacterium Salmonella typhi. Typhoid is characterized by fever, headache, constipation, malaise, stomach pains, anorexia and myalgia. Severe cases of typhoid can result in confusion, delirium, intestinal perforation and death. Typhoid is transmitted by consuming contaminated food or drinks. Contamination usually results from poor hygiene and sanitation. Typhoid is often endemic in developing countries in which there is limited access to treated water supplies and sanitation.

Market opportunity and current treatment. According to the CDC, approximately 400 cases of typhoid are reported annually in the United States, of which approximately 70% are contracted abroad. An estimated 22 million cases of typhoid occur per year worldwide, resulting in approximately 200,000 deaths annually. The CDC recommends that all persons from the United States traveling to developing countries consider receiving a typhoid vaccination, with travelers to Asia, Africa and Latin America deemed to be especially at risk. U.S. military personnel deployed in these areas are also at risk of infection.

One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in both the United States and Europe. The approved oral typhoid vaccine is available in liquid and capsule formulations. Both formulations require three to four doses to generate a protective immune response. The capsule formulation requires a booster every five years thereafter. The liquid formulation has been reported to provide 77% of recipients in clinical trials with protection three years after vaccination. The approved injectable vaccine requires only a single dose. However, it is poorly immunogenic in children, requires a booster dose every three years thereafter and was effective in only 55% to 75% of recipients in clinical trials. Both approved vaccines have good safety profiles with relatively few adverse events reported. Antibiotics are used to treat typhoid after infection and usually lead to recovery commencing within four days. Without antibiotic therapy, the CDC estimates that the mortality rate of a typhoid infection is as high as 20%.

Description and development status. We are developing a live attenuated typhoid vaccine that contains deletions in two genes of the Salmonella typhi bacterium designed to eliminate virulence. We have designed our vaccine candidate to be administered in a single drinkable dose prior to travel to countries where typhoid is endemic. We believe that, if approved, the method of administration of our vaccine candidate would provide a competitive advantage compared to both currently approved typhoid vaccines.

We have completed preclinical studies in which we assessed the immunogenicity and toxicity of our vaccine candidate, with the following results:

- · In in vitro tests in which human cells were exposed to our vaccine candidate, the live attenuated bacteria contained in the vaccine did not multiply.
- In pharmacology studies in mice, our vaccine candidate was immunogenic and had higher relative immunogenicity when delivered subcutaneously than
  the currently approved oral typhoid vaccine.

• In safety and toxicity studies in mice, a strain of Salmonella that causes a disease similar to typhoid in mice, which contained deletions of the genes that are also deleted in our vaccine candidate, did not cause disease.

We also have completed the following clinical trials of our typhoid vaccine candidate in the United States and Europe:

- An open-label, non-placebo controlled, pilot study conducted in the United Kingdom in nine healthy adult volunteers. The purpose of this study was to
  evaluate the safety and immunogenicity of our vaccine candidate. In this study, our vaccine candidate was immunogenic, eliciting both cell mediated and
  humoral immunogenicity, and well tolerated.
- A double-blind, placebo controlled, single dose escalating Phase I clinical trial conducted in the United States in 60 healthy adult volunteers. The purpose
  of this trial was to evaluate the safety, tolerability and immunogenicity of three dose levels of our vaccine candidate. In this trial, our vaccine candidate
  was immunogenic and well tolerated at all dose levels.
- An open-label, non-placebo controlled, single dose Phase I clinical trial conducted in the United States in 32 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of two different presentations of the vaccine candidate, one using bottled water and another using tap water. We vaccinated 16 subjects with each presentation. Because one subject who received the tap water presentation of the vaccine candidate was excluded from the trial results due to a lack of post-baseline immunology data, the tap water presentation data reflected data from only 15 subjects. More than 90% of the subjects vaccinated with each presentation had a humoral antibody response to S. typhi. Because the two presentations were equally immunogenic and both were well tolerated by trial participants, we selected the tap water presentation for further development based on its relative convenience.

In these three clinical trials, our vaccine candidate demonstrated immunogenicity response levels following a single drinkable dose similar to those seen with multiple doses of the currently approved oral vaccine. As a result of these trials, we were able to establish the dose and regimen for our vaccine candidate with a formulation that we believe is appropriate for commercialization.

We recently completed a single-blind, placebo controlled Phase I clinical trial of our vaccine candidate in Vietnam in 27 healthy adult volunteers using the dose and regimen established in our Phase I clinical trials in the United States. The Wellcome Trust provided funding for the trial. The purpose of the trial was to evaluate the safety and immunogenicity of the vaccine candidate in adults living in an endemic area. In this trial, the vaccine candidate met the criterion for immunogenicity, with approximately 68% of subjects who received the vaccine candidate mounting a humoral antibody response. The vaccine candidate was well tolerated by trial participants, with no serious adverse events reported.

The remainder of our planned clinical development program for this vaccine candidate consists of the following:

• Phase II clinical trial. In the fourth quarter of 2006, we plan to initiate a single-blind, placebo controlled Phase II clinical trial in Vietnamese children between five and 14 years of age. The Wellcome Trust has agreed to provide funding for this trial. The purpose of this trial will be to evaluate the safety and immunogenicity of our vaccine candidate. The trial design calls for 100 subjects to receive vaccine and 50 to receive placebo, with at least 70% of the subjects being between five and ten years of age. We will assess safety and immunogenicity up to 28 days after vaccination.

- Disease surveillance study. Concurrently with the planned Phase II clinical trial, we plan to conduct a disease surveillance study in the areas where we
  are considering conducting a Phase III clinical trial of our vaccine candidate in order to confirm that a sufficient number of subjects will be included in the
  Phase III trial
- Phase III clinical trial. We plan to conduct a single-blind Phase III clinical trial in an area where typhoid is endemic. The purpose of this trial will be to
  evaluate the efficacy of our vaccine candidate in children who are likely to be exposed to the typhoid bacterium. We expect to undertake an interim
  analysis of the data from the trial after approximately one year, which, if the results are favorable, we plan to use to support the filing with the FDA of a
  BLA for marketing approval of our vaccine candidate. We plan to continue to monitor the incidence of typhoid in the trial participants for several years
  after vaccination
- Tolerability and immunogenicity study. Concurrently with our Phase III clinical trial, we plan to conduct a Phase III clinical trial in the United States or Europe in healthy volunteers. The purpose of this trial will be to evaluate the safety and immunogenicity of our vaccine candidate in the target population to support marketing approval in the United Sates and Europe.

Since typhoid fever in Asia is largely a disease of children, we plan to conduct our Phase II and Phase III clinical trials in this age group. We plan to conduct our Phase II and Phase III clinical trials in endemic areas because there are no agreed immune correlates of efficacy for live attenuated typhoid vaccines and it is not practicable to demonstrate clinical efficacy in travelers from the United States or Europe due to the prohibitively large number of subjects that would be needed. The currently approved typhoid vaccines relied on similar clinical trials for regulatory approval.

We plan to seek additional grant funding for development of this product candidate.

# Hepatitis B therapeutic vaccine

Disease overview. Hepatitis B is a highly infectious virus transmitted from person to person by contact with blood and bodily fluids. Most hepatitis B infections in adults result in acute hepatitis, with the immune system eventually clearing the infection. However, in approximately 8% to 10% of infected adults and a much larger proportion of infected children, the immune system fails to clear the virus, resulting in immune tolerance of the virus and chronic infection. In addition, pregnant women suffering from hepatitis B can pass the infection on to their babies during childbirth. Babies born infected rarely clear the infection, with over 90% becoming chronically infected. According to the World Health Organization, approximately 25% of people with chronic hepatitis B infection develop serious liver disease, including cirrhosis and liver cancer.

Market opportunity and current treatment. Chronic infection with the hepatitis B virus is a global problem, with an estimated 350 million carriers worldwide. The World Health Organization estimates that approximately one million people per year worldwide die from complications of hepatitis B infection. Infection rates are highest in the developing world, posing an infection risk to travelers from industrialized countries. Infection is less common in the United States and Europe. In the United States, there are an estimated 1.2 million people with chronic hepatitis B infection, resulting in approximately 4,000 to 5,000 deaths annually.

Prophylactic vaccines based on recombinant protein subunit preparations are effective in preventing hepatitis B infection. Childhood vaccination with these vaccines is common in industrialized countries and in some of the developing world. Childhood immunization programs have reduced the number of carriers of chronic hepatitis B infection by up to 90% in parts of the world where hepatitis B is most common. In

the United States, infection rates for acute hepatitis B have decreased by approximately 77% over the past 20 years. However, these existing vaccines have not proven to be effective in treating people with chronic hepatitis B infection. As a result, there remain a large number of people who are chronically infected with hepatitis B and require treatment to prevent the development of liver disease and reduce the risk of transmitting the infection to others.

There is no vaccine currently on the market that is licensed for therapeutic use for chronic hepatitis B infection. Currently available therapies for this patient population consist mainly of antiviral drugs, such as an immunotherapy with interferons. However, these treatments are subject to a number of shortcomings. Both of these treatments can only be used in a subset of patients, and their efficacy is limited. In addition, the use of antiviral drugs may lead to the development of resistant forms of the virus and Interferon has side effects that reduce patient compliance.

Description and development status. We are developing a live attenuated therapeutic vaccine for treatment of patients with chronic hepatitis B infection. We have designed our vaccine candidate to be administered in multiple drinkable doses over several months. It may require further booster doses. Because chronic carriers have weak cellular responses to the hepatitis B virus, they cannot clear the virus. Our vaccine candidate is intended to redirect the immune system to make strong cellular responses to a hepatitis B antigen known as hepatitis B core in chronic carriers, leading to suppression of viral replication and associated liver damage.

Our vaccine candidate uses our proprietary *spi*-VEC® oral delivery system technology to deliver hepatitis B core antigen to the human immune system. *Spi*-VEC is based on our live attenuated typhoid vaccine and employs recombinant technology to insert the gene for hepatitis B core into the live attenuated *Salmonella* bacteria. The bacteria produce the antigen once inside the patient. Because we are relying on recombinant technology to insert the gene for hepatitis B core into a vector delivery system, we do not need to separately purify the vaccine.

We have completed a program of pharmacology and toxicity studies of our hepatitis B therapeutic vaccine candidate in animals. In mice that were administered our vaccine candidate, the hepatitis B core antigen was manufactured and immune responses were elicited against the antigen. In separate toxicity studies also conducted in mice, our vaccine candidate was non-toxic.

In February 2004, we completed an open-label, dose escalating Phase I clinical trial of our vaccine candidate in the United Kingdom in 30 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of our vaccine candidate. In this trial, we administered volunteers two doses of vaccine over a period of approximately two months. The vaccine elicited a cellular immune response in all subjects after two doses, indicating that the antigen had been successfully delivered to the immune system. In addition, 100% of subjects in the high dose group and 90% of subjects in the low dose group demonstrated the type of immune response known to be important in promoting clearance of hepatitis B. The vaccine candidate was well tolerated by trial participants, with no serious adverse events reported.

In March 2006, the U.K. Medicines and Healthcare products Regulatory Agency approved our clinical trial application, including a trial protocol to initiate a Phase II clinical trial of our vaccine candidate in patients chronically infected with hepatitis B. The protocol provides for a placebo controlled, randomized, dose escalating study to be conducted in the United Kingdom in 45 chronic carriers of hepatitis B. If necessary, we may expand the study to additional sites in Europe to increase the recruitment rate. The primary purpose of this trial will be to evaluate the safety and tolerability of six monthly doses of our vaccine candidate. The secondary purpose will be to investigate whether the vaccine candidate can reduce the

hepatitis B viral DNA load, a recognized surrogate endpoint for treatment of hepatitis B using current therapeutics. We expect to begin dosing patients in the trial in the second half of 2006.

#### Group B streptococcus vaccine

Disease overview. Group B streptococcus is a bacterium that causes illness in newborn babies, pregnant women, the elderly and adults with other illnesses, such as diabetes or liver disease. Group B streptococcus is the most common cause of sepsis and meningitis in newborns in the developed world and is a frequent cause of pneumonia in newborns. It affects more babies than any other newborn health problem. Group B streptococcus bacteria can cause bladder and womb infections in pregnant women that in turn lead to infection of the fetus and premature delivery and stillbirth. In pregnant women carrying the group B streptococcus bacteria, the baby may become infected either before or during birth.

In the United States, approximately half of all neonatal group B streptococcus infections occur in newborns less than seven days old and are categorized as "early onset disease." Infections in babies between seven days and three months old are categorized as "late onset disease." Early onset disease is often associated with complicated or premature deliveries and usually results in pneumonia and the blood infection septicemia in the baby. It is also associated with meningitis. Approximately 5% of babies with early onset disease die. A high number of survivors of early onset disease are left with significant permanent disabilities, including sight or hearing loss and mental retardation. The majority of late onset cases occur in the first month of life. Late onset disease usually results in meningitis. Up to 5% of babies with late onset disease die. A high number of survivors of late onset disease are left with permanent disabilities, with up to one-third suffering long-term mental or physical handicaps.

Group B streptococcus infections in the elderly cause blood infections, skin or soft tissue infections and pneumonia.

Market opportunity and current treatment. The NIH has identified prevention of group B streptococcus infection in newborns as a major vaccine objective. Concern about the number of group B streptococcus neonatal infections prompted the CDC to recommend routine screening of pregnant women for group B streptococcus bacteria and preventative antibiotic treatment at the time of labor for women found to be infected. Screening of pregnant women for infection is recommended during weeks 35 to 37 of pregnancy. Approximately 10% to 30% of women are found to be carrying the bacterium as a normal component of the vaginal microflora. These women are offered intravenous antibiotics throughout their labor as a preventative measure. In the absence of antibiotic treatment, the CDC estimates that the risk is one in 200 of delivering a baby with group B streptococcus infection. While the level of group B streptococcus disease decreased in the United States from 1.7 cases per 1,000 live births in 1993 to 0.4 cases per 1,000 live births in 2002, the CDC projects that there are approximately 2,750 neonatal infections each year in the United States. In a study of 338 of these cases of neonatal infections, the death rate was approximately 6%. We expect the target market for our vaccine candidate to be women of childbearing age.

The existing method of prevention of group B streptococcus infection in neonates is the targeted administration of intravenous antibiotics to women during labor. However, this approach is invasive and only partially effective. In addition, antibiotics create the risk of possible adverse reactions and may lead to the development of antibiotic resistant strains of the disease. Direct vaccination of newborns is not effective because their immune system is too immature to respond to the vaccine. Antibiotics are used to treat babies after infection.

Approximately 17,500 cases of group B streptococcus infection occur each year in the U.S. population over one year of age, with most occurring in those over age 50. According to the CDC, the average death rates for invasive infections are approximately 8% to 10% for adults 18 to 64 years of age and 15% to 25% for adults 65 years of age and over. Antibiotics are used to treat infected individuals.

Description and development status. We are developing a recombinant protein subunit group B streptococcus vaccine initially for administration to women of childbearing age for protection of the fetus and newborn babies. We are designing our vaccine candidate to be administered by injection with an alum adjuvant in a three dose regimen. We expect that a booster dose may also be required. We anticipate that the vaccine will elicit an antibody response resulting in the production of antibody in the mother, which may the cross the placenta to protect the fetus and the newborn baby by passive immunity.

We have identified several novel surface associated proteins and are working on the development of three of these proteins as components of our vaccine candidate. We believe that a combination of proteins will be required to provide effective protection. We have completed preclinical studies in which we evaluated the safety and immunogenicity of our vaccine candidate, with the following results:

- · In studies in rabbits and mice, the three protein components of our vaccine candidate were immunogenic.
- · In a passive immunization study in which we administered rabbit antibody to rat pups, the rat pups were protected against challenge with disease.
- Antibodies elicited by one of the protein components of our vaccine candidate recognized a number of group B streptococcus types, indicating that the
  protein component has potential to generate immune responses with broad coverage.
- · In a toxicology study in mice with one of the protein components of our vaccine candidate, the protein was non-toxic.

We have completed an open-label, dose escalating Phase I clinical trial of the first protein component of our vaccine candidate in the United Kingdom in 47 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of this protein as an individual recombinant protein. We adjuvanted the protein with alum and tested it at four different strengths, with two doses given 28 days apart. In this trial, the protein was immunogenic at all doses tested. The immunogenic response rate was 83% at the lowest dose tested and 100% at the highest dose tested. The vaccine candidate was well tolerated by trial participants at all dose levels tested, with no serious adverse events reported. None of the subjects withdrew due to an adverse event.

As the next steps in our development plan, we plan to initiate two additional Phase I clinical trials for the other two proposed protein components of our vaccine candidate. First, we plan to evaluate the safety and immunogenicity of the protein that we already have tested together with one of these other proteins in a Phase I clinical trial in healthy adults. If the results of that trial are favorable, we plan to evaluate the safety and immunogenicity of all three proteins together in a further Phase I clinical trial.

#### Chlamydia vaccine

Disease overview. Chlamydia is the most prevalent sexually transmitted disease in the world. It is caused by infection with the bacterium *Chlamydium trachomatis*. Chlamydia trachomatis can cause urogenital disorders such as uritheritis, cervicitis, pelvic inflammatory disease, ectopic pregnancy and infertility among females and is the leading cause of non-gonococcal uritheritis and epidemiditis in males.

Chlamydia trachomatis also causes the ocular disease trachoma, which is a form of vesicular conjunctivitis. Trachoma is the leading cause of preventable blindness worldwide.

Market opportunity and current treatment. The World Health Organization estimates that more than 92 million new cases of Chlamydia trachomatis infection occur annually worldwide, more than four million of which occur in North America. Chlamydia trachomatis infections are the most commonly reported notifiable disease in the United States, with an estimated 2.8 million Americans becoming infected with Chlamydia trachomatis each year. Epidemiological studies indicate that in the United States, Chlamydia trachomatis infections are most prevalent among young sexually active individuals between the ages of 15 to 24 years of age. There is no vaccine currently on the market for Chlamydia trachomatis. However, screening tests and effective antibiotic treatments have been effective at containing Chlamydia trachomatis in the United States and Europe. Although Chlamydia trachomatis infection can be treated with antibiotics, control measures based on antimicrobial treatment alone are difficult due to the incidence of infection, the percentage of asymptomatic infections and deficiencies in diagnosis.

Description and development status. We are developing a recombinant protein subunit chlamydia vaccine for all clinically relevant strains of Chlamydia trachomatis, including strains that cause ocular disease. We are designing our vaccine candidate to be administered by injection with a novel adjuvant in a three dose regimen. We are currently evaluating in-license opportunities for the adjuvant. We have cloned our vaccine candidate and produced it in E. coli. In studies in mice, our vaccine candidate protected against both upper reproductive tract disease and lower reproductive tract infection induced by Chlamydia trachomatis. In addition, there was no evidence of infertility in the mice following treatment with our vaccine candidate.

#### Meningitis B vaccine

Disease overview. Meningococcal disease is a life threatening condition caused by infection with the bacterium Neisseria meningitidis. Neisseria meningitidis is classified into 12 groups based on differences in the surface coating of the bacterium that elicit distinct immune responses. According to the World Health Organization, group B is the most common cause of endemic meningitis in industrialized countries, accounting for 30% to 40% of cases in North America and 30% to 80% of cases in Europe. Meningococcal disease has a fatality rate of approximately 10%. The infection can develop very rapidly and cause death within 24 hours of the symptoms first becoming apparent. Children from six months to two years of age are at the highest risk of group B meningococcal infection, with teenagers also at enhanced risk.

Market opportunity and current treatment. The World Health Organization estimates that approximately 1.2 million cases of meningococcal disease caused by the bacterium Neisseria meningitidis occur annually worldwide, resulting in approximately 135,000 deaths. In the United States, 2,333 cases of meningococcal disease were reported in 2001, with approximately one-third due to group B. In 2003, 1,756 cases of meningococcal disease were reported in the United States. Currently, there is no meningitis vaccine on the market that is protective against group B meningococcal infection. Current meningitis B treatments include antibiotics and clinical support. The rapid progression of the infection means that antibiotic therapy can be ineffective in preventing serious morbidity and mortality.

Description and development status. We are developing a recombinant protein subunit meningitis B vaccine for babies, children and adolescents. We are designing our vaccine candidate to be administered by injection with an alum adjuvant in a two dose regimen for children under age five and a single dose regimen for children over age five. We do not expect that a booster dose will be required. We anticipate

that the vaccine will consist of two or three protein antigens. We are currently evaluating a pool of 46 protein candidates in a number of preclinical studies. We are producing recombinant proteins in *E. coli*.

We have entered into a collaboration agreement with Sanofi Pasteur for this vaccine candidate.

# Sanofi Pasteur collaboration

In May 2006, we entered into a license and co-development agreement effective April 1, 2006 with Sanofi Pasteur, the vaccines business of Sanofi-Aventis, pursuant to which we granted Sanofi Pasteur an exclusive, worldwide license to develop and commercialize a meningitis vaccine that contains program antigens evaluated and selected under the agreement. We retain the right and obligation to conduct development activities through Phase I clinical trials. Under specified circumstances, we also retain the right to exploit antigens that have been terminated from development under the agreement on an exclusive basis and other specified antigens on a co-exclusive basis. Sanofi Pasteur has agreed to use commercially reasonable efforts to develop and commercialize a meningitis B vaccine in the United States, the European Union and other major market countries.

A steering committee made up of an equal number of representatives from us and Sanofi Pasteur oversees all development and commercialization activities under the agreement. The steering committee has the authority to make strategic decisions by unanimous vote relating to the development of a meningitis vaccine. Sanofi Pasteur has ultimate decision-making authority over matters that are not resolved at the steering committee and executive officer levels, but does not have the unilateral authority to amend the agreement or the development plan in a manner that would alter our obligations. In addition, Sanofi Pasteur has the right to make all strategic decisions relating to the development of any combination product and has sole discretion over the commercialization of any meningitis vaccine developed under the agreement.

Under the agreement, Sanofi Pasteur paid us initial fees of €3 million. In addition, Sanofi Pasteur has agreed to pay all expenses incurred by us under the development program. We are also eligible to receive payments of up to a maximum of €73 million upon the achievement of specified research, development and commercialization milestones. Sanofi Pasteur has agreed to pay royalties to us based on net sales by Sanofi Pasteur, its affiliates and sublicensees of licensed products from the collaboration, including specified minimum royalties with respect to sales of any combination product. In addition, Sanofi Pasteur has agreed to pay us a portion of specified sublicense income received by Sanofi Pasteur or its affiliates.

The term of the agreement ends, on a country-by-country basis, upon the later of ten years from first commercial sale or the expiration of the last-to-expire patent covering a licensed product in such country. Sanofi Pasteur may terminate the agreement for convenience beginning April 1, 2007 upon six months' prior written notice. Sanofi Pasteur also may terminate the agreement upon any change of control involving us or as a result of our uncurred material breach of the agreement or bankruptcy.

# **Facilities**

The following table sets forth general information regarding our materially important facilities.

			Approximate	
Location	Use	Segment	square feet	Owned/leased
Lansing, Michigan	Manufacturing operations facility and office space	Biodefense	214,000	Owned
Frederick, Maryland	Future manufacturing facilities	Biodefense/	290,000	Owned
		Commercial		
Gaithersburg, Maryland	Office and laboratory space	Biodefense/	36,000	Leases expire 2008
		Commercial		
Rockville, Maryland	Office space	Biodefense/	23,000	Lease expires 2016
		Commercial		
Wokingham, England	Office and laboratory space	Commercial	16,000	Leases expire 2016

Lansing, Michigan. We own a multi-building campus on approximately 12.5 acres in Lansing, Michigan that includes facilities for bulk manufacturing of BioThrax, including fermentation, filtration and formulation, as well as for raw material storage and in-process and final product warehousing. The campus is secured through perimeter fencing, limited and controlled ingress and 24 hour on-site security personnel. We acquired these facilities in 1998 from the Michigan Biologic Products Institute after the State of Michigan, with the concurrence of the DoD, suspended the production of BioThrax to renovate these manufacturing facilities. Following our acquisition of BioThrax, we completed the facility renovations initiated by the State of Michigan. Our comprehensive renovations included the implementation of work plans to systematically improve numerous aspects of the production and release of BioThrax, including process validation, quality systems and testing methods. In December 2001, the FDA approved a supplement to our manufacturing facility license for the manufacture of BioThrax at the renovated facilities.

In February 2006, we began construction of a new 50,000 square foot manufacturing facility on our Lansing campus. We expect the construction of the facility to cost approximately \$75 million, including approximately \$55 million for the building and associated capital equipment. We are constructing this new facility as a large scale commercial manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures. Subject to regulatory approval, we expect that the new manufacturing facility will serve as our primary BioThrax manufacturing facility. We anticipate that we will initiate large scale manufacturing of BioThrax at the new facility in 2008. We are constructing this facility to accommodate production of up to 40 million doses of BioThrax per year on a single production line, which we could expand for production of up to 80 million doses per year through the addition of a second production line. In comparison, our current facility has a maximum production capacity of approximately nine million doses of BioThrax per year. In addition to construction of a new manufacturing facility, we recently commissioned a new pilot plant on our Lansing campus.

Frederick, Maryland. We own two buildings of approximately 145,000 square feet each on a 15-acre site in Frederick, Maryland. We financed the purchase of these buildings with a forgivable loan from the Department of Business and Economic Development of the State of Maryland and mortgage loans from commercial lenders. These buildings serve as collateral for our financing obligations. For more information, see "Management's discussion and analysis of financial condition and results of operations — Liquidity and capital resources — Debt financing."

We are in the preliminary phase of establishing plans to build out this site for a portion of our potential future product manufacturing requirements. Our preliminary plans contemplate that the site would be

designed to provide pilot plant production capabilities, full scale commercial manufacturing operations, warehouse and storage facilities and fill and finish operations. We expect that we will complete the build out of this site in two stages. In the first stage, our preliminary plans contemplate a build out of one of the two buildings on this site to accommodate pilot plant and initial product launch capabilities. In the second stage, our preliminary plans contemplate a build out of commercial manufacturing operations.

Other. We lease two separate product development facilities. Our facility in Gaithersburg, Maryland of approximately 36,000 square feet contains a combination of laboratory and office space, including our executive offices. We conduct product development programs at this site for both our biodefense and commercial product candidates. Our facility in Wokingham, England of approximately 16,000 square feet contains a combination of laboratory and office space. We conduct product development programs at this site primarily for our commercial product candidates. Our facility in Rockville, Maryland contains approximately 23,000 square feet of office space for our future needs.

## Manufacturing

We manufacture BioThrax at our facilities in Lansing, Michigan using well established vaccine manufacturing procedures. We currently rely on contract manufacturers and other third parties to manufacture the supplies of our immunobiotic product candidates that we require for preclinical and clinical development. We acquire these supplies on a purchase order basis. We anticipate that we will use our existing plant facilities in Michigan, including our recently commissioned pilot plant, and, when constructed and approved, our planned new plant facilities in Michigan and Maryland to support both continued process development and the manufacture of clinical supplies of our product candidates. We believe that manufacturing our products and product candidates independently will provide us cost savings and greater control over the manufacturing and regulatory approval and oversight process, accelerate product development timelines and allow us to expand our base of manufacturing know-how that we can then apply to the development and manufacture of future product candidates.

Hollister-Stier Laboratories LLC performs the contract filling operation for BioThrax vials at its FDA approved facility located in Spokane, Washington. Hollister-Stier has agreed to meet all of our firm purchase orders for contract filling of BioThrax based on a good faith annual estimate that we provide prior to each calendar year. In addition, Hollister-Stier has agreed to accommodate fill requests in excess of our annual estimate subject to its available production capacity. Our contract with Hollister-Stier expires December 31, 2007. The contract also can be terminated by either party following an uncured material breach by the other party.

Talecris Biotherapeutics has agreed to perform plasma fractionation and purification and contract filling relating to the manufacture of our anthrax immune globulin candidate at its FDA approved facilities located in Melville, New York and Clayton, North Carolina. Subject to limited exceptions, we have agreed to obtain all of our anthrax immune globulin requirements exclusively from Talecris. While our agreement with Talecris remain in effect, Talecris has agreed not to market, sell or acquire any competing product that contains anthrax immune globulin as an active ingredient.

Talecris has agreed to perform plasma fractionation and purification and contract filling for the manufacture of our anthrax immune globulin candidate for preclinical or animal studies, for clinical use or for non-clinical testing required for clinical trials and for commercial sale. We have agreed to pay Talecris royalties on net sales on a country-by-country basis for commercial product manufactured by Talecris under the contract.

Our contract with Talecris expires December 31, 2013 or five years following initiation of commercial manufacturing. We have the option to extend the term for an additional five-year period upon notice to Talecris at least 12 months prior to the expiration of the initial term. After three years following initiation of commercial manufacturing, either party may terminate the contract upon two years' advance notice. The contract can also be terminated by either party following an uncured material breach by the other party. We have the right to terminate the contract, under specified circumstances, if we discontinue our production of anthrax immune globulin source plasma or the development of our anthrax immune globulin candidate.

We expect to engage one or more third parties to perform the plasma fractionation and purification processes and contract filling for our botulinum immune globulin candidate.

We rely on third parties for supplies and raw materials used for the production of BioThrax and our immunobiotic product candidates. We purchase these supplies and raw materials from various suppliers in quantities adequate to meet our needs. We believe that there are adequate alternative sources of supply available if any of our current suppliers were unable to meet our needs.

# Marketing and sales

We currently market and sell BioThrax directly to the DoD and HHS with a small, targeted marketing and sales group. We plan to continue to do so and expect that we will use a similar approach for sales to the U.S. government of any other biodefense product candidates that we successfully develop. We plan to expand our sales and marketing organization as we broaden our sales activities of biodefense products to state and local governments, which we expect will be interested in these products to protect first responders, such as police, fire and emergency medical personnel. We have established marketing and sales offices in Singapore and Munich, Germany to target sales of biodefense products to foreign governments. We have engaged third party marketing representatives to market BioThrax in the Middle East, Turkey, India, Australia and several Scandinavian countries in Europe.

We expect to establish a separate internal organization to market and sell commercial products for which we retain commercialization or cocommercialization rights. We anticipate that our internal marketing and sales organization will be complemented by selective co-promotion and other arrangements with leading pharmaceutical and biotechnology companies.

We generally expect to retain commercial rights for our product candidates that we successfully develop in situations in which we believe it is possible to access the market through a focused, specialized sales force. In particular, we believe that such a sales force could address commercial markets, such as the market for typhoid vaccines and other vaccines for travelers to developing countries, that overlap with markets for our biodefense products. We expect that we will selectively pursue collaboration arrangements in situations in which the collaborator has particular expertise or resources for the development or commercialization of our products or product candidates or to access particular markets.

## Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience, and resources provide us with competitive advantages, we face potential competition from many different sources, including commercial pharmaceutical and biotechnology companies, academic institutions, government agencies and private and public research institutions.

GlaxoSmithKline, Sanofi-Aventis, Wyeth, Merck and Chiron generated approximately 85% of total vaccine revenues in 2005. The concentration of the industry reflects a number of factors, including:

- the need for significant, long-term investment in research and development;
- · the importance of manufacturing capacity, capability and specialty know-how, such as techniques, processes and biological starting materials; and
- · the high regulatory burden for prophylactic products, which generally are administered to healthy people.

These factors have created a significant barrier to entry into the vaccine industry.

Many of our competitors, including those named above, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring products, product candidates and technologies complementary to, or necessary for, our programs. Smaller or more focused companies, including Vaxgen, Cangene, Human Genome Sciences, Acambis, Avant Immunotherapeutics and Avecia, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop. In addition, we may not be able to compete effectively if our products and product candidates do not satisfy government procurement requirements, particularly requirements of the U.S. government with respect to biodefense products.

Any immunobiotic product candidates that we successfully develop and commercialize is likely to compete with currently marketed products, such as vaccines and therapeutics, including antibiotics, and with other product candidates that are in development for the same indications.

BioThrax. Although BioThrax is the only product approved by the FDA for human use for the prevention of anthrax infection, we face significant competition for the supply of this vaccine to the U.S. government. The NIAID Biodefense Research Agenda for CDC Category A Agents includes the development of an anthrax vaccine based on recombinant protective antigen. In September 2003, NIAID awarded joint three-year contracts totaling \$151.6 million to VaxGen and Avecia to fund development of a recombinant protective antigen anthrax vaccine. In November 2004, HHS awarded VaxGen a contract with a value of \$877.5 million to supply 75 million doses of recombinant protective antigen vaccine for the strategic national stockpile. Avecia submitted a competing proposal to supply vaccine for the strategic national stockpile, which HHS did not accept. The HHS procurement request was limited to a recombinant anthrax vaccine. Because BioThrax is not a recombinant vaccine, BioThrax was precluded from consideration under that procurement program.

The VaxGen vaccine candidate is based on technology developed by USAMRIID. VaxGen has announced that studies of its vaccine candidate in animal models have indicated results that are approximately equivalent to those experienced with BioThrax. VaxGen has not yet delivered any vaccine doses under its contract with HHS. In May 2006, VaxGen announced that HHS unilaterally modified its contract to provide its anthrax vaccine for the strategic national stockpile. The contract modification extends the deadlines by which VaxGen is required to complete various milestones, including deliveries, and imposes additional requirements for clinical and non-clinical studies to be completed prior to the initiation of vaccine deliveries to the strategic national stockpile. VaxGen announced that meeting the new

requirements would delay deliveries to the strategic national stockpile to the end of 2007 at best or more likely into 2008. VaxGen is obligated under the modified contract to initiate deliveries no later than November 2008. Prior to the modification, VaxGen had stated that it intended to initiate deliveries by the end of 2006 or early 2007. According to VaxGen, the new requirements under the contract modification and the delays in delivery will increase the cost of contract performance for VaxGen and postpone revenues triggered by delivery of a vaccine to the stockpile. As a result, VaxGen announced that it is pursuing financial compensation for the unilateral contract modifications. In May 2006, an HHS official stated in Congressional testimony that delays in accelerated development programs are not unexpected or unprecedented and that HHS maintains a commitment to develop a next generation recombinant protective antigen anthrax vaccine.

HPA manufactures an anthrax vaccine for use by the government of the United Kingdom. In addition, other countries may have anthrax vaccines for use by or in development for their own internal purposes.

Other biodefense products. The competition for our biodefense immunobiotic product candidates includes the following:

- Anthrax immune globulin. Cangene, in collaboration with the CDC, is currently developing an anthrax immune globulin using plasma collected from
  military personnel who have been vaccinated with BioThrax. In July 2006, HHS exercised an option under a modification to an existing development and
  supply contract for Cangene to supply 10,000 doses of anthrax immune globulin for the strategic national stockpile. In June 2006, HHS awarded a
  contract to Human Genome Sciences to supply 20,000 treatment courses of a monoclonal antibody to Bacillus anthracis, referred to as ABthrax, for the
  strategic national stockpile.
- Recombinant bivalent botulinum vaccine. DynPort Vaccine Company has a recombinant bivalent botulinum vaccine in Phase I clinical development with funding from the DoD and NIAID.
- Botulinum immune globulin. The current recommended therapy for clinical symptoms of botulism following exposure consists of passive immunization
  with an immune globulin derivied from equine plasma. In June 2006, HHS awarded a five-year development and supply contract to Cangene for a
  heptavalent botulinum immune globulin derived from equine plasma. The contract provides for the supply of 200,000 doses of a botulinum immune
  globulin for the strategic national stockpile.

BioThrax and our biodefense product candidates also face competition for BioShield funds from other defensive measures, including protective gear such as bio-suits and gas masks.

Commercial products. The competition for our commercial immunobiotic product candidates includes the following:

- Typhoid vaccine. One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the United States and Europe.
  In addition, combination vaccines are available for the prevention of hepatitis A and typhoid infections. Antibiotics typically are used to treat typhoid after infection. For more information, see "— Products Commercial business Typhoid vaccine." We believe that Avant Immunotherapeutics Inc. has an oral, single dose, live attenuated typhoid vaccine candidate in Phase I clinical development with funding from the NIH.
- Hepatitis B therapeutic vaccine. There is no vaccine currently on the market that is licensed for therapeutic use for hepatitis B infection. Currently available therapies for this patient population consist mainly of antiviral drugs, such as an immunotherapy with interferons. For more information, see "— Products Commercial business Hepatitis B therapeutic vaccine." Several other companies have

vaccine candidates in clinical development, including Enzo Biochem, Oxxon Therapeutics and Genencor International.

- Group B streptococcus vaccine. The existing method of prevention of group B streptococcus infection in neonates is the targeted administration of intravenous antibiotics to women during labor. A number of competitors have passive immune vaccines in preclinical development.
- Chlamydia vaccine. There is no vaccine currently on the market for chlamydia, and we are not aware of any competing chlamydia vaccine candidate in clinical development. Several competitors may have chlamydia vaccine candidates in preclinical development. Screening tests and effective antibiotic treatments have been effective at containing chlamydia in the United States and Europe.
- Meningitis B vaccine. Currently, there is no meningitis vaccine on the market that is protective against group B meningococcal infection. Novartis markets
  a meningitis B vaccine in New Zealand to people under the age of 20 and is also developing a broad coverage protein subunit vaccine candidate.
  Current meningitis B treatment strategies include antibiotics and clinical support.

# Intellectual property and licenses

Our success, particularly with respect to our commercial business, depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business. U.S. patents generally have a term of 20 years from the date of nonprovisional filing. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of July 31, 2006, we owned or licensed a total of 40 U.S. patents and 42 U.S. patent applications relating to our biodefense and commercial product candidates described in this prospectus, as well as numerous foreign counterparts to many of these patents and patent applications. Our patent portfolio includes patents and patent applications with claims directed to compositions of matter, pharmaceutical formulations and methods of use.

We consider the patent rights that we have licensed from HPA relating to our recombinant bivalent botulinum vaccine candidate and our botulinum toxoid vaccine, which we plan to use in the development of our botulinum immune globulin candidate, to be most important to the protection of our biodefense product portfolio. These patents rights are described below under "— License agreements — HPA agreements."

We consider the following patents that we own or license to be most important to the protection of our vaccine candidates in our commercial business that are in clinical development.

• Typhoid vaccine. We hold five U.S. patents relating to our typhoid vaccine candidate. Some of these patents have claims to the composition of matter of the vaccine candidate and methods of use of attenuated Salmonella typhi bacteria as vaccines for the treatment and prevention of typhoid and for the delivery of vaccine antigens. In addition, we have two pending U.S. patent applications with claims to additional compositions and methods of therapy that are generally related to our typhoid vaccine candidate. Our issued U.S. patents expire, and, if issued, our U.S. patent applications would expire, between 2015 and 2020. We hold 25 foreign counterparts to our issued U.S. patents relating to our typhoid vaccine candidate, including counterparts under the European Patent Convention and in Japan, that expire, and 31 foreign patent applications that, if issued, would expire, between 2015 and 2020.

- Hepatitis B therapeutic vaccine. Our hepatitis B therapeutic vaccine candidate uses our proprietary spi-VEC oral delivery system technology to deliver hepatitis B core antigen to the human immune system. Spi-VEC is based on our live attenuated typhoid vaccine candidate and employs recombinant technology to insert the gene for hepatitis B core into the live attenuated Salmonella bacteria. As a result, the patents relating to our typhoid vaccine candidate also protect our hepatitis B therapeutic vaccine candidate. We also hold one U.S. patent with claims to the use of attenuated Salmonella organisms for the delivery of hepatitis B vaccine antigens, which expires in 2019. In addition, we have one pending U.S. patent application relating to our hepatitis B therapeutic vaccine candidate, which if issued also would expire in 2019. We have four foreign patent applications relating to our hepatitis B therapeutic vaccine candidate that, if issued, would expire in 2019.
- Group B streptococcus vaccine. We hold two U.S. patents relating to our group B streptococcus vaccine candidate with claims to the composition of
  matter of the vaccine candidate and methods of use for the prevention or treatment of infection caused by Streptococcus agalactiae. In addition, we have
  four pending U.S. patent applications with claims to additional compositions and methods of therapy relating to our group B streptococcus vaccine
  candidate. Our issued U.S. patents expire, and, if issued, our U.S. patent applications would expire, between 2019 and 2022. We hold 19 foreign
  counterparts to our issued U.S. patents relating to our group B streptococcus vaccine candidate, including counterparts under the European Patent
  Convention and in Japan, that expire, and 39 foreign patent applications that, if issued, would expire, in 2019.
- STM technology. We jointly own with Imperial College Innovations Limited patents with claims to methods for the identification of virulence genes using our signature tagged mutagenesis, or STM, technology, which we used to identify and develop the gene mutations that form the basis of our typhoid vaccine and hepatitis B therapeutic vaccine candidates. We also jointly own with Imperial Innovations the composition of matter patents covering these gene mutations. We have exclusive rights, even as to Imperial Innovations, under these jointly owned patents in all fields of use, except in the field of diagnosis, prevention, treatment, or palliation of microbial diseases, disorders and infections in humans and animals where our rights are generally non-exclusive and are subject to existing license agreements with third parties. Because our typhoid vaccine and hepatitis B therapeutic vaccine candidates are outside of this non-exclusive field of use, we have exclusive rights with respect to these vaccine candidates. We exclusively own the composition of matter patents covering the specific combination of mutations employed in our typhoid vaccine and hepatitis B therapeutic vaccine candidates.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, our competitors may independently develops similar technologies or duplicate any technology developed by us, and the rights granted under any issued patents may not provide us with any meaningful competitive advantages against these competitors. Furthermore, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We also rely on trade secrets relating to manufacturing processes and product development to protect our business. Because we do not have patent protection for BioThrax, the label expansions and improvements that we are pursuing for BioThrax or our anthrax immune globulin candidate, our only intellectual property protection for BioThrax and our anthrax immune globulin candidate is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and biological starting materials. However, these types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, with agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

## License agreements

We are a party to a number of license agreements under which we license patents, patent applications, and other intellectual property. We enter into these agreements to augment our owned intellectual property. These agreements impose various diligence and financial payment obligations on us. We expect to continue to enter into these types of license agreements in the future. The only existing licenses that we consider to be material to our business, are our agreements with HPA, which are described below.

HPA agreements. In November 2004, we entered into two separate license agreements with HPA for our botulinum toxoid vaccine and our recombinant bivalent botulinum vaccine candidate. Under the license agreements, we obtained the exclusive, worldwide right to develop, manufacture and commercialize pharmaceutical products that consist of botulinum toxoid components or recombinant botulinum toxin components for the prevention or treatment of illness in humans caused by exposure to the botulinum toxin, subject to HPA's non-exclusive right to make, use or sell recombinant botulinum products to meet public health requirements in the United Kingdom.

The licensed patent portfolio includes one U.S. patent with claims to the composition of matter of recombinant components of *Clostridium botulinum*, which expires in 2016. Additional composition of matter and method of use claims are pending in three U.S. patent applications, which if issued as patents also would expire in 2016. The licensed portfolio also includes seven foreign applications, which if issued would expire in 2016.

Under each license agreement, we are required to pay HPA royalties on sales of the licensed product by us, our affiliates or third party sublicensees in the major market countries of the United States, United Kingdom, France, Germany, Italy and Japan, and a separate royalty on sales of the licensed product by us and our affiliates in any other country.

Under each license agreement, we are generally obligated to use commercially reasonable efforts to respond to applicable solicitations or procurement proposals from, and to enter into contracts with, governmental agencies in each of the major market countries with respect to the licensed product. We may satisfy this obligation by filing an IND with respect to a licensed product by November 2009. If we fail to file an IND within that time period under either of the license agreements, we are obligated to pay HPA an annual fee until an IND has been filed.

In November 2004, we also entered into two separate development agreements with HPA pursuant to which HPA agreed to conduct specified tests, studies and other development activities with respect to the botulinum toxoid product and the recombinant botulinum product in accordance with mutually-agreed development plans. We have satisfied minimum contractual commitments to compensate HPA for this development work. HPA also agreed to provide us with clinical supplies of the botulinum toxoid product and the recombinant botulinum product for clinical trials.

The term of each development agreement lasts until the development activities are completed. HPA may terminate each development agreement as a result of our uncured material breach or insolvency. Each of the development agreements automatically terminates if the applicable license agreement is

The term of each license agreement lasts until the expiration of all of our royalty obligations under the applicable license agreement. We are obligated to pay royalties under each license agreement, on a product-by-product and country-by-country basis, until the later of seven years from first commercial sale of the first licensed product in that country and the expiration of the last-to-expire licensed patent in that country. HPA may terminate each license agreement if we terminate the applicable development agreement without cause before we have paid, or if HPA terminates such development agreement due to our failure to pay, the minimum commitment amount set forth in such development agreement. In addition, HPA may terminate each license agreement as a result of our uncured material breach or insolvency.

# **Government contracts**

We have an ongoing BioThrax supply contract with the DoD, which purchases BioThrax for immunization of military personnel. In addition, we supply BioThrax to HHS for placement into the strategic national stockpile.

Department of Defense. Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. We have completed delivery of all of the doses of BioThrax under our first contract with the DoD. In November 2003, we entered into a follow-on, second supply contract with the DoD. This second contract is referred to as an indefinite delivery/indefinite quantity contract. Under this contract, the DoD is obligated to acquire a minimum number of doses of BioThrax and has the right to acquire up to a maximum number of doses. We invoice the DoD for progress payments under the contract upon reaching pre-determined process stages in the manufacture of BioThrax. The contract provides for the supply of BioThrax to the DoD through September 30, 2006. We expect to deliver all of the remaining doses of BioThrax under our contract with the DoD within the contract term.

Department of Health and Human Services. In May 2005, we entered into an agreement to supply five million doses of BioThrax to HHS for placement into the strategic national stockpile for a fixed price of \$123 million. We have completed delivery of all of the five million doses of BioThrax to HHS. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax to HHS by May 2007 for a fixed price of \$120 million. Our contract with the HHS does not provide for progress payments. We invoice HHS under the contract upon completing delivery of the specified doses of BioThrax.

U.S. government indemnification. Under contractual provisions, the U.S. government indemnifies us against claims by third parties for death, personal injury and other damages related to BioThrax, including reasonable litigation and settlement costs, to the extent that the claim or loss results from specified risks not covered by insurance or caused by our grossly negligent or criminal behavior. As required under such contracts, we have notified the DoD of personal injury claims that have been filed against us as a result of the vaccination of U.S. military personnel with BioThrax and are seeking reimbursement from DoD for

all costs incurred in defending these claims. In addition, HHS has agreed that BioThrax delivered for inclusion in the strategic national stockpile will not be used in humans unless mutually agreeable indemnification is approved.

Safety Act and other statutory protections. We have applied to the Department of Homeland Security pursuant to the Safety Act enacted by the U.S. Congress in 2002 for liability protection for sales of BioThrax. The Safety Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. In addition, the Safety Act provides a process by which an anti-terrorism technology may be certified as an "approved product" by the Department of Homeland Security and therefore entitled to a rebuttable presumption that the government contractor defense applies to sales of the product. If the Department of Homeland Security does not designate BioThrax as a qualifying anti-terrorism technology, we would not be entitled to the benefits of the Safety Act.

The government contractor defense, under specified circumstances, extends the sovereign immunity of the United States to government contractors who manufacture a product for the government. Specifically, for the government contractor defense to apply, the government must approve reasonably precise specifications, the product must conform to those specifications and the supplier must warn the government about known dangers arising from the use of the product. We have successfully asserted the government contractor defense in product liability litigation in federal district court in Michigan.

As part of the 2006 Defense Authorization Act, the U.S. Congress adopted the Public Readiness and Emergency Preparedness Act, which offers targeted liability protections to those involved in the development, manufacturing and deployment of pandemic and epidemic products and security countermeasures. The Public Readiness and Emergency Preparedness Act provides immunity, subject to limited exceptions, for claims arising out of, related to or resulting from the administration or use of a covered countermeasure.

## Government regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements for the preclinical and clinical development, manufacture, distribution and marketing of pharmaceutical and biological products, including immunobiotics. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, recordkeeping, approval, advertising, sale, promotion, import, and export of our products and product candidates.

#### U.S. government regulation

In the United States, BioThrax and our product candidates are regulated by the FDA as biological products. Biologics are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, or the PHSA, the regulations promulgated under the FDCA and the PHSA and other federal, state, and local statutes and regulations. Violations of regulatory requirements at any stage may result in various adverse consequences, including delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions, including withdrawal of approval, labeling restrictions, seizure of products, fines, injunctions or civil or criminal penalties.

The process required by the FDA under these laws before our product candidates may be marketed in the United States generally involves the following:

- · preclinical laboratory and animal tests;
- · submission to the FDA of an IND, which must become effective before clinical trials may begin;
- · completion of human clinical trials and other studies to establish the safety and efficacy of the proposed product for each intended use;
- FDA review of whether the facility in which the product is manufactured, processed, packed or held complies with cGMP requirements designed to
  assure the product's continued quality; and
- submission to the FDA and approval of an NDA in the case of a drug, or a BLA in the case of a biologic, containing preclinical and clinical data, proposed labeling and information to demonstrate that the product will be manufactured to appropriate standards of identity, purity and quality.

The research, development and approval process requires substantial time, effort and financial resources, and approvals may not be granted on a timely or commercially viable basis, if at all.

#### Preclinical studies

Preclinical studies include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to assess its potential safety and efficacy. We submit the results of the preclinical studies, together with manufacturing information, analytical data and any available clinical data or literature to the FDA as part of an IND, which must become effective before we may begin human clinical trials. The IND submission also contains clinical trial protocols, which describe the design of the proposed clinical trials. The IND becomes effective 30 days after the FDA receives the filling, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the preclinical trials or the design of the proposed clinical trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. In addition, an independent Institutional Review Board charged with protecting the welfare of human subjects involved in research at each medical center proposing to conduct the clinical trials must review and approve any clinical trial. Furthermore, study subjects must provide informed consent for their participation in the

## Clinical trials

Human clinical trials are typically conducted in three sequential phases, which may overlap:

- In a Phase I clinical trial, the drug or biologic is initially administered into healthy human subjects or subjects with the target condition and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- In a Phase II clinical trial, the drug or biologic is administered to a limited subject population to identify possible adverse effects and safety risks, the efficacy of the product for specific targeted diseases and dosage tolerance and optimal dosage.
- A Phase III clinical trial is undertaken if a Phase II clinical trial demonstrates that a dosage range of the drug or biologic is effective and has an acceptable safety profile. In a Phase III clinical trial, the drug or biologic is administered to an expanded population, often at geographically dispersed clinical trial sites, to further evaluate dosage and clinical efficacy and to further test for safety.

U.S. law requires that trials to support approval for product marketing be "adequate and well controlled." In general, this means that pivotal clinical trials typically must be prospective, randomized, blinded and controlled. The design of the clinical trials must be described in appropriate protocols submitted to the FDA and approved by an Institutional Review Board. Clinical trials typically compare the experimental product to either a placebo or, in some cases, a product already approved for the treatment of the applicable disease or condition. Trials must also be conducted in compliance with good clinical practice, or GCP, requirements.

In the case of product candidates that are intended to treat rare life-threatening diseases, such as infection caused by exposure to the anthrax toxin, conducting controlled clinical trials to determine efficacy may be unethical or infeasible. Under regulations issued by the FDA in 2002, often referred to as "the animal rule," the FDA described the circumstances under which it will rely on evidence from studies in animals to provide substantial evidence of efficacy for products for which human efficacy studies are not ethical or feasible. The animal rule provides that, under these circumstances, approval of the product can be based on clinical data from trials in healthy subjects that demonstrate adequate safety and immunogenicity and efficacy data from adequate and well controlled animal studies. Among other requirements, the animal studies must establish that the biological product is reasonably likely to produce clinical benefits in humans. Because the FDA must agree that data derived from animal studies may be extrapolated to establish safety and effectiveness in humans, these studies add complexity and uncertainty to the testing and approval process. In addition, products approved under the animal rule are subject to additional regulation not normally requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

We may not successfully complete Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all. Furthermore, the FDA or the Institutional Review Boards or the sponsor may prevent clinical trials from beginning or may place clinical trials on hold or terminate them at any point in this process if, among other reasons, they conclude that study subjects are being exposed to an unacceptable health risk.

#### Marketing approval

In the United States, the results of product development, preclinical studies and clinical trials must be submitted to the FDA for review and approval prior to marketing and commercial shipment of the product candidate. If the product is regulated as a drug, an NDA must be submitted and approved before commercial marketing may begin. If the product is regulated as a biologic, a BLA must be submitted and approved before commercial marketing may begin. The NDA or BLA must include a substantial amount of data and other information concerning the safety and effectiveness and, in the case of a biologic, purity and potency of the product candidate from laboratory, animal and clinical testing, as well as data and information on the finished product, including manufacturing, product stability and proposed product labeling.

Each domestic and foreign manufacturing establishment, including any contract manufacturers we may decide to use, must be listed in the NDA or BLA and must be registered with the FDA. The FDA generally will not approve an application until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process for the drug or biological product and determines that the facility is in compliance with cGMP requirements. If the manufacturing facilities and processes fail to pass the FDA inspection, we will not receive approval to market these products.

Under applicable laws and FDA regulations, each NDA or BLA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will "file" the NDA or BLA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA or BLA that it deems incomplete or not properly reviewable.

The FDA may deny an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if additional clinical data is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. If the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that contraindications, warning statements or precautions be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan or otherwise limit the scope of any approval or post-approval, or limit labeling. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized. The FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies often takes many years and the actual time required may vary substantially, based upon the type, complexity and novelty of the product candidate. Government regulation may delay or prevent marketing of potential products for a considerable period of time or permanently and impose costly procedures upon our activities. The FDA or other regulatory agencies may not grant approval for any of our product candidates on a timely basis, or on a commercially viable basis, if at all. Success in preclinical testing or early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. Data obtained from preclinical and clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Even if a product candidate receives regulatory approval may be significantly limited to specific indications. Furthermore, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market

#### Ongoing regulation

Any products manufactured or distributed by us pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including:

- · recordkeeping requirements;
- · periodic reporting requirements;
- · cGMP requirements related to all stages of manufacturing, testing, storage, packaging, labeling and distribution of finished dosage forms of the product;
- · reporting of adverse experiences with the drug or biologic; and
- · advertising and promotion restrictions.

The FDA's rules for advertising and promotion require in particular that we not promote our products for unapproved uses and that our promotion be fairly balanced and adequately substantiated. We must also

submit appropriate new and supplemental applications and obtain FDA approval for some changes to the approved product, product labeling or manufacturing process.

Drug and biologics manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies. The cGMP requirements for biological products are extensive and require considerable time, resources, and ongoing investment to comply. The regulations require manufacturers to establish validated systems to ensure that products meet high standards of sterility, purity and potency. The requirements apply to all stages of the manufacturing process, including the synthesis, processing, sterilization, packaging, labeling, storage and shipment of the biological product. The regulations require investigation and correction of any deviations from cGMP and impose documentation requirements upon us and any third party manufactures that we may decide to use. Manufacturing establishments are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP. The FDA is authorized to inspect manufacturing facilities without a warrant at reasonable times and in a reasonable manner. We or our present or future suppliers may not be able to comply with cGMP and other FDA regulatory requirements.

In addition, cGMP requirements are constantly evolving, and new or different requirements may apply in the future. We, our collaborators or third party contract manufacturers may not be able to comply with the applicable regulations. After regulatory approvals are obtained, the subsequent discovery of previously unknown problems, or the failure to maintain compliance with existing or new regulatory requirements, may result in:

- restrictions on the marketing or manufacturing of a product;
- warning letters:
- withdrawal of the product from the market;
- · refusal to approve pending applications or supplements to approved applications;
- voluntary or mandatory product recall;
- fines or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- · refusal to permit the import or export of products;
- product seizure; and
- · injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action in the United States or abroad. We and our product candidates are also subject to a variety of state laws and regulations in those states or localities where they are or will be marketed. Any applicable state or local regulations may hinder our ability to market our product candidates in those states or localities.

#### **Biologics review for BioThrax**

The NIH originally approved the manufacture and sale of BioThrax in 1970 pursuant to the regulatory process in effect at the time. In 1972, responsibility for approving biological products was transferred from the NIH to the FDA. Following that transfer of responsibility, the FDA established procedures for reviewing the safety, efficacy and labeling of biological products, including BioThrax, that had been approved by the NIH prior to July 1, 1972. Under the biologics review process, the FDA appointed advisory panels of independent experts to evaluate previously approved biologic products and to advise the FDA as to whether the products were safe, effective and not misbranded. After reviewing a particular panel's recommendation, the FDA publishes the panel's report, along with a proposed order recommending classification of the biological product into one of three categories: Category I, safe, effective and not misbranded; Category II, unsafe, ineffective or misbranded; or Category III, not within Category I or Category II because further studies are required. After a ninety-day comment period, the FDA reviews any comments and then publishes a final rule or order classifying the product at issue as Category I, II or III. Only after publishing a final order does the FDA then take action with respect to individual products. For example, if the biologics review determines that a specific product is not safe and effective, the FDA would initiate the process of revoking the approval for the product. Likewise, if further study is required before the status of a product can be determined, the sponsor would be required to come forward with additional data within prescribed time periods. The FDA completed the biologics review for BioThrax in 2005, classifying the product as Category I, safe, effective and not misbranded.

#### Regulation of immune globulin products

Products derived from humans, including our immune globulin candidates, are subject to additional regulation. The FDA regulates the screening and vaccination of human donors and the process of collecting source plasma. FDA regulations require that all donors be tested for suitability and provide informed consent prior to vaccination or collection of source plasma for the immune globulin. The vaccination and collection of source plasma may also be subject to Institutional Review Board approval or to an IND, depending on factors such as whether donors are to be vaccinated according to the vaccine's approved schedule. The FDA also regulates the process of testing, storage and processing of source plasma, which is used to manufacture immune globulin candidates for use in clinical trials and, after approval by the FDA, for commercial distribution.

#### Regulation related to bioterrorism counteragents and pandemic preparedness

Because some of our products or product candidates are intended for the treatment of diseases that may result from acts of bioterrorism or for pandemic preparedness, they may be subject to the specific requirements described below.

## Project BioShield

The Project BioShield Act of 2004 provides expedited procedures for bioterrorism related procurement, hiring and awarding of research grants, making it easier for HHS to quickly commit funds to countermeasure projects. Project BioShield relaxes procedures under the Federal Acquisition Regulation for procuring up to \$25 million of property or services used in performing, administering or supporting biomedical countermeasure research and development. In addition, if the Secretary of HHS deems that there is a pressing need, Project BioShield authorizes the Secretary to use an expedited award process, rather than the normal peer review process, for grants, contracts and cooperative agreements related to biomedical countermeasure research and development activity. This power is limited to awards of \$1.5 million or less.

Under Project BioShield, the Secretary of HHS, with the concurrence of the Secretary of the Department of Homeland Security and upon the approval of the President, can contract to purchase unapproved countermeasures for the strategic national stockpile in specified circumstances. Congress is notified of a recommendation for a stockpile purchase after Presidential approval. Project BioShield specifies that a company supplying the countermeasure to the strategic national stockpile is paid on delivery of a substantial portion of the countermeasure. To be eligible for purchase under these provisions, the Secretary of HHS must determine that there is sufficient and satisfactory clinical results or research data, including data, if available, from preclinical and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years. Project BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA. To exercise this authority, the Secretary of HHS must conclude that:

- the agent for which the countermeasure is designed can cause serious or life-threatening disease;
- · the product may reasonably be believed to be effective in detecting, diagnosing, treating or preventing the disease;
- the known and potential benefits of the product outweigh its known and potential risks;
- there is no adequate alternative to the product that is approved and available; and
- · any other criteria prescribed in regulations are met.

Although this provision permits the Secretary of HHS to circumvent the FDA approval process, its use would be limited to rare circumstances. We cannot predict whether these authorities would be applicable to any of our current product candidates.

#### Safety Act

The Safety Act enacted by the U.S. Congress in 2002 creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. In addition, the Safety Act provides a process by which an anti-terrorism technology may be certified as an "approved product" by the Department of Homeland Security and therefore entitled to a rebuttable presumption that the government contractor defense applies to sales of the product. The government contractor defense, under specified circumstances, extends the sovereign immunity of the United States to government contractors who manufacture a product for the government. Specifically, for the government contractor defense to apply, the government must approve reasonably precise specifications, the product must conform to those specifications and the supplier must warn the government about known dangers arising from the use of the product. Our products or product candidates may not qualify for the protections of the Safety Act or the government contractor defense.

## Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act enacted by the U.S. Congress in 2005 provides immunity for manufacturers from all claims under state or federal law for "loss" arising out of the administration or use of a "covered countermeasure." "Covered countermeasures" include security countermeasures and "qualified pandemic or epidemic products," including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or "credible risk" of a future public health emergency. In the declaration, the Secretary may recommend the manufacture, administration or

use of one or more countermeasures. Once the Secretary issues a declaration invoking the immunity provisions of the Act for the specified countermeasures, immunity applies with regard to administration or use of those countermeasures during the effective period of the declaration and for the diseases specified in the declaration. However, injured persons may still bring a suit for "willful misconduct" against the manufacturer under some circumstances. A declaration also triggers the establishment of a compensation program. If Congress funds the compensation program, persons injured by a qualified countermeasure must first seek compensation under the program before they may bring a suit alleging willful misconduct. We cannot predict whether our products or product candidates would fall within the provisions of this law, whether Congress would fund the relevant compensation program or if the necessary prerequisites for immunity would be triggered.

#### Foreign regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The actual time required to obtain clearance to market a product in a particular foreign jurisdiction may vary substantially, based upon the type, complexity and novelty of the pharmaceutical product candidate and the specific requirements of that jurisdiction. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary from country to country.

In the European Union, our products are subject to extensive regulatory requirements. As in the United States, the marketing of medicinal products has for many years been subject to the granting of marketing authorizations by regulatory agencies. European Union member states require both regulatory clearance and a favorable ethics committee opinion prior to the commencement of a clinical trial, whatever its phase. Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is currently mandatory for products developed by means of a biotechnological process, including recombinant DNA technology, the controlled expression of genes coding for biologically active proteins and monoclonal antibody methods, and new chemical entities for the treatment of acquired immune deficiency syndrome, cancer and neurodegenerative disorder or diabetes. Beginning in May 2008, the centralized procedure will be mandatory for products for the treatment of auto-immune diseases and other immune dysfunctions and viral diseases. The centralized process is optional for medicines that constitute a "significant therapeutic, scientific or technical innovation" or for which a centralized process is in the interest of patients.

The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and an assessment report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

Unlike the United States, the European Union member states do not have separate rules or review procedures for biologics and vaccines. Regulators apply broadly consistent principles and standards when reviewing applications, although they accept that the nature of the efficacy data supporting a vaccine

application is likely to differ from the data that would support applications for the majority of therapeutic products. However, there are special procedures for some types of vaccine products. For example, influenza vaccines are subject to accelerated review and approval each year, following the release by the World Health Organization of the annual influenza strains. European Union member states have the discretion to require that marketing authorization holders submit samples of live vaccines or other immunological products for examination and formal batch release by a government control laboratory prior to release onto the market.

#### Orphan drugs

Under the Orphan Drug Act, special incentives exist for sponsors to develop products for rare diseases or conditions, which are defined to include those diseases or conditions that affect fewer than 200,000 people in the United States. A vaccine also can receive these incentives if it is expected to be administered to fewer than 200,000 persons per year. Sponsors may request that the FDA grant a drug orphan designation prior to approval. Biologics may qualify for designation as an orphan drug.

Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, reduced filing fees for marketing applications and a special seven-year period of market exclusivity after marketing approval. Orphan drug exclusivity prevents FDA approval of applications by others for the same drug or biologic intended for use for the designated orphan disease or condition. The FDA may approve a subsequent application from another person if the FDA determines that the application is for a different product or different use, or if the FDA determines that the subsequent product is clinically superior or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug or biologic to meet the public's need. The FDA also may approve another application for the same drug or biologic that has orphan exclusivity but for a different use, in which case the competing drug or biologic could be prescribed by physicians outside its FDA approval for the orphan use notwithstanding the existence of orphan exclusivity. A grant of an orphan designation is not a guarantee that a product will be approved.

The European Union operates an equivalent system to encourage the development and marketing of medicinal products for rare diseases. Applications for orphan designations are submitted to the European Medicines Agency and reviewed by a Committee on Orphan Medicinal Products, comprising representatives of the member states, patient groups and other persons. The final decision is made by the European Commission.

A product can be designated as an orphan drug if it is intended for either a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Community when the application is made or a life-threatening, seriously debilitating or serious and chronic condition in the European Community for which, without incentives, it is unlikely that the marketing of the product in the Community would generate sufficient return to justify the necessary investment. In either case, the applicant must also demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition.

After a marketing authorization has been granted in the European Community for an orphan product, no similar product may be approved for a period of ten years. At the end of the fifth year, however, any member state can initiate proceedings to restrict that period to six years if it believes the criteria for orphan designation no longer apply, for example, because the prevalence of disease has increased or the manufacturer is earning an unreasonable profit. In addition, competitive products can be approved during

the marketing exclusivity period if they are not similar to the original product or are safer, more effective or otherwise clinically superior to it.

None of our products or product candidates have been designated as orphan drugs.

## Reimbursement and pricing controls

In many of the markets where we or our potential collaborators would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to direct price controls by law and to reimbursement programs with varying price control mechanisms.

In the United States, there has been an increased focus on drug and biologic pricing in recent years. Although there are currently no direct government price controls over private sector purchases in the United States, federal legislation requires pharmaceutical manufacturers to pay prescribed rebates on specified drugs and biologics to enable them to be eligible for reimbursement under public health care programs such as Medicaid. Vaccines are generally exempt from these programs. Various states have adopted further mechanisms that seek to control drug and biologic prices, including by disfavoring higher priced products and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products. Federal legislation, enacted in December 2003, has altered the way in which physician-administered drugs and biologics covered by Medicare are reimbursed. Under the new reimbursement methodology, physicians are reimbursed based on a product's "average sales price." This new reimbursement methodology has generally led to lower reimbursement levels. The new federal legislation also has added an outpatient prescription drug benefit to Medicare, which went into effect in January 2006. These benefits will be provided primarily through private entities, which we expect will attempt to negotiate price concessions from pharmaceutical manufacturers.

Public and private health care payors control costs and influence drug and biologic pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to particular products over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug or biologic that will be deemed medically appropriate and therefore reimbursed or otherwise covered. In particular, many public and private health care payors limit reimbursement and coverage to the uses that are either approved by the FDA or that are supported by other appropriate evidence, such as published medical literature, and appear in a recognized compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA.

Most non-pediatric commercial vaccines are purchased and paid for, or reimbursed by, managed care organizations, other private health plans or public insurers or paid for directly by patients. In the United States, pediatric vaccines are funded by a variety of federal entitlements and grants, as well as state appropriations. The CDC currently distributes pediatric grant funding on a discretionary basis under the Public Health Service Act. Federal and state governments purchase the majority of all pediatric vaccines produced in the United States, primarily through the Vaccine for Children Program implemented by the U.S. Congress in 1994. The Vaccine for Children Program is designed to help pay for vaccinations to disadvantaged children, including uninsured children on Medicaid and underinsured children who receive vaccinations at federally qualified health centers.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement

rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

#### Regulations regarding government contracting

Our status as a government contractor in the United States and elsewhere means that we are also subject to various statutes and regulations, including the Federal Acquisition Regulation, which govern the procurement of goods and services by agencies of the United States and other countries. These governing statutes and regulations can impose stricter penalties than those normally applicable to commercial contracts, such as criminal and civil damages liability and suspension and debarment from future government contracting. In addition, pursuant to various statutes and regulations, our government contracts can be subject to unilateral termination by the government for convenience in the United States and elsewhere, detailed auditing requirements, statutorily controlled pricing, sourcing and subcontracting restrictions and statutorily mandated processes for adjudicating contract disputes.

## Vaccine Injury Compensation Program

Because the cost of vaccine related litigation had reduced significantly the number of manufacturers willing to sell childhood vaccines, the U.S. Congress enacted the National Childhood Vaccine Injury Act in 1986. The Vaccine Injury Compensation Program established under the Vaccine Injury Act is a no-fault compensation program funded by an excise tax on each dose of a covered vaccine and is designed to streamline the process of seeking compensation for those injured by childhood vaccines. The Vaccine Injury Act requires all individuals injured by a vaccine to go through the compensation program before pursuing others remedies. Although claimants can reject decisions issued under the compensation program and pursue subsequent legal action through the courts, the Vaccine Injury Act determines the circumstances under which a manufacturer may be found liable in a civil action. The Vaccine Injury Act may not protect us if our products or product candidates cause injury.

#### Hazardous materials and select agents

Our development and manufacturing processes involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS and the DoD.

The Public Health Security and Bioterrorism Preparedness and Response Act and the Agricultural Protection Act require us to register with the CDC and the Department of Agriculture our possession, use or transfer of select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires increased safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel, and establishes a comprehensive national database of registered entities.

In particular, this legislation and related regulations require that we

· develop and implement biosafety, security and emergency response plans;

- restrict access to select agents and toxins;
- provide appropriate training to our employees for safety, security and emergency response;
- comply with strict requirements governing transfer of select agents and toxins;
- provide timely notice to the government of any theft, loss or release of a select agent or toxin; and
- · maintain detailed records of information necessary to give a complete accounting of all activities related to select agents and toxins.

#### Other regulations

In the United States and elsewhere, the research, manufacturing, distribution, sale and promotion of drug and biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of HHS, such as the Office of Inspector General, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice and state and local governments. For example, sales, marketing and scientific and educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provisions of the Health Insurance Portability and Accountability Act and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Outside the United States, advertising and promotion of medicinal products, along with associated commercial practices, are often subject to significant government regulation. We are subject to the Export Administration Regulations implemented by the Bureau of Industry and Security governing the export of BioThrax and technology for the development and use of pathogens and toxins used in the development and manufacture of BioThrax and our product candidates. In connection with our international sales activity, we are also subject to export regulations and other sanctions imposed by the Office of Foreign Assets Control of the Department of the Treasury, the antiboycott provisions of the Export Administration Act and the Internal Revenue Code and the Foreign Corrupt Practices Act.

# Litigation

BioThrax product liability litigation. We currently are a defendant in three federal lawsuits filed on behalf of three individuals vaccinated with BioThrax by the U.S. Army on October 14, 2005, January 9, 2006 and January 17, 2006 that claim damages resulting from personal injuries allegedly suffered because of the vaccination. We have moved to dismiss these three lawsuits for lack of personal jurisdiction, or, in the alternative to transfer the lawsuits to federal court in Michigan. These lawsuits are in the preliminary stages of litigation, and we believe that we are entitled to indemnification under our contract with the DoD for legal fees and any damages that may result from these claims. In April 2006, the U.S. District Court for the Western District of Michigan entered summary judgment in our favor in four other lawsuits asserting similar claims asserted by approximately 120 individuals. These four lawsuits had previously been consolidated in the Michigan District Court. The District Court's ruling in the consolidated Michigan cases was based on two grounds. First, the District Court found that we are entitled to protection under a Michigan state statute that provides immunity for drug manufacturers if the drug was approved by the FDA and its labeling is in compliance with FDA approval, unless the plaintiffs establish that the manufacturer intentionally withheld or misrepresented information to the FDA and the drug would not have been approved, or the FDA would have withdrawn approval, if the information had been accurately submitted. Second, the District Court found that we are entitled to the immunity afforded by the

government contractor defense, which, under specified circumstances, extends the sovereign immunity of the United States to government contractors who manufacture a product for the government. Specifically, the government contractor defense applies when the government approves reasonably precise specifications, the product conforms to those specifications and the supplier warns the government about known dangers arising from the use of the product. The District Court found that we established each of those factors. We intend to rely on similar defenses with respect to the substantive claims asserted in our three pending lawsuits.

Mil/Vax litigation. In 2003, six unidentified plaintiffs filed suit in the U.S. District Court for the District of Columbia against the U.S. government seeking to enjoin the Anthrax Vaccine Immunization Program administered under Mil/Vax under which all military personnel were required to be vaccinated with BioThrax. On October 27, 2004, the District Court enjoined the DoD from administering BioThrax to military personnel without their informed consent or a Presidential waiver. This ruling was based in part on the District Court's finding that the FDA, as part of its review of all biological products approved prior to 1972, had not properly issued a final order determining that BioThrax is safe and effective and not misbranded. In December 2005, the FDA issued a final order determining that BioThrax is safe and effective and not misbranded. On February 9, 2006, the U.S. Court of Appeals for the District of Columbia, on appeal of the injunction by the government, ruled that the injunction had dissolved by its own terms as a result of the FDA's final order and remanded the case to the District Court with instructions that the District Court consider the government's request to vacate the District Court's opinion. Although we are not a party to this lawsuit, if the District Court institutes another injunction or otherwise restricts the administration of BioThrax by the DoD, the amount of future purchases of BioThrax by the DoD could be limited.

Other. We are, and may in the future become, subject to other legal proceedings, claims and litigation arising in the ordinary course of our business in connection with the manufacture, distribution and use of our products and product candidates. For example, BioPort is a defendant, along with many other vaccine manufacturers, in a series of lawsuits that have been filled in various state and federal courts in the United States alleging that thimerosal, a mercury-containing preservative used in the manufacture of some vaccines, caused personal injuries. BioPort is currently a named defendant in 41 lawsuits pending in two jurisdictions: four in California and 37 in Illinois. The products at issue in these lawsuits are pediatric vaccines and immune globulins. Because we are not currently and have not historically been in the business of manufacturing or selling pediatric vaccines, we do not believe that we manufactured the pediatric vaccines at issue in the lawsuits. Under a contractual obligation to the State of Michigan, we manufactured one batch of vaccine suitable for pediatric use. However, the contract required the State to use the vaccine solely for Michigan public health purposes. One plaintiff in a thimerosal lawsuit alleges that he was injured by immune globulin containing thimerosal. We previously manufactured human immune globulin that contained thimerosal. We no longer manufacture any products that contain thimerosal. We believe that our defense costs for these thimerosal lawsuits will be covered by applicable product liability insurance and have submitted a request for coverage to our carriers for defense costs incurred to date.

#### Personnel

As of July 31, 2006, we had 469 employees, including 125 employees engaged in product development, 246 employees engaged in manufacturing, seven employees engaged in sales and marketing and 91 employees engaged in general and administrative activities. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

# Management

Our executive officers and directors and their respective ages and positions as of July 31, 2006 are as follows:

Name	Age Position
Fuad El-Hibri	48 President, Chief Executive Officer and Chairman of the Board of Directors
Edward J. Arcuri, Ph.D.	55 Executive Vice President and Chief Operating Officer
Robert G. Kramer, Sr.	49 President and Chief Executive Officer, BioPort Corporation
Steven N. Chatfield, Ph.D.	49 Chief Scientific Officer and President, Emergent Produc Development UK Limited
Daniel J. Abdun-Nabi	51 Senior Vice President Corporate Affairs, General Counsel and Secretary
Kyle W. Keese	44 Senior Vice President Marketing and Communications
R. Don Elsey	53 Vice President Finance, Chief Financial Officer and Treasurer
Joe M. Allbaugh	54 Director
Zsolt Harsanyi, Ph.D.(1)(2)(3)	62 Director
Jerome M. Hauer	54 Director
Shahzad Malik, M.D.(1)(2)	39 Director
Ronald B. Richard(1)(2)(3)	50 Director
Louis W. Sullivan, M.D.	72 Director

- (1) Member of the Audit Committee.
- (2) Member of the Compensation Committee.
- (3) Member of the Nominating and Corporate Governance Committee.

Fuad El-Hibri. Mr. El-Hibri has served as chief executive officer and as chairman of our board of directors since June 2004 and as president since March 2006. Mr. El-Hibri served as chief executive officer and chairman of the board of directors of BioPort Corporation from May 1998 until June 2004, when, as a result of our corporate reorganization, BioPort became a wholly owned subsidiary of Emergent. Mr. El-Hibri has served as chairman of Digicel Holdings, Ltd., a privately held telecommunications firm, since August 2000. He served as president of Digicel from August 2000 to February 2005. Mr. El-Hibri has served as chairman of East West Resources Corporation, a venture capital and financial consulting firm, since June 1990. He served as president of East West Resources from September 1990 to January 2004. Mr. El-Hibri is a member of the board of trustees of American University and a member of the board of directors of the International Biomedical Research Alliance, an academic joint venture among the NIH, Oxford University and Cambridge University. He also serves as director and treasurer of El-Hibri Charitable Foundation. Mr. El-Hibri received a master's degree in public and private management from Yale University and a B.A. in economics from Stanford University.

Edward J. Arcuri, Ph.D. Dr. Arcuri has served as executive vice president and chief operating officer since January 2005. Dr. Arcuri served as senior vice president of manufacturing operations from September 2003 to January 2005 and senior vice president of vaccine manufacturing from January 2002 to

September 2003 for MedImmune, Inc., a biotechnology company. Dr. Arcuri served as senior vice president, operations from May 1999 to January 2002, vice president, manufacturing from July 1999 to May 2000 and chief operating officer from May 2001 to January 2002 at Aviron, Inc., a biotechnology company, which was acquired by MedImmune in January 2002. Prior to joining Aviron, Dr. Arcuri served in various management positions at North American Vaccine, Inc., Merck & Co. and SmithKline Beecham Pharmaceuticals, formerly SmithKline & French Laboratories. Dr. Arcuri received both a Ph.D. and an M.S. in biology from Rensselaer Polytechnic Institute and a B.S. in biology from the State University of New York at Albany.

Robert G. Kramer, Sr. Mr. Kramer has served as president and chief executive officer of BioPort Corporation since July 2004. Mr. Kramer served as chief financial officer of BioPort from February 1999 to August 2000, as chief operating officer of BioPort from September 2000 to June 2004 and as president of BioPort from October 2001 to June 2004. Prior to joining BioPort, Mr. Kramer served in various financial management positions at Pharmacia Corp., which was subsequently acquired by Pfizer Inc., and with subsidiaries of Northwest Industries. Mr. Kramer received an M.B.A. from Western Kentucky University and a B.S. in industrial management from Clemson University.

Steven N. Chatfield, Ph.D. Dr. Chatfield has served as chief scientific officer since January 2005 and as president of our subsidiary, Emergent Product Development UK Limited, since June 2005. Dr. Chatfield served as development director and chief scientific officer of Microscience Limited, a U.K. biotechnology company, from March 1999 to December 2004. We acquired Microscience in June 2005. Prior to joining Microscience, Dr. Chatfield held various positions in the field of vaccine research and development, including director of biotechnology at Medeva plc, director of research at Evans Medical and several positions at Wellcome Biotechnology and the Wellcome Foundation. Dr. Chatfield received a Ph.D. from the Council for National Academic Awards in association with the University of Birmingham in the United Kingdom.

Daniel J. Abdun-Nabi. Mr. Abdun-Nabi has served as senior vice president corporate affairs, general counsel and secretary since December 2004. Mr. Abdun-Nabi served as vice president and general counsel from May 2004 to December 2004. Mr. Abdun-Nabi served as general counsel for IGEN International, Inc., a biotechnology company, and its successor BioVeris Corporation, from September 1999 to May 2004. Prior to joining IGEN, Mr. Abdun-Nabi served as senior vice president, legal affairs, general counsel and secretary of North American Vaccine, Inc. Mr. Abdun-Nabi received an L.L.M. in taxation from Georgetown University Law Center, a J.D. from the University of San Diego School of Law and a B.A. in political science from the University of Massachusetts. Amherst.

Kyle W. Keese. Mr. Keese has served as senior vice president marketing and communications since March 2006. Mr. Keese served as vice president of sales and marketing of Emergent from June 2004 to March 2006 and of BioPort Corporation from June 2003 to June 2004. Mr. Keese served as vice president, business development for Antex Biologics, Inc., a biotechnology company, from March 2001 to May 2003, when we acquired substantially all of the assets of Antex. Prior to joining Antex, Mr. Keese served in various business development, marketing and sales management positions at IGEN International and Abbott Laboratories and as an officer in the U.S. Navy. Mr. Keese received an M.B.A. from National University and a B.A. in mathematics and computer science from Tulane University.

R. Don Elsey. Mr. Elsey has served as chief financial officer since March 2006 and as vice president finance and treasurer since June 2005. Mr. Elsey served as the director of finance and administration at IGEN International, Inc., a biotechnology company, and its successor BioVeris Corporation, from April 2000 to June 2005. Prior to joining IGEN, Mr. Elsey served as director of finance at Applera, a genomics and sequencing company, and in several finance positions at International Business Machines, Inc.

Mr. Elsey received an M.B.A. in finance and a B.A. in economics from Michigan State University. Mr. Elsey is a certified management accountant.

Joe M. Allbaugh. Mr. Allbaugh has served as a director since June 2006. Mr. Allbaugh has served as president and chief executive officer of The Allbaugh Company, LLC, a corporate strategy and consulting services firm, since March 2003. Mr. Allbaugh served as director of the Federal Emergency Management Agency from February 2001 to March 2003. Previously, Mr. Allbaugh served as deputy secretary of transportation of the Oklahoma Department of Transportation and manager of a number of state and federal political campaigns. Mr. Allbaugh serves on the boards of directors of Citadel Security Software Inc., a publicly held enterprise security software company, and UltraStrip Systems, Inc., a publicly held technology company in the defense, homeland security and global ship repair markets. Mr. Allbaugh also serves on the board of advisors of Compressus Inc., a privately held software company. Mr. Allbaugh received a B.A. in political science from the Oklahoma State University.

Zsolt Harsanyi, Ph.D. Dr. Harsanyi has served as a director since August 2004. Dr. Harsanyi has served as chief executive officer and chairman of the board of directors of Exponential Biotherapies Inc., a private biotechnology company, since December 2004. Dr. Harsanyi served as president of Porton International plc, a pharmaceutical and vaccine company, from January 1983 to December 2004. Dr. Harsanyi was a founder of Dynport Vaccine Company LLC in September 1996. Prior to joining Porton International, Dr. Harsanyi was vice-president of corporate finance at E.F. Hutton, Inc. Previously, Dr. Harsanyi directed the first assessment of biotechnology for the U.S. Congress' Office of Technology Assessment, served as a consultant to the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and was on the faculties of Microbiology and Genetics at Cornell Medical College. Dr. Harsanyi received a Ph.D. from Albert Einstein College of Medicine and a B.A. from Amherst College.

Jerome M. Hauer. Mr. Hauer has served as a director since June 2005. Mr. Hauer has served as chief executive officer at The Hauer Group, a consulting services firm, since March 2006. Mr. Hauer served as senior vice president and co-chair of the homeland security practice of Fleishman-Hillard Government Relations, a government relations service firm, from January 2005 to March 2006. Prior to joining Fleishman-Hillard, Mr. Hauer served as the director of Response to Disaster and Emergencies Institute and assistant professor at the George Washington University School of Public Health from November 2003 to December 2004. Mr. Hauer served as acting assistant secretary for public health emergency preparedness of HHS from June 2002 to November 2003 and as director of the office of public health preparedness of HHS from May 2002 to June 2002. He also served as managing director of the crisis and consequence management group at Kroll Associates, a risk consulting firm, from October 2000 to February 2002. Mr. Hauer served as the first director of the New York City Mayor's Office of Emergency Management under Mayor Rudolph Giuliani. He also served as the director of Emergency Medical Services and Emergency Management as well as director of the Department of Fire and Buildings for the State of Indiana under Governor Evan Bayh. Mr. Hauer serves on the board of directors of Hollis Eden Pharmaceuticals, Inc., a publicly held pharmaceutical company. Mr. Hauer previously served as a member of the Health Advisory Board of the Johns Hopkins School of Public Health and as a member of the National Academy of Science's Institute of Medicine's Committee to Evaluate the R&D Needs for Improving Clinical Medical Response to Chemical or Biological Terrorism Incidents. Mr. Hauer received an M.H.S. in public health from Johns Hopkins University School of Hygiene and Public Health and a B.A. from New York University.

Shahzad Malik, M.D. Dr. Malik has served as a director since June 2005. Dr. Malik has served as a general partner of Advent Venture Partners, a venture capital firm, since April 1999. Prior to joining Advent Venture Partners, Dr. Malik spent two years at McKinsey & Company where he focused on

healthcare and investment banking and six years as a practicing physician specializing in cardiology. Dr. Malik also serves on the board of directors for several private biotechnology companies. Dr. Malik received his M.D. from Cambridge University and an M.A. in physiological sciences from Oxford University

Ronald B. Richard. Mr. Richard has served as a director since January 2005. Mr. Richard has served as the president and chief executive officer of the Cleveland Foundation, the nation's oldest community foundation, since June 2003. Mr. Richard served as chief operating officer of In-Q-Tel, a venture capital fund that provides technologies to the Central Intelligence Agency, from March 2001 to August 2002. Prior to joining In-Q-Tel, Mr. Richard served in various senior management positions at Matsushita Electric Industrial Co., a consumer electronics company. Mr. Richard is a former U.S. foreign service officer. He served in Osaka/Kobe, Japan and as a desk officer for North Korean, Greek and Turkish affairs at the U.S. Department of State in Washington, D.C. Mr. Richard previously served as chairman of the board of trustees of the International Biomedical Research Alliance, an academic joint venture among the NIH, Oxford University and Cambridge University. Mr. Richard received an M.A. in international relations from Johns Hopkins University School of Advanced International Studies and a B.A. in history from Washington University. He holds an honorary doctorate in humane letters from Notre Dame College.

Louis W. Sullivan, M.D. Dr. Sullivan has served as a director since June 2006. Dr. Sullivan has served as president emeritus of Morehouse School of Medicine since July 2002. Dr. Sullivan served as president of Morehouse School of Medicine from 1981 to 1989 and from 1993 to 2002. From 1989 to 1993, Dr. Sullivan was Secretary of HHS. Dr. Sullivan also serves on the boards of directors of United Therapeutics Corporation, BioSante Pharmaceuticals, Inhibitex, Inc., and Henry Schein, Inc., publicly traded biotechnology companies. He is a founder and chairman of Medical Education for South African Blacks, Inc., a trustee of Morehouse School of Medicine and Africare and a director of the National Center on Addiction and Substance Abuse at Columbia University. Dr. Sullivan recently retired from the boards of directors of Bristol-Myers Squibb Company, 3-M Corporation, Georgia Pacific Corporation, Cigna Corporation and Equifax, Inc. Dr. Sullivan received his M.D. from Boston University and a B.S. from Morehouse College.

## Board composition and election of directors

Our board of directors is currently authorized to have and currently has seven members. Upon completion of this offering, our board of directors will be divided into three classes, each of whose members will serve for staggered three-year terms:

- · , and will serve as class I directors, and their terms will expire at our 2007 annual meeting;
- and will serve as class II directors, and their terms will expire at our 2008 annual meeting; and
- and will serve as class III directors, and their terms will expire at our 2009 annual meeting.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

Until the fifth anniversary of the completion of this offering, any change in the number of directors serving on our board and the appointment and removal of the chairman of our board will require the vote of at least 75% of the directors then in office. Our directors may be removed from office only for cause and only by the affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote. Mr. El-Hibri, through his ownership interests in our

common stock and voting arrangements among our significant stockholders, will be able to control the election of directors. See "Description of capital stock — Anti-takeover effects of Delaware law and our certificate of incorporation and by-laws."

Four of our current directors, Mr. Allbaugh, Dr. Harsanyi, Dr. Malik and Mr. Richard are independent directors, as defined in applicable Nasdaq Stock Market rules. We refer to these directors as our "independent directors." There are no family relationships among any of our directors or executive officers.

#### **Board committees**

## Audit committee

The members of our audit committee are Dr. Harsanyi, Dr. Malik and Mr. Richard. Dr. Harsanyi chairs the committee. Our audit committee assists our board of directors in its oversight of our accounting and financial reporting processes and the integrity of our financial statements, our compliance with legal and regulatory requirements, the audits of our financial statements and the qualifications, independence and performance of our independent registered public accounting firm.

Upon the completion of this offering, our audit committee's responsibilities will include:

- · appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from our independent registered public accounting firm;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures:
- coordinating our board of directors' oversight of internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- · establishing procedures for the receipt and retention of accounting related complaints and concerns;
- · meeting independently with our independent registered public accounting firm and management; and
- · preparing the audit committee report required by Securities and Exchange Commission rules.

All audit services to be provided to us and all non-audit services, other than de minimis non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Dr. Harsanyi and Dr. Malik are audit committee financial experts. We believe that the composition of our audit committee meets the requirements for independence under current Nasdaq Stock Market and Securities and Exchange Commission rules and regulations.

#### Compensation committee

The members of our compensation committee are Dr. Harsanyi, Dr. Malik and Mr. Richard. Mr. Richard chairs the committee. Our compensation committee assists the board of directors in the discharge of its responsibilities relating to the compensation of our executive officers and establishing and maintaining broad-based employee benefit plans and programs.

Upon the completion of this offering, our compensation committee's responsibilities will include:

- reviewing and approving, or making recommendations to the board of directors with respect to, the compensation of our chief executive officer and our
  other executive officers:
- overseeing the evaluation of the performance of our senior executives;
- overseeing and administering, and making recommendations to the board of directors with respect to, our broad-based compensation programs and our
  cash and equity incentive plans;
- · reviewing and making recommendations to the board of directors with respect to director compensation; and
- · preparing the compensation committee report required by Securities and Exchange Commission rules.

#### Nominating and corporate governance committee

The members of our nominating and corporate governance committee are Dr. Harsanyi and Mr. Richard. Dr. Harsanyi chairs the committee.

Upon the completion of this offering, our nominating and corporate governance committee's responsibilities will include:

- recommending to the board of directors the persons to be nominated for election as directors or to fill vacancies and to be appointed to each of the board's committees;
- · overseeing an annual review by the board of directors with respect to management succession planning;
- · developing and recommending to the board of directors corporate governance principles and guidelines; and
- · overseeing periodic evaluations of the board of directors.

## Compensation committee interlocks and insider participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of our board of directors or our compensation committee. None of the members of our compensation committee has ever been our employee.

## **Director compensation**

Under our director compensation program, we pay each of our non-employee directors an annual retainer of \$20,000 for service as a director. Each non-employee director also receives a fee for each board and committee meeting attended. The board meeting fee is \$1,500 for attendance in person and \$500 for attendance by telephone. The audit committee meeting fee is \$1,500 for attendance in person and \$500 for attendance by telephone. The compensation committee meeting fee is \$1,000 for attendance in person and \$300 for attendance by telephone. Following the completion of this offering, the nominating and corporate governance committee meeting fee will be \$1,000 for attendance in person and \$300 for attendance by telephone. Each member of our audit committee receives an additional annual retainer of \$5,000. Each member of our compensation committee receives an additional annual retainer of \$3,000. Following the completion of this offering, each member of our

nominating and corporate governance committee will receive an annual retainer of \$3,000. We reimburse our non-employee directors for out-of-pocket expenses incurred in connection with attending our board and committee meetings.

Under the director compensation program, we have granted a non-qualified option to purchase 15,000 shares of our class B common stock to each of our independent directors, unless the director's appointment was pursuant to any transaction or other arrangement requiring such appointment, and to each of our non-employee directors who does not qualify as an independent director if our board of directors determined that the option grant was necessary to attract such non-employee director to join the board. These options vest over three years and expire ten years from the date of grant, subject to the director's continued service as a director. Upon a change in control, as defined in each director stock option agreement, we will have the option to purchase and redeem all the options owned by the director, or held for the benefit of the director, for a purchase price equal to the difference between the option exercise price and the fair market value. In the event we exercise such repurchase option, any unvested options will be deemed fully vested on the day preceding the date of repurchase.

We have granted the following non-qualified stock options to our independent and non-employee directors:

- On December 1, 2004, we granted a stock option to purchase 15,000 shares at an exercise price of \$7.89 per share to Dr. Harsanyi.
- · On January 26, 2005, we granted a stock option to purchase 15,000 shares at an exercise price of \$7.89 per share to Mr. Richard.
- On June 15, 2005, we granted a stock option to purchase 15,000 shares at an exercise price of \$10.06 per share to Mr. Hauer.
- On June 30, 2006, we granted a stock option to purchase 15,000 shares at an exercise price of \$29.58 per share to Dr. Sullivan.
- On June 30, 2006, we granted a stock option to purchase 15,000 shares at an exercise price of \$29.58 per share to Mr. Allbaugh.

Following the completion of this offering, pursuant to automatic option grants to non-employee directors under our 2006 stock incentive plan, we will grant each of our non-employee directors a nonstatutory option to purchase:

- 7,500 shares of common stock upon commencement of service on our board of directors;
- 5,000 shares of common stock, on the date of each of our annual meetings of stockholders, provided that the director continues serving as a director after the annual meeting and has served on our board of directors for at least six months; and
- if the non-employee director is serving as the chair of one or more committees of our board of directors, an additional 2,500 shares of common stock, on the date of each of our annual meetings of stockholders, provided that the director continues serving as a director after the annual meeting and has served on our board of directors for at least six months.

See "— Stock option and other compensation plans — 2006 stock incentive plan" for additional information regarding these option grants.

# **Executive compensation**

The following table sets forth a summary of the compensation paid or accrued during the year ended December 31, 2005 to our chief executive officer and to our four most highly compensated executive officers other than our chief executive officer who were serving as executive officers as of December 31, 2005. We refer to these individuals as our named executive officers.

# Summary compensation table

		An	nnual	compensation Other annual	Long-term compensation Shares underlying	All other
Name and principal position	Salary	Bonus(1)		compensation	options	compensation(2)
Fuad El-Hibri						
President, Chief Executive Officer and Chairman of						
the Board of Directors	\$ 490,818	_	\$	_	75,000	\$ 7,000
Edward J. Arcuri, Ph.D.						
Executive Vice President and Chief Operating Officer	280,192	_		_	40,000	_
Robert G. Kramer, Sr.						
President and Chief Executive Officer, BioPort						
Corporation	371,192	_		_	40,000	7,000
Steven N. Chatfield, Ph.D.						
President, Emergent Product Development UK	205 400			20.752(2)	20,000	
Limited and Chief Scientific Officer	225,162	_		38,752(3)	20,000	_
Daniel J. Abdun-Nabi						
Senior Vice President Corporate Affairs, General	070 004					
Counsel and Secretary	272,631	_		<del>-</del>	_	_

- (1) Bonus amounts for 2005 have not yet been determined. Each of the named executive officers is eligible to receive a bonus in an amount determined by our board of directors.
- (2) Represents the value of our contributions on behalf of the named executive officer to our 401(k) savings plan.
- (3) Represents a relocation payment of \$15,000 and a living allowance of \$23,752.

## Stock option grants

The following table sets forth information regarding grants of stock options to purchase shares of our common stock to our named executive officers during the year ended December 31, 2005. Immediately prior to the completion of this offering, each outstanding option to purchase shares of our class B common stock automatically will become an option to purchase an equal number of shares of our common stock.

Potential realizable values are calculated using the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and assuming that the market price appreciates from this price at the indicated rate for the entire term of each option and that each option is exercised and sold on the last day of its term at the assumed appreciated price. The assumed 5% and 10% rates of stock price appreciation are required by the rules of the Securities and Exchange Commission and do not represent our estimate or projection of the future price of our common stock. Actual gains, if any, on stock option exercises depend on the future performance of our common stock and the date on which the options are exercised.

## Option grants in last fiscal year

Name	Number of shares underlying options granted	Percentage of total options granted to employees in fiscal year	Exercise price per share	Expiration date	vali	ntial realizable ue at assumed innual rates of stock price option term(1) 10% (\$)
Fuad El-Hibri	75,000(2)	30.0%	\$ 10.06	5/25/10		
Edward J. Arcuri, Ph.D.	40,000(3)	16.0	7.89	2/9/10		
Robert G. Kramer, Sr.	40,000(2)	16.0	10.06	5/25/10		
Steven N. Chatfield, Ph.D.	20,000(3)	8.0	7.89	2/9/10		
Daniel J. Abdun-Nabi	<del>_</del> ``	_	_	_		

- (1) The dollar amounts under these columns are the result of calculations at rates set by the Securities and Exchange Commission and, therefore, are not intended to forecast possible future appreciation, if any, in the price of the underlying common stock.
- (2) These options vest in three annual installments, with 40% of the original number of shares having vested on December 31, 2005 and 30% of the original number of shares vesting on each of December 31, 2006 and December 31, 2007.
- (3) These options vest in three equal annual installments beginning on December 31, 2005.

## Option exercises and year-end option values

The following table sets forth information regarding the number of shares of our common stock issued upon option exercises by our named executive officers during the year ended December 31, 2005 and the value realized by our named executive officers. In addition, the table sets forth information regarding the number and value of unexercised options held by our named executive officers at December 31, 2005. There was no public trading market for our common stock as of December 31, 2005. Accordingly, as permitted by the rules of the Securities and Exchange Commission, we have calculated the value of

unexercised in-the-money options at December 31, 2005 assuming that the fair market value of our common stock as of December 31, 2005 was equal to the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, less the aggregate exercise price.

# Aggregated option exercises in last fiscal year and fiscal year-end option values

	Number of shares acquired on	Value		Number of securities underlying unexercised options at December 31, 2005	in-the	lue of unexercised -money options at December 31, 2005
Name	exercise	realized	Exercisable	Unexercisable	Exercisable	Unexercisable
Fuad El-Hibri	_	_	30,000	45,000		
Edward J. Arcuri, Ph.D.	_	_	13,334	26,666		
Robert G. Kramer, Sr.	_	_	178,500	24,000		
Steven N. Chatfield, Ph.D.	_	_	6,667	13,333		
Daniel J. Abdun-Nabi	_	_	25,900	11,100		

## Employment agreement with Steven Chatfield, Ph.D.

In December 2005, our wholly owned subsidiary, Emergent Product Development UK Limited, formerly Emergent Europe Limited, entered into an employment contract with Dr. Chatfield to serve as President of Emergent Product Development UK. Under this agreement, Dr. Chatfield is entitled to an annual base salary of £149,914, which may be reviewed annually in the discretion of Emergent Product Development UK. Dr. Chatfield is also eligible to participate in any bonus plan established by Emergent Product Development UK from time to time. Under the agreement, Emergent Product Development UK agreed to contribute 10% of Dr. Chatfield's salary, which amount will be capped at Inland Revenue Limits, in equal monthly installments to a qualified pension plan, subject to Dr. Chatfield making monthly contributions to the qualified pension plan in an amount equal to 2.5% of his salary. Either party may terminate the agreement upon not less than six months' prior written notice. Emergent Product Development UK may terminate Dr. Chatfield's employment without prior notice for conduct amounting to gross misconduct or any other equivalent conduct or performance issues. Subject to any contrary provision of applicable law, Dr. Chatfield's employment will end automatically without the need for notice of termination at the end of the month in which Dr. Chatfield reaches the age of 65.

Under the terms of a prior employment contract with us, which has been superseded in all other respects, Dr. Chatfield remains subject to the following noncompetition obligations. Dr. Chatfield is prohibited from competing with us during the term of his employment and for a period thereafter of not less than six months and not more than 12 months as may be required by us, provided that we notify Dr. Chatfield in writing not less than three months prior to expiration of employment or any severance pay period, or in the event of termination by us for cause, at the time of termination, and that we continue to pay Dr. Chatfield 50% of his base salary in effect at termination during the additional period. Dr. Chatfield is also prohibited, during his term of employment and for a period of six months after termination of employment, from inducing or soliciting our employees, including any employees who left our employ within the previous six months, to leave our employ or inducing or soliciting customers, clients or business partners to reduce their relationship or breach their agreements with us. Dr. Chatfield

is also bound by the terms of Emergent Product Development UK's standard non-disclosure, invention and assignment agreement.

Dr. Chatfield currently serves as our chief scientific officer pursuant to a letter agreement dated July 11, 2006.

## Severance plan and termination protection program

In May 2006, our board of directors approved a severance plan and termination protection program effective April 1, 2006 for the benefit of employees with the title of chief executive officer, president, executive vice president, senior vice president or vice president who have been designated to participate in the severance plan by our board of directors or, with the authorization of our board of directors, by our chief executive officer. Our chief executive officer may designate the greater of 7% of the total number of our employees or 35 employees to be participants in the severance plan at any particular time, on the basis of name, title, function or compensation level. Our chief executive officer will at all times be a participant under the severance plan and shall have no less favorable rights under the severance plan than any other participant. Each of our executive officers based in the United States is currently a participant in the severance plan.

The severance plan is effective through December 31, 2009. Commencing on December 31, 2009, and on December 31 of each year thereafter, the severance plan will automatically extend for additional one-year periods unless we provide 90 days' prior written notice that the term will not be extended.

If during the term of the severance plan, we terminate a participant's employment without cause, as defined in the severance plan, then the participant will be entitled to:

- any unpaid base salary and accrued paid time-off through the date of termination;
- · a pro rata target annual bonus in respect of the year of termination;
- any bonus earned but unpaid as of the date of termination for any previously completed year;
- · reimbursement for any unreimbursed expenses incurred by the participant prior to the date of termination;
- an amount equal to a specified percentage of the participant's annual base salary;
- employee and fringe benefits and perquisites, if any, to which the participant may be entitled as of the date of termination under our relevant plans, policies and programs; and
- continued eligibility for the participant and his or her eligible dependents to receive employee benefits, for a stated period following the participant's date of termination, except when the provision of employee benefits would result in a duplication of benefits provided by any subsequent employer.

The following table sets forth the percentage of base salary and the stated period for continued employee benefits that each of our executive officers who participates in the plan is entitled if we terminate the executive officer's employment without cause.

Name	Percentage of annual base salary	Stated period for continued employee benefits
Fuad El-Hibri	150%	18 months
Robert G. Kramer, Sr.	100	12 months
Edward J. Arcuri, Ph.D.	100	12 months
Daniel J. Abdun-Nabi	100	12 months
Kyle W. Keese	100	12 months
R. Don Elsey	75	9 months

We may pay any amount under the severance plan, in our sole and absolute discretion, either in a single lump sum amount within 30 days following termination or in equal monthly installments over the same stated period during which we have agreed to provide continued employee benefits to the terminated employee.

As a condition to payment of any amounts under the severance plan, the participant is required:

- · for the same stated period during which we have agreed to provide continued employee benefits to the terminated employee, not to:
  - · induce, counsel, advise, solicit or encourage our employees to leave our employ or to accept employment with any other person or entity,
  - induce, counsel, advise, solicit or encourage any person who we employed within six months prior to that time to accept employment with any person or entity besides us or hire or engage that person as an independent contractor,
  - solicit, interfere with or endeavor to cause any of our customers, clients or business partners to cease or reduce its relationship with us or induce any such customer, client or business partner to breach any agreement that such customer, client or business partner may have with us, and
  - engage in or have a financial interest in any business competing with us within any state, region or locality in which we are then doing business or marketing products;
- upon reasonable notice and at our expense, to cooperate fully with any reasonable request that may be made by us in connection with any investigation, litigation or other similar activity to which we are or may be a party or may otherwise be involved and for which the participant may have relevant information; and
- to sign and deliver a suitable waiver and release under which the participant will release and discharge us from and on account of any and all claims that relate to or arise out of our employment relationship.

In connection with our implementation of the severance plan, in August 2006, we agreed to the following modifications and clarifications to Mr. El-Hibri's contractual obligations and duties:

- Mr. El-Hibri's service as chairman of Digicel Holdings, chairman of East West Resources, a member of the board of trustees of American University, a member of the board of directors of the International Biomedical Research Alliance and director and treasurer of El-Hibri Charitable Foundation and his management of his personal investments at levels of time and attention comparable to those that Mr. El-Hibri provided to such entities within the preceding twelve months, do not violate his contractual obligations to us or interfere with his ability to perform his duties to us;
- it is not a violation of Mr. El-Hibri's contractual obligations to us if he pursues a business transaction or opportunity where such transaction or opportunity was first presented to Mr. El-Hibri in his capacity as an officer or director of the entities listed above or where such transaction or opportunity was first presented to us and our board of directors declined to pursue such transaction or opportunity; and
- with respect to three employees who, at Mr. El-Hibri's invitation, left their employment with East West Resources to accept employment with us, it is not a violation of Mr. El-Hibri's non-solicitation agreement to induce, counsel, advise, solicit or encourage, or attempt to induce, counsel, advise, solicit or encourage those employees to return to employment with East West Resources.

If during the term of the severance plan, we terminate a participant's employment with cause, then the participant will not be entitled to receive any compensation, benefits or rights under the severance plan, and any stock options or other equity participation benefits vested on or prior to the date of the termination, but not yet exercised, will immediately terminate.

If during the term of the severance plan, we terminate a participant's employment without cause or a participant resigns for good reason, as defined in the severance plan, in each case within 18 months following a change of control, as defined in the severance plan, or we terminate a participant's employment prior to a change of control, which subsequently occurs, at the request of a party involved in the change of control, or otherwise in connection with or in anticipation of a change of control, then the participant will be entitled to:

- · a lump sum amount, payable within 30 days following the date of termination, equal to the sum of:
  - · any unpaid base salary and accrued paid time-off through the date of termination,
  - · a pro rata target annual bonus in respect of the year of termination,
  - · any bonus earned but unpaid as of the date of termination for any previously completed year,
  - · any unreimbursed expenses incurred by the participant prior to the date of termination, and
  - an amount equal to a specified percentage of the sum of the participant's base salary and the greater of the annual bonus that was paid to the
    participant in respect of the most recently completed year or the maximum annual bonus that could have been paid to the participant under an
    established bonus plan for the most recently completed year;
- employee and fringe benefits and perquisites, if any, to which the participant may be entitled as of the date of termination of employment under our relevant plans, policies and programs;
- any unvested stock options held by the participant that are outstanding on the date of termination will become fully vested as of that date, and the period, during which any stock options held by the participant that are outstanding on that date may be exercised, shall be extended to a date that is the later of the 15th day of the third month following the termination date, or December 31 of the

calendar year in which the stock option would otherwise have expired if the exercise period had not been extended, but not beyond the final date the stock option could have been exercised if the participant's employment had not terminated, in each case based on the term of the option at the original grant date:

- continued eligibility for the participant and his or her eligible dependents to receive employee benefits, for a stated period following the participant's date of termination, except when the provision of employee benefits would result in a duplication of benefits provided by any subsequent employer;
- · a gross-up payment with respect to applicable taxes on any payment to the participant;
- the retention for the maximum period permitted by applicable law of all rights the participant has to indemnification from us immediately prior to the
  change of control and the continuation throughout the period of any applicable statute of limitations of any director's and officer's liability insurance
  covering the participant immediately prior to the change of control; and
- the advancement to the participant of all costs and expenses, including attorney's fees and disbursements, incurred by the participant in connection with
  any legal proceedings that relate to the termination of employment or the interpretation or enforcement of any provision of the severance plan, for which
  the participant will have no obligation to reimburse us if the participant prevails in the proceeding with respect to at least one material issue or the
  proceeding is settled.

The following table sets forth the percentage of base salary and the stated period for continued employee benefits that each of our executive officers who participates in the plan is entitled under the circumstances described above in connection with a change of control.

Name	Percentage of annual base salary	Stated period for continued employee benefits
Fuad El-Hibri	250%	30 months
Robert G. Kramer, Sr.	200	24 months
Edward J. Arcuri, Ph.D.	200	24 months
Daniel J. Abdun-Nabi	150	18 months
Kyle W. Keese	100	12 months
R. Don Elsey	75	9 months

Our chief executive officer may designate up to two participants for whom any reason for resigning within the 30-day period following the first anniversary of a change of control shall also constitute good reason. Mr. El-Hibri has been designated as a participant to receive this benefit.

All payments under the severance plan will be reduced by any applicable taxes required by applicable law to be paid or withheld by us. All payments and benefits provided under the severance plan are intended to either comply with or be exempt from Section 409A of the Internal Revenue Code. If at the time a participant's employment is terminated, the participant is a specified employee within the meaning of Section 409A(a)(2)(B)(ii), then any payments to the participant that constitute nonqualified deferred compensation within the meaning of Section 409A will be delayed by a period of six months. All such payments that would have been made to the participant during the six-month period will be made in a lump sum in the seventh month following the date of termination, and all remaining payments will commence in the seventh month following the date of termination.

Our board of directors or any committee of our board of directors is authorized to administer the plan and has authority to adopt, amend and repeal the administrative rules, guidelines and practices relating to the severance plan as it deems advisable.

## Limitation of liability and indemnification

Our certificate of incorporation that will be in effect upon the completion of this offering limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the General Corporation Law of Delaware. Our certificate of incorporation provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty or other duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- · for any breach of their duty of loyalty to us or our stockholders;
- · for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- · for voting or assenting to unlawful payments of dividends or other distributions; or
- · for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act or failure to act, or any cause of action, suit or claim that would accrue or arise prior to any amendment or repeal or adoption of an inconsistent provision. If the General Corporation Law of Delaware is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the General Corporation Law of Delaware.

In addition, our certificate of incorporation provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to limited exceptions.

We have entered into agreements to indemnify our directors and executive officers. These agreements, among other things, provide that we will indemnify the director or executive officer to the fullest extent permitted by law for claims arising in his or her capacity as our director, officer, manager, employee, agent or representative and advance expenses, including attorneys' fees, to these individuals in connection with legal proceedings, subject to limited exceptions. The indemnification agreements also establish the procedures that will apply in the event a director or officer makes a claim for indemnification.

## Stock option and other compensation plans

#### Employee stock option plan

Our employee stock option plan was adopted by our board of directors and approved by our stockholders on June 30, 2004 and amended and restated on January 26, 2005. We refer to this employee stock option plan, as amended and restated, as our employee stock option plan. Our employee stock option plan became effective on the date that our board of directors adopted the plan. We assumed all options outstanding under the BioPort Corporation employee stock option plan as of June 30, 2004 and granted option holders replacement stock options to purchase an equal number of shares of our class B common stock under our employee stock option plan. Under our employee stock option plan, the exercise period for options under the BioPort Corporation employee stock option plan that would

have otherwise expired on June 30, 2004 was extended to June 30, 2007. For incentive stock options, the extension of the exercise period caused the options to be considered nonqualified stock options after June 30, 2004. Under our employee stock option plan, 1,250,000 shares of our class B common stock are reserved for issuance. Our board of directors has authorized our compensation committee to administer our employee stock option plan. Immediately prior to the completion of this offering, each outstanding option to purchase shares of our class B common stock automatically will become an option to purchase an equal number of shares of our common stock, with no other changes to the option.

If a merger or other reorganization event occurs, options granted under our employee stock option plan may be substituted or assumed. In the event of our merger, consolidation or combination with or into another corporation, other than a merger, consolidation or combination in which we are the surviving corporation and which does not result in any reclassification or other change in the number of outstanding shares of our common stock, each option holder will have the right after the merger, consolidation or combination and during the term of the option to receive upon exercise of the option, for each share of common stock as to which the option could be exercised, the kind and amount of shares of the surviving or new corporation, cash, securities, evidence of indebtedness, other property or any combination which would have been received upon the merger, consolidation or combination by the holder of a share of common stock immediately prior to the merger, consolidation or combination. Upon the occurrence of a change in control, as defined in our employee stock option plan, we have the option to purchase and redeem from any option holder all the options owned by the option holder for a purchase price equal to the difference between the option exercise price and the fair market value of the common stock. In the event that we exercise our right to repurchase the options, any unvested options will be deemed fully vested on the day preceding the date we exercise our repurchase option. We may exercise this option at any time during the six-month period following the date of change in control or such longer period of time as is reasonable.

Under our employee stock option plan, no award may be granted under the plan after June 30, 2009, unless the plan is terminated sooner. Our board of directors may amend, suspend or discontinue the employee stock option plan at any time, except that stockholder approval will be required for any revision that would increase the number of shares reserved for issuance under the plan, or otherwise as required to comply with applicable law or stock market requirements. No amendment may materially impair any rights or materially increase any obligations of an option holder under an outstanding option without the consent of the option holder.

As of July 31, 2006, options to purchase 1,062,779 shares of our class B common stock at a weighted average exercise price of \$6.38 were outstanding under our employee stock option plan, options to purchase 68,999 shares of class B common stock have been exercised and options to purchase 139,451 shares of class B common stock have been forfeited. After the effective date of our 2006 stock incentive plan, which is described below, we will grant no additional options under our employee stock option plan.

#### 2006 stock incentive plan

Our 2006 stock incentive plan was adopted by our board of directors on May 9, 2006 and approved by our stockholders on , 2006. The 2006 stock incentive plan will become effective immediately prior to the completion of this offering. The 2006 stock incentive plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock unit awards. Our 2006 stock incentive plan provides that 175,000 shares of common stock, plus the number of shares of common stock, up to shares, reserved for issuance under our existing employee stock option plan that remain available for grant as of the

completion of this offering, will be reserved for issuance under the 2006 stock incentive plan immediately following this offering.

In addition, our 2006 stock incentive plan contains an "evergreen provision" that allows for increases in the number of shares available for issuance under our 2006 stock incentive plan on the first day of the first and third quarter of each year from 2007 though 2009. Each semi-annual increase in the number of shares will be equal to the lowest of a specified number of shares, a specified percentage of the aggregate number of shares outstanding and an amount determined by our board of directors. The following table sets forth the maximum specified number of shares and maximum specified percentage of outstanding shares for each semi-annual increase in the number of shares.

	Maximum specified number of shares	Maximum specified percentage of outstanding shares
First Quarter of 2007	149,000	1.5%
Third Quarter of 2007	161,000	1.5
First Quarter of 2008	322,000	3.0
Third Quarter of 2008	162,000	1.5
First Quarter of 2009	326,000	3.0
Third Quarter of 2009	164,000	1.5

Our employees, officers, directors, consultants and advisors are eligible to receive awards under our 2006 stock incentive plan. Incentive stock options may only be granted to our employees. The maximum number of shares of common stock with respect to which awards may be granted to any participant under the plan is 100,000 per fiscal year.

In accordance with the terms of the 2006 stock incentive plan, our board of directors has authorized our compensation committee to administer the plan. Our compensation committee selects the recipients of awards and determines:

- the number of shares of common stock covered by options and the dates upon which the options become exercisable;
- · the exercise price of options, which may not be less than 100% of the fair market value of the stock on the date of grant;
- · the duration of options, which may not be in excess of 10 years;
- · the method of payment of the exercise price; and
- the number of shares of common stock subject to any stock appreciation right, restricted stock, restricted stock units or other stock-unit awards and the
  terms and conditions of such awards, including conditions for exercise, repurchase, issue price and repurchase price.

If our board of directors delegates authority to an executive officer, the executive officer has the power to make awards to all of our employees, except to executive officers. Our board of directors will fix the terms of the awards to be granted by such executive officer, including the exercise price of such awards and the maximum number of shares subject to awards that such executive officer may make.

Our 2006 stock incentive plan provides for an automatic grant of options to non-employee directors as follows:

- 7,500 shares of common stock, upon the commencement of service on our board of directors;
- 5,000 shares of common stock, on the date of each of our annual meetings of stockholders, provided that the director continues serving as a director
  after the annual meeting and has served on our board of directors for at least six months; and
- if the non-employee director is serving as the chair of one or more committees of our board of directors, an additional 2,500 shares of common stock, on the date of each of our annual meetings of stockholders, provided that the director continues serving as a director after the annual meeting and has served on our board of directors for at least six months.

Automatic option grants to directors will:

- have an exercise price equal to the closing sale price of the common stock on the Nasdaq Stock Market or the national securities exchange on which the
  common stock is then traded on the trading date immediately prior to the date of grant, or the fair market value of the common stock on such date as
  determined by our board of directors, if the common stock is not then traded on The Nasdaq Stock Market or on a national securities exchange;
- vest in three equal annual installments beginning on the anniversary of the date of grant provided that the individual is serving on our board of directors
  on such date, or, with respect to annual grants, on the date which is one business day prior to the date of our next annual meeting, if earlier, provided
  that no additional vesting will take place after the individual ceases to serve as a director and that our board of directors may provide for accelerated
  vesting in the case of death, disability, attainment of mandatory retirement age or retirement following at least 10 years of service;
- · expire on the earlier of 10 years from the date of grant or three months following cessation of service on our board of directors; and
- · contain other terms and conditions as our board of directors determines.

Our board of directors may increase or decrease the number of shares subject to automatic option grants to directors.

If a merger or other reorganization event occurs, our board of directors will provide that all of our outstanding options are to be assumed or substituted by the successor corporation. If the merger or reorganization event also constitutes a change in control event, as defined under our 2006 stock incentive plan, the assumed or substituted options will become immediately exercisable in full if on or prior to the first anniversary of the reorganization event an option holder's employment with us or our succeeding corporation is terminated by the option holder for good reason or is terminated by us or the succeeding corporation without cause, each as defined in our 2006 stock incentive plan. In the event the succeeding corporation does not agree to assume, or substitute for, outstanding options, then our board of directors will provide that all unexercised options will become exercisable in full prior to the completion of the merger or other reorganization event and that these options will terminate immediately prior to the completion of the merger or other reorganization event if not previously exercised. Our board of directors may also provide for a cash out of the value of any outstanding options. In addition, upon the occurrence of a change in control event that does not also constitute a reorganization event under our 2006 stock incentive plan, each option will continue to vest according to its original vesting schedule, except that an option will become immediately exercisable in full if on or prior to the first anniversary of the change in control event an option holder's employment with us or our succeeding corporation is

terminated by the option holder for good reason or is terminated by us or our succeeding corporation without cause.

No award may be granted under the 2006 stock incentive plan after December 31, 2009, but the vesting and effectiveness of awards granted before that date may extend beyond that date. Our board of directors may amend, suspend or terminate the 2006 stock incentive plan at any time, except that stockholder approval will be required for any revision that would materially increase the number of shares reserved for issuance, expand the types of awards available under the plan, materially modify plan eligibility requirements, extend the term of the plan or materially modify the method of determining the exercise price of options granted under the plan, or otherwise as required to comply with applicable law or stock market requirements.

## 401(k) retirement plan

We maintain a 401(k) retirement plan that is intended to be a tax-qualified defined contribution savings plan under Section 401(k) of the Internal Revenue Code. Substantially all of our employees are eligible to participate. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to the statutorily prescribed limit, equal to \$15,000 in 2006, and have the amount of the reduction contributed to the 401(k) plan. We are permitted to match employees' 401(k) plan contributions. For the year ended December 31, 2005, we have elected to match 50% of the first 6% of the eligible employees' contributions to the 401(k) plan.

# Certain relationships and related party transactions

Since January 1, 2003, we have engaged in the following transactions with our executive officers, directors and holders of more than 5% of our voting securities, and affiliates of our executive officers, directors and holders of more than 5% of our voting securities. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

## Corporate reorganization

On June 30, 2004, we completed a corporate reorganization in which:

- Emergent BioSolutions Inc., a newly formed Delaware corporation, issued 6,487,950 shares of class A common stock to stockholders of BioPort Corporation in exchange for 6,262,554 shares of BioPort class A common stock and 225,396 shares of BioPort class B common stock;
- · we repurchased and retired all other issued and outstanding shares of BioPort class B common stock; and
- we assumed all outstanding stock options to purchase BioPort class B common stock and granted option holders replacement stock options to purchase an equal number of shares of our class B common stock under our employee stock option plan.

As a result of this reorganization, BioPort became a wholly owned subsidiary of Emergent.

#### Issuance of class A common stock

The following table sets forth the number of shares of our class A common stock that we issued to the former stockholders of BioPort in our corporate reorganization.

Name	Number of shares of class A common stock
Intervac, L.L.C.	2,890,000
BioPharm, L.L.C.	1,412,896
Michigan Biologics Products, Inc.	672,500
BioVac, L.L.C.	555,822
Biologika, LLC	477,941
Intervac Management, L.L.C.	250,000
ARPI, L.L.C.	228,791

Intervac, BioPharm, Michigan Biologics Products, Biovac, Biologika, Intervac Management and ARPI are parties to a voting agreement dated June 30, 2004. We refer to these stockholders collectively as the voting group. Under the voting agreement, each stockholder in the voting group has agreed to vote all shares of our capital stock owned by it for and against and abstain from voting with respect to any matter as directed by a majority in interest of the voting group as measured by the aggregate percentage of ownership of our capital stock. Fuad El-Hibri, our president, chief executive officer and chairman of our board of directors, has the power to direct the voting of a majority in interest of the voting group. As a result, Mr. El-Hibri is considered the beneficial owner of all of the shares held by Intervac, BioPharm, Michigan Biologics Products, BioVac, Biologika, Intervac Management and ARPI. See "Principal and selling stockholders" for additional information regarding the beneficial ownership of our common stock.

## Grant of options to purchase class B common stock

The following table sets forth the number of shares of our class B common stock underlying options that we granted under our employee stock option plan to our executive officers and directors contemporaneously with our corporate reorganization.

Name	Number of shares of class B common stock underlying options granted
Robert G. Kramer, Sr.	162,500
Daniel J. Abdun-Nabi	37,000
Kyle W. Keese	15,000

## Special cash dividend

On June 15, 2005, our board of directors declared a special cash dividend to the holders of our outstanding shares of common stock in an aggregate amount of approximately \$5.4 million. Our board of directors declared this special dividend in order to distribute the net proceeds of a payment that we received as a result of the settlement of litigation that we initiated against Elan Pharmaceuticals, Inc., Athena Neurosciences, Inc. and Solstice Neurosciences, Inc. BioPort filed the lawsuit in 2002 in an effort to clarify intellectual property rights and recover royalties that BioPort asserted were owed under a series of agreements regarding the development of botulinum toxin products. We paid the special cash dividend on July 13, 2005 to stockholders of record as of June 15, 2005. The following table sets forth the amount of the special cash dividend that we paid to our 5% stockholders and their affiliates.

Name	Amount of special cash dividend
Intervac, L.L.C.	\$ 2,402,864
BioPharm, L.L.C.	1,174,739
Michigan Biologics Products, Inc.	559,144
BioVac, L.L.C.	462,133
Biologika, LLC	397,380
Intervac Management, L.L.C.	207,860
ARPI, L.L.C.	190,226

See "Principal and selling stockholders" for additional information regarding the beneficial ownership of our common stock.

## Microscience acquisition

On June 23, 2005, we acquired all of the outstanding shares of capital stock of Microscience Limited from Microscience Investments Limited, formerly Microscience Holdings plc, in exchange for 1,264,051 shares of our class A common stock. We subsequently renamed Microscience Limited as Emergent Product Development UK Limited.

## Registration rights

Upon the completion of this offering, holders of 7,752,001 shares of our common stock as of July 31, 2006 will have the right to require us to register these shares of common stock under the Securities Act of 1933, as amended, or the Securities Act, under specified circumstances. In connection with our acquisition of Microscience Limited, we granted to Microscience Investments registration rights with respect to the shares of our common stock that we issued to Microscience Investments in the acquisition. We also have granted registration rights with respect to shares of our common stock to the holders of our existing class A common stock, in addition to Microscience Investments. The following table sets forth the number of shares of our common stock subject to these registration rights that are held by our 5% stockholders and their affiliates.

Name	Number of shares of common stock
Intervac, L.L.C.	2,890,000
BioPharm, L.L.C.	1,412,896
Microscience Investments Limited	1,264,051
Michigan Biologics Products, Inc.	672,500
BioVac, L.L.C.	555,822
Biologika, LLC	477,941
Intervac Management, L.L.C.	250,000
ARPI, L.L.C.	228,791

See "Description of capital stock — Registration rights" for additional information regarding these registration rights. See "Principal and selling stockholders" for additional information regarding the beneficial ownership of our common stock.

# **Consulting agreements**

In January 2005, we entered into an agreement with Fleishman-Hillard Inc. under which Fleishman-Hillard provided us government relations, strategic consulting and communication services. Jerome Hauer, a member of our board of directors, was a senior vice president of Fleishman-Hillard until March 2006. Under the agreement, we have agreed to pay Fleishman-Hillard \$20,000 per month for its services. The monthly fee increased to \$30,000 per month in March 2005. We paid Fleishman-Hillard \$342,663 in 2005 and \$87,059 in the three months ended March 31, 2006 for these services. The agreement terminated on March 31, 2006.

In March 2006, we entered into an agreement with The Hauer Group under which The Hauer Group provides us strategic consulting and domestic marketing advice. Jerome Hauer is the chief executive officer of The Hauer Group. Mr. Hauer and his wife are the sole owners of The Hauer Group. Under the terms of the agreement, we agreed to pay The Hauer Group \$15,000 per month for its services. The agreement expires on March 31, 2007.

In November 2004, we entered into a consulting services agreement with Yasmine Gibellini to provide public relations services. Ms. Gibellini is the sister of Fuad El-Hibri, our president, chief executive officer and chairman of our board of directors. Under the agreement, we agreed to pay Ms. Gibellini \$220 per hour for a maximum of 20 hours per week, as needed, for her services, the total of which was not to exceed \$60,000, and reimburse her reasonable out-of-pocket expenses. The agreement expired in June

2005. In March 2005, we entered into a separate consulting agreement with Ms. Gibellini to provide sales and marketing services. We agreed to pay Ms. Gibellini \$700 per day for a time commitment of approximately two to three days per week, as needed, for her services, the total of which was not to exceed \$60,000, and reimburse her reasonable out-of-pocket expenses. In addition, we agreed to pay Ms. Gibellini a sales commission equal to 4% of BioThrax net sales, not to exceed \$2.00 per dose, from contracts to any customer in which Ms. Gibellini had direct involvement. The agreement terminated on August 31, 2005. We paid Ms. Gibellini \$39,353 in 2005 and \$25,200 in 2006 under these agreements.

From September 2004 through November 2004, we retained Louis W. Sullivan, M.D., a member of our board of directors, to provide consulting services for a fixed fee of \$25,000 per month.

## Agreements with Intergen N.V.

In November 1997, BioPort entered into a marketing agreement, which was amended and restated in January 2000, with Intergen N.V. Yasmine Gibellini, the chairperson of Intergen N.V., is the sister of Fuad El-Hibri, our president, chief executive officer and chairman of our board of directors. Ibrahim El-Hibri, the president of Intergen, is the father of Fuad El-Hibri. Ibrahim El-Hibri and his wife are the sole stockholders of Intergen. Under the agreement, Intergen is the sole and exclusive marketing representative for BioThrax and any other biodefense vaccine that BioPort becomes licensed to manufacture or sell in countries in the Middle East and North Africa, except Israel and those countries to which export is prohibited by the U.S. government. Under the agreement, we agreed to pay Intergen a fee equal to 40% of the gross sales in these countries. We have not paid Intergen any fee under the agreement. The term of the agreement is scheduled to expire in 2007. The agreement will automatically extend for an additional five years if BioPort achieves \$5.0 million of sales in the territory during the initial three-year term of the agreement.

In January 2000, BioPort entered into a termination and settlement agreement with Intergen. Under the agreement, BioPort is obligated to pay Intergen a \$70,000 settlement payment when it receives more than \$3.0 million pursuant to a contract for sale of anthrax vaccine to a party other than the U.S. government. The settlement payment is in consideration for Intergen's agreement to terminate a consulting agreement entered into between the parties in November 1997 and reduce the scope of its rights under the marketing agreement described above. This settlement payment has not yet become due and has not been paid.

## **Agreements with East West Resources Corporation**

In January 2004, BioPort entered into a consulting agreement with East West Resources Corporation under which East West Resources provided financial analysis, business modeling and corporate and business development consulting services. Fuad EI-Hibri is the chairman of East West Resources and was president of East West Resources from September 1990 to January 2004. Fuad EI-Hibri and his wife are the sole stockholders of East West Resources. The agreement terminated in September 2005. We paid East West Resources \$180,000 in 2004 and \$135,000 in 2005 under the agreement.

In January 2004, BioPort entered into an amended and restated sublease and office services agreement with East West Resources under which East West Resources leased us office space in Rockville, Maryland and provided us administrative, transportation and logistics support. Under the agreement, we agreed to pay East West Resources monthly rent of \$10,707. The monthly rent increased by 3% each year. In September 2004, we terminated in part the agreement with respect to the lease of office space for a settlement fee of \$69,687, an amount equal to eight months' rent, including the 3% escalation fee, but excluding the portion of monthly rent applicable to transportation and logistics support. We paid East

West Resources \$120,000 in 2003, \$173,647 in 2004, \$33,750 in 2005 and \$8,021 in the three months ended March 31, 2006 under the agreement. The agreement expired on July 31, 2006.

In August 2006, we entered into a services agreement with East West Resources under which East West Resources agreed to provide us transportation and logistics support. Under the agreement, we agreed to pay East West Resources a fee of \$2,450 per month and reimburse fees and expenses associated with these services. The term of the agreement ends on July 31, 2007. The agreement will automatically extend for additional successive terms of one year unless terminated by either party with at least 60 days' notice. Under the agreement, the monthly fee increases by 3% each year upon extension of the term.

# Airplane charter from Simba LLC

From time to time from March 2004 until April 2006, we chartered a private airplane for business purposes from Simba LLC. Fuad El-Hibri and his wife own 100% of the interests in Simba. Mr. El-Hibri also is the managing member of Simba. Simba sold the airplane in May 2006. The plane was managed and chartered by Frederick Aviation and was available for charter by the general public. We paid Simba \$32,148 in 2004, \$33,999 in 2005 and \$13,283 in the three months ended March 31, 2006 for charter fees and reimbursement of costs. Frederick Aviation provided us with a discount of \$300 per hour from its commercial charter rate. In all other respects, the fees and expenses that we paid to Simba were equivalent to fees charged to third parties for charter flights.

# **Employee relationships**

Mauro Gibellini, a brother-in-law of Fuad El-Hibri, is our vice president corporate planning and business development. In addition, Mauro Gibellini and his wife, Yasmine Gibellini, as tenants by the entirety, hold 100% of the ownership interests in Biologika LLC, one of our 5% stockholders, and have the power to dispose of all shares of our capital stock held by Biologika. We paid total cash compensation to Mr. Gibellini of \$228,994 in 2003, \$320,765 in 2004 and \$233,409 in 2005. Mr. Gibellini's current annual base salary is \$195,624. He is also eligible for an annual bonus for 2006. Mr. Gibellini is a participant in our severance plan and termination protection program. As of July 31, 2006, we have granted Mr. Gibellini options to purchase 25,000 shares of our class B common stock at a weighted average exercise price of \$4.83 per share.

Mark Grunenwald, a brother-in-law of Fuad El-Hibri, is our manager of information systems. We paid total cash compensation to Mr. Grunenwald of \$1,115 in 2003, \$63,282 in 2004 and \$65,090 in 2005. Mr. Grunenwald's current annual base salary is \$74,000. He is also eligible for an annual bonus for 2006.

Robert Myers, who serves as senior policy and science advisor and director of BioPort Corporation, is also the President of Michigan Biologics Products, Inc., one of our 5% stockholders, and has the power to direct the disposition of all shares of our capital stock held by Michigan Biologics Products. We paid total cash compensation to Dr. Myers of \$492,351 in 2003, \$258,369 in 2004 and \$204,655 in 2005. In June 2005, BioPort entered into an employment agreement with Dr. Myers in his role as senior policy and science advisor to BioPort. Under this employment agreement, Dr. Myers is entitled to an annual base salary of \$180,000 and an annual bonus of \$15,000. The employment agreement terminates upon the completion of this offering. Upon the completion of this offering, Dr. Myers is entitled to the following termination benefits:

• payment of any previously unpaid base salary and accrued paid time off and other benefits through the date of termination;

- · payment of any unpaid, pro-rated bonus through the date of termination; and
- a lump sum payment in the amount of \$100,000, less applicable withholding and related taxes.

As of July 31, 2006, we have granted Dr. Myers options to purchase 159,604 shares of our common stock at an exercise price of \$0.25 per share.

# **Executive compensation**

See "Management — Executive compensation" and "Management — Stock option grants" for additional information regarding compensation of our executive officers.

# **Director compensation**

See "Management — Director compensation" for a discussion of options granted and other compensation to our non-employee directors.

# Severance plan and termination protection program

Our executive officers participate in our severance plan and termination protection program. See "Management — Severance plan and termination protection program" for additional information regarding these arrangements.

# Indemnification agreements

We have entered into an indemnification agreement with each of our executive officers and directors. See "Management — Limitation of liability and indemnification" for additional information regarding these agreements.

# Principal and selling stockholders

The following table sets forth information with respect to the beneficial ownership of our common stock as of July 31, 2006 by:

- · each of our named executive officers;
- · each of our directors:
- · all of our directors and executive officers as a group; and
- · each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

The information in the following table assumes that our previously existing class A common stock has been reclassified as common stock and all previously outstanding shares of class B common stock have been converted into shares of common stock prior to the completion of this offering. The column entitled "Percentage of shares beneficially owned before offering" is based on 7,782,016 shares of our common stock outstanding as of July 31, 2006. The column entitled "Percentage of shares beneficially owned after offering" is based on shares of our common stock to be outstanding immediately after the completion of this offering, including the shares of common stock that we are selling in this offering. The holders of our existing class A common stock have granted an option to the underwriters to purchase up to an aggregate of information regarding the shares subject to the over-allotment option, see "— Selling stockholders" below. No other stockholder is participating in the offering.

Beneficial ownership is determined in accordance with the rules and regulations of the Securities and Exchange Commission and includes voting or investment power with respect to our common stock. In computing the number of shares of common stock beneficially owned and percentage ownership, shares subject to options held by a person are deemed to be outstanding and beneficially owned by that person if the options are currently exercisable or exercisable within 60 days of July 31, 2006. Shares subject to options are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of the beneficial owner is c/o Emergent BioSolutions Inc., 300 Professional Drive, Suite 250, Gaithersburg, Maryland 20879.

	Number of shares		Percentage of shares beneficially owned
Name of beneficial owner	beneficially owned	Before offering	After offering
Executive officers and directors			
Fuad El-Hibri(1)	7,782,001	99.6%	
Edward J. Arcuri, Ph.D.(2)	13,334	*	
Robert G. Kramer, Sr.(3)	178,500	2.2	
Steven N. Chatfield, Ph.D.(4)	6,667	*	
Daniel J. Abdun-Nabi(5)	25,900	*	
Joe M. Allbaugh	_	_	
Zsolt Harsanyi, Ph.D.(6)	10,000	*	
Jerome M. Hauer(7)	5,000	*	
Shahzad Malik, M.D.	_	_	
Ronald B. Richard(8)	5,000	*	
Louis W. Sullivan, M.D.	_	_	
All executive officers and directors as a group (13 persons)(9)	8,038,902	99.6	
5% stockholders			
Stockholder voting group under voting agreement dated June 30, 2004(10)	7,752,001	99.6	
Microscience Investments Limited(11)	1,264,051	16.2	
Robert Myers, D.V.M.(12)	832,104	10.5	
Mauro and Yasmine Gibellini(13)	502,941	6.4	

- \* Less than 1%.
- (1) Consists of the following shares of our common stock:
  - 2,890,000 shares held by Intervac, L.L.C.;
  - 1,412,896 shares held by BioPharm, L.L.C.;
  - 672,500 shares held by Michigan Biologics Products, Inc.;
  - 555,822 shares held by Biovac, L.L.C.;
  - 477,941 shares held by Biologika LLC;
  - 250,000 shares held by Intervac Management, L.L.C.;
  - 228,791 shares held by ARPI, L.L.C.;
  - 1,264,051 shares held by Microscience Investments Limited; and
  - 30,000 shares subject to stock options held by Mr. El-Hibri exercisable within 60 days of July 31, 2006.

If the underwriters exercise their over-allotment option in full, Mr. El-Hibri will beneficially own or % of our outstanding common stock, consisting of the following shares of our common stock:

shares of our common stock after this offering,

shares held by Intervac, L.L.C.;

- shares held by BioPharm, L.L.C.;
- shares held by Michigan Biologics Products, Inc.;
- shares held by Biovac, L.L.C.;
- shares held by Biologika LLC;
- shares held by Intervac Management, L.L.C.;
- shares held by ARPI, L.L.C.;
- · shares held by Microscience Investments Limited; and
- 30,000 shares subject to stock options held by Mr. El-Hibri exercisable within 60 days of July 31, 2006.

Robert Myers has the power to direct the disposition of all shares of our capital stock held by Michigan Biologics Products.

Mauro and Yasmine Gibellini, as tenants by the entirety, have the power to dispose of all shares of our capital stock held by Biologika.

Janice Mugrditchian has the power to dispose of all shares of our capital stock held by ARPI.

The holders of series B preferred ordinary shares of Microscience Investments have the power to dispose of all shares of our capital stock held by Microscience Investments and share the power to vote these shares with BioPharm, L.L.C.

For more information regarding the beneficial ownership of these shares, see "— Stockholder arrangements" below.

- (2) Consists of 13,334 shares of common stock subject to stock options exercisable within 60 days of July 31, 2006.
- (3) Consists of 178,500 shares of common stock subject to stock options exercisable within 60 days of July 31, 2006.
- (4) Consists of 6,667 shares of common stock subject to stock options exercisable within 60 days of July 31, 2006.
- (5) Consists of 25,900 shares of common stock subject to stock options exercisable within 60 days of July 31, 2006.
- (6) Consists of 10,000 shares of common stock subject to stock options exercisable within 60 days of July 31, 2006.
- (7) Consists of 5,000 shares of common stock subject to stock options exercisable within 60 days of July 31, 2006.
- (8) Consists of 5,000 shares of common stock subject to stock options exercisable within 60 days of July 31, 2006.
- (9) Consists of 286,901 shares of common stock subject to stock options exercisable within 60 days of July 31, 2006.
- (10) Consists of the following shares of our common stock:
  - 2,890,000 shares held by Intervac, L.L.C.;
  - 1,412,896 shares held by BioPharm, L.L.C.;
  - 672,500 shares held by Michigan Biologics Products, Inc.;
  - 555,822 shares held by Biovac, L.L.C.;

- 477,941 shares held by Biologika LLC;
- 250,000 shares held by Intervac Management, L.L.C.;
- 228,791 shares held by ARPI, L.L.C.; and
- 1,264,051 shares held by Microscience Investments Limited.

If the underwriters exercise their over-allotment option in full, these stockholders will beneficially own shares of our common stock after this offering, or % of our outstanding common stock, consisting of the following shares of our common stock:

- shares held by Intervac, L.L.C.;
- shares held by BioPharm, L.L.C.;
- shares held by Michigan Biologics Products, Inc.;
- shares held by Biovac, L.L.C.;
- shares held by Biologika LLC;
- shares held by Intervac Management, L.L.C.;
- · shares held by ARPI, L.L.C.; and
- shares held by Microscience Investments Limited.

Intervac, BioPharm, Michigan Biologics Products, Biovac, Biologika, Intervac Management and ARPI are parties to a voting agreement dated June 30, 2004. BioPharm also is a party to separate voting agreements with Michigan Biologics Products, Biologika and Microscience Investments.

Robert Myers has the power to direct the disposition of all shares of our capital stock held by Michigan Biologics Products.

Mauro and Yasmine Gibellini, as tenants by the entirety, have the power to dispose of all shares of our capital stock held by Biologika.

Janice Mugrditchian has the power to dispose of all shares of our capital stock held by ARPI.

The holders of series B preferred ordinary shares of Microscience Investments have the power to dispose of all shares of our capital stock held by Microscience Investments.

For more information regarding the beneficial ownership of these shares, see "— Stockholder arrangements" below.

- (11) The holders of series B preferred ordinary shares of Microscience Investments have the power to dispose of all shares of our capital stock held by Microscience Investments and share the power to vote these shares with BioPharm, L.L.C. Investment funds affiliated with Apax Funds Nominees Limited, Advent Private Equity Funds, JP Morgan Partners LLC and The Merlin Biosciences Funds are the holders of the Microscience Investments series B preferred ordinary shares. No holder or group of affiliated holders of series B preferred ordinary shares of Microscience Investments alone has the power to direct the disposition of the shares of our capital stock held by Microscience Investments. Microscience Investments is a party to a voting agreement with BioPharm, L.L.C. For more information regarding this voting agreement, see "— Stockholder arrangements" below.
- (12) Consists of the following shares of our common stock:
  - 672,500 shares held by Michigan Biologics Products, Inc.; and
  - 159,604 shares subject to stock options held by Dr. Myers exercisable within 60 days of July 31, 2006.

If the underwriters exercise their over-allotment option in full, Dr. Myers will beneficially own or % of our outstanding common stock, consisting of the following shares of our common stock:

- shares held by Michigan Biologics Products, Inc.; and
- 159,604 shares subject to stock options held by Dr. Myers exercisable within 60 days of July 31, 2006.

Dr. Myers has the power to direct the disposition of all shares of our capital stock held by Michigan Biologics Products. Mr. El-Hibri has the power to direct the voting of all shares of our capital stock held by Michigan Biologics Products. For more information regarding the beneficial ownership of these shares, see "— Stockholder arrangements" below.

- (13) Consists of the following shares of our common stock:
  - 477,941 shares held by Biologika LLC; and
  - 25,000 shares subject to stock options held by Mr. Gibellini exercisable within 60 days of July 31, 2006.

If the underwriters exercise their over-allotment option in full, Mr. and Mrs. Gibellini will beneficially own offering, or % of our outstanding common stock, consisting of the following shares of our common stock:

shares of our common stock after this

- · shares held by Biologika LLC; and
- 25,000 shares subject to stock options held by Mr. Gibellini exercisable within 60 days of July 31, 2006.

Mr. and Mrs. Gibellini, as tenants by the entirety, have the power to dispose of all shares of our capital stock held by Biologika. Mr. El-Hibri has the power to direct the voting of all shares of our capital stock held by Biologika. For more information regarding the beneficial ownership of these shares, see "— Stockholder arrangements" below.

# Selling stockholders

The holders of our existing class A common stock have granted an option to the underwriters to purchase up to an aggregate of our common stock to cover over-allotments. The following table sets forth for each selling stockholder the number of shares of our common stock subject to the over-allotment option.

Number of shares of Name common stock

# Stockholder arrangements

Our principal stockholders are parties to voting agreements that result in Mr. El-Hibri having the power to direct the voting of all shares of our capital stock owned by the stockholders who are party to these voting agreements. These voting agreements are described below.

#### Voting agreement dated June 30, 2004

Intervac, BioPharm, Michigan Biologics Products, Biovac, Biologika, Intervac Management and ARPI are parties to a voting agreement dated June 30, 2004. We refer to these stockholders collectively as the voting group. Under the voting agreement, each stockholder in the voting group has agreed to vote all shares of our capital stock owned by it for and against and abstain from voting with respect to any matter as directed by a majority in interest of the voting group as measured by the aggregate percentage of ownership of our capital stock. As described below, Mr. El-Hibri has the power to direct the voting of a majority in interest of the voting group. In addition, under the voting agreement, each stockholder in the voting group has appointed Mr. El-Hibri, in his capacity as the general manager of Intervac, as proxy to vote the shares of our capital stock in the manner provided in the voting agreement. The voting agreement automatically terminates on June 30, 2014. Under the voting agreement, any person to whom any stockholder in the voting group transfers any shares of our capital stock must agree to be bound by the terms of the voting agreement, other than as a result of a transfer pursuant to an effective registration statement filed with the Securities Act.

#### Intervac, L.L.C.

Mr. El-Hibri is the general manager of Intervac and in that capacity has the power to vote and dispose of all shares of our capital stock held by Intervac. The board of executive directors of Intervac, consisting of William J. Crowe, Jr., Mr. El-Hibri and Nancy El-Hibri, supervises the management of the company and has the power to remove the general manager. Nancy El-Hibri is the wife of Mr. El-Hibri. A majority of the executive directors of Intervac is required to decide any matter on which the board of executive directors may take action, including the removal of the general manager. Any member of the board of executive directors may be removed by members of Intervac holding more than 50% of the aggregate ownership interests in Intervac. Mr. El-Hibri and his wife, as tenants by the entirety, hold 32.5% of the ownership interests in Intervac. Under a voting agreement with the William J. Crowe, Jr. Revocable Living Trust, Mr. El-Hibri has the power to vote an additional 18.0% of the ownership interests in Intervac on any matter. As a result, Mr. El-Hibri has the power to direct the voting of more than 50% of the aggregate ownership interests in Intervac. The voting agreement between Mr. El-Hibri and the William J. Crowe, Jr. Revocable Living Trust automatically terminates on October 21, 2010.

#### BioPharm, L.L.C.

Mr. EI-Hibri is the holder of more than 50% of the class B ownership units of BioPharm and in that capacity has the power to direct the voting and disposition of all shares of our capital stock held by BioPharm.

# Michigan Biologics Products, Inc.

Michigan Biologics Products has agreed, pursuant to a separate voting agreement with BioPharm, to vote all shares of our capital stock owned by it for and against and abstain from voting with respect to any matter in the same manner and to the same extent as BioPharm. As a result, Mr. El-Hibri has the power

to direct the voting of all shares of our capital stock held by Michigan Biologics Products. The voting agreement automatically terminates on June 30, 2014. Under the voting agreement, any person to whom Michigan Biologics Products transfers any shares of our capital stock must agree to be bound by the terms of the voting agreement, other than as a result of a transfer in a brokers' transaction or directly with a market maker, subject to BioPharm's right to purchase at fair market value the shares that Michigan Biologics Products proposes to sell. Robert Myers, the president of Michigan Biologics Products, who also serves as senior science and policy advisor and director of BioPort Corporation, has the power to direct the disposition of all shares of our capital stock held by Michigan Biologics Products.

# Biovac, L.L.C.

Mr. El-Hibri and his wife, as tenants by the entirety, hold 89.2% of the ownership interests in Biovac and have the power to vote and dispose of all shares of our capital stock held by Biovac.

# Biologika LLC

Biologika has agreed, pursuant to a separate voting agreement with BioPharm, to vote all shares of our capital stock owned by it for and against and abstain from voting with respect to any matter in the same manner and to the same extent as BioPharm. As a result, Mr. El-Hibri has the power to direct the voting of all shares of our capital stock held by Biologika. The voting agreement automatically terminates on June 30, 2014. Under the voting agreement, any person to whom Biologika transfers any shares of our capital stock must agree to be bound by the terms of the voting agreement, other than as a result of a transfer in a brokers' transaction or directly with a market maker, subject to BioPharm's right to purchase at fair market value the shares that Biologika proposes to sell. Mauro Gibellini and Yasmine Gibellini, as tenants by the entirety, hold 100% of the ownership interests in Biologika and have the power to dispose of all shares of our capital stock held by Biologika. Yasmine Gibellini is the sister of Mr. El-Hibri. Mauro Gibellini is the brother-in-law of Mr. El-Hibri.

# Intervac Management, L.L.C.

Mr. El-Hibri is the general manager of Intervac Management and in that capacity has the power to vote and dispose of all shares of our capital stock held by Intervac Management. Mr. El-Hibri is appointed as general manager pursuant to the terms of the operating agreement of Intervac Management, which may only be amended with the unanimous consent of the members of Intervac Management. Mr. El-Hibri and his wife, as tenants by the entirety, hold 31.1% of the ownership interests in Intervac Management.

#### ARPI. L.L.C.

Janice Mugrditchian holds 100% of the ownership interests in ARPI and has the power to vote and dispose of all shares of our capital stock held by ARPI.

#### Microscience Investments Limited

Microscience Investments has agreed, pursuant to a separate voting agreement with BioPharm, to vote all shares of our common stock owned by it for and against and abstain from voting with respect to any proposal in the same manner and to the same extent as BioPharm. The voting agreement automatically terminates upon the conclusion of our first annual meeting of stockholders following the completion of this offering.

# **Description of capital stock**

The following description of our capital stock and provisions of our restated certificate of incorporation, which we refer to as our certificate of incorporation, and our amended and restated by-laws, which we refer to as our by-laws, are summaries and are qualified by reference to the certificate of incorporation and the by-laws that will be in effect upon completion of this offering. We have filed copies of these documents with the Securities and Exchange Commission as exhibits to our registration statement of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur prior to and upon completion of this offering.

Upon the completion of this offering, our authorized capital stock will consist of shares of common stock, par value \$0.01 per share, and shares of preferred stock, par value \$0.01 per share.

As of July 31, 2006, we had issued and outstanding 7,752,001 shares of class A common stock and 30,015 shares of class B common stock, held by 32 stockholders of record. As of July 31, 2006, we also had outstanding options to purchase 1,062,779 shares of class B common stock at a weighted average exercise price of \$6.38 per share.

Prior to the completion of this offering:

- our class A common stock will be reclassified as common stock and each outstanding share of our class B common stock will be converted into one share of common stock; and
- each outstanding option to purchase shares of our class B common stock will automatically become an option to purchase an equal number of shares of common stock at the same exercise price per share.

#### Common stock

The holders of our common stock are entitled to one vote per share with respect to each matter presented to our stockholders on which the holders of common stock are entitled to vote and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive ratably all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

# Preferred stock

Under the terms of our certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

Authorizing our board of directors to issue preferred stock and determine its rights and preferences has the effect of eliminating delays associated with a stockholder vote on specific issuances. The issuance of

preferred stock or of rights to purchase preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Currently, we have no shares of preferred stock outstanding. Our board of directors has authorized shares of series A junior participating preferred stock for issuance under our stockholder rights plan. See "— Stockholder rights plan" below. We have no current plans to issue any preferred stock other than as may be provided for by the stockholder rights plan.

# **Options**

Upon the completion of this offering, based on options outstanding as of July 31, 2006, we will have outstanding options to purchase an aggregate of 1,062,779 shares of our common stock at a weighted average exercise price of \$6.38 per share.

# Anti-takeover effects of Delaware law and our certificate of incorporation and by-laws

Our certificate of incorporation and by-laws and Delaware law contain provisions that could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Immediately prior to this offering, Fuad El-Hibri, our president, chief executive officer and chairman of our board of directors, was the beneficial owner of 99.6% of our outstanding common stock. Immediately following this offering, Mr. El-Hibri will be the beneficial owner of % of our outstanding common stock if the underwriters exercise their over-allotment option in full. As a result, Mr. El-Hibri will be able to control the election of the members of our board of directors following this offering. In addition, some of the provisions summarized below may further enhance Mr. El-Hibri's control of our corporate affairs for at least the next several years, including control of our board of directors. This control could discourage others from initiating a potential merger, takeover or other change of control transaction that other stockholders may view as beneficial.

#### Number of directors

Subject to the rights of holders of any series of preferred stock to elect directors, our board of directors will establish the number of directors. Until the fifth anniversary of the completion of this offering, any change in the number of directors will require the affirmative vote of at least 75% of the directors then in office

# Staggered board; removal of directors

Our certificate of incorporation and our by-laws divide our directors into three classes with staggered three-year terms. Our directors may be removed from office only for cause and only by the affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote.

Any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by the affirmative vote of a majority of our directors present at a meeting duly held at which a quorum is present.

The classification of our board of directors and the limitations on the removal of directors and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

#### Appointment and removal of chairman of the board

Until the fifth anniversary of the completion of this offering, the appointment and removal of the chairman of our board of directors will require the affirmative vote of at least 75% of our directors then in office. Mr. El-Hibri currently serves as the chairman of our board of directors.

#### Stockholder action by written consent; special meetings

Our certificate of incorporation and our by-laws provide that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of such holders and may not be effected by any consent in writing by such holders. Our certificate of incorporation and our by-laws also provide that, except as otherwise required by law, special meetings of our stockholders can only be called by our board of directors, our chairman of the board or our president.

# Advance notice requirements

Following the second anniversary of the completion of this offering, our by-laws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to the board of directors. Following the second anniversary of the completion of this offering, stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

# Delaware business combination statute

We are subject to Section 203 of the General Corporation Law of Delaware. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of our board of directors or unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person. The restrictions contained in Section 203 are not applicable to any of our existing stockholders.

# Super-majority voting

The General Corporation Law of Delaware provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Until the second anniversary of the completion of this offering, the affirmative vote

of holders of our capital stock representing a majority of the voting power of all outstanding stock entitled to vote is required to amend or repeal the provisions of our certificate of incorporation described in this section entitled "Anti-takeover effects of Delaware law and our certificate of incorporation and by-laws." Following the second anniversary of the completion of this offering, the affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal these provisions of our certificate of incorporation. Until the second anniversary of the completion of this offering, the affirmative vote of either at least 75% of the directors then in office or holders of our capital stock representing a majority of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws. Following the second anniversary of the completion of this offering, the affirmative vote of either a majority of the directors present at a meeting of our board of directors or holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws.

# Stockholder rights plan

In connection with this offering, we will enter into a rights agreement pursuant to which we will issue to our stockholders one preferred stock purchase right for each outstanding share of our common stock. Each right, when exercisable, will entitle the registered holder to purchase from us a unit consisting of one one-thousandth of a share of series A junior participating preferred stock at a purchase price to be determined by our board of directors. We will enter into the rights agreement with , as rights agent.

The following description is a summary of the material terms of our stockholder rights plan. It does not restate these terms in their entirety. We urge you to read our stockholder rights plan because it, and not this description, defines its terms and provisions. We have filed a copy of the rights agreement that establishes our stockholder rights plan as an exhibit to our registration statement of which this prospectus forms a part.

Rights. Each share of common stock will have attached to it one right. Initially, the rights are not exercisable and are attached to all certificates representing outstanding shares of our common stock, and we will not distribute separate rights certificates. The rights will only be exercisable under limited circumstances specified in the rights agreement when there has been a distribution of the rights and the rights are no longer redeemable by us.

The rights will expire at the close of business on the tenth anniversary of the date the rights plan was adopted, unless we redeem or exchange them earlier as described below.

Prior to the rights distribution date. Prior to the rights distribution date:

- · the rights are evidenced by our common stock certificates and will be transferred with and only with such common stock certificates; and
- the surrender for transfer of any certificates of our common stock will also constitute the transfer of the rights associated with our common stock represented by such certificate.

Rights distribution date. The rights will separate from our common stock, and a rights distribution date will occur, upon the earlier of the following events:

10 business days following the later of (1) a public announcement that a person or group, other than an exempted person, has acquired, or obtained the
right to acquire beneficial ownership of 15% or more of the outstanding shares of our common stock or (2) the first date on which one of our executive
officers has actual knowledge of such an event; and

• 10 business days following the start of a tender offer or exchange offer that would result in a person or group, other than an exempted person, beneficially owning 15% or more of the outstanding shares of our common stock.

The distribution date may be deferred by our board of directors and some inadvertent actions will not trigger the occurrence of the rights distribution date. In addition, a rights distribution date will not occur as a result of the ownership of our stock by the following exempted persons:

- Fuad Fl-Hibri
- Microscience Investments Limited, unless and until such time as Microscience, together with its affiliates and associates, directly or indirectly, becomes
  the beneficial owner of any additional shares of common stock, except under certain specified circumstances, and disregarding any shares Microscience
  is or becomes the beneficial owner of solely as a result of the fact that it is a party to any of the voting agreements described under "Principal and selling
  stockholders Stockholder arrangements;" and
- each other holder of our class A common stock immediately prior to this offering to the extent such person's beneficial ownership exceeds 15% solely as
  a result of the fact that the person is a party to any of the voting agreements described under "Principal and selling stockholders Stockholder
  arrangements"

As soon as practicable after the rights distribution date, separate rights certificates will be mailed to the holders of record of our common stock as of the close of business on the rights distribution date. From and after the rights distribution date, the separate rights certificates alone will represent the rights. All shares of our common stock issued prior to the rights distribution date, including shares of common stock issued in this offering, will be issued with rights. Shares of our common stock issued after the rights distribution date in connection with specified employee benefit plans or upon conversion of specified securities will be issued with rights. Except as otherwise determined by our board of directors, no other shares of our common stock issued after the rights distribution date will be issued with rights.

Flip-in event. If a person or group, other than an exempted person, becomes the beneficial owner of 15% or more of the outstanding shares of our common stock, except as described below, each holder of a right will thereafter have the right to receive, upon exercise, a number of shares of our common stock, or, in some circumstances, cash, property or other securities of ours, which equals the exercise price of the right divided by one-half of the current market price of our common stock on the date the acquisition occurs. However, following the acquisition:

- · rights will not be exercisable until the rights are no longer redeemable by us as set forth below; and
- · all rights that are, or were, under the circumstances specified in the rights agreement, beneficially owned by any acquiring person will be null and void.

The event set forth in this paragraph is referred to as a flip-in event. A flip-in event would not occur if there is an offer for all of our outstanding shares of common stock that at least 75% of our board of directors determines is fair to our stockholders and in their best interests.

Flip-over event. If at any time after a person or group, other than an exempted person, has become the beneficial owner of 15% or more of the outstanding shares of our common stock:

· we are acquired in a merger or other business combination transaction in which we are not the surviving corporation;

- we are the surviving entity in a merger of other business combination transaction but our common stock is changed or exchanged for stock or securities
  of any other person or for cash or any other property; or
- 50% or more of our assets or earning power is sold or transferred,

then each holder of a right, except rights which previously have been voided as set forth above, shall thereafter have the right to receive, upon exercise, that number of shares of common stock of the acquiring company which equals the exercise price of the right divided by one-half of the current market price of that company's common stock at the date of the occurrence of the event. This exercise right does not arise if the merger or other transaction follows an offer for all of our outstanding shares of common stock that at least 75% of our board of directors determines is fair to our stockholders and in their best interests.

Exchange of rights. At any time after a flip-in event, when no person owns a majority of our common stock, our board of directors may exchange the rights, other than rights owned by the acquiring person that have become void, in whole or in part, at an exchange ratio of one share of our common stock, or one one-thousandth of a share of preferred stock, or of a share of a class or series of preferred stock having equivalent rights, preferences and privileges, per right.

Adjustments. The purchase price of the rights, and the number of securities purchasable, are subject to adjustment from time to time to prevent dilution. The number of rights associated with each share of common stock is also subject to adjustment in the event of a stock splits, subdivisions, consolidations or combinations of our common stock that occur prior to the rights distribution date.

Series A junior participating preferred stock. Series A preferred stock purchasable upon exercise of the rights will not be redeemable. Each share of series A preferred stock will be entitled to receive when, as and if declared by our board of directors, a minimum preferential quarterly dividend payment of \$10 per share or, if greater, an aggregate dividend of 1,000 times the dividend declared per share of our common stock. In the event of liquidation, the holders of the series A preferred stock will be entitled to a minimum preferential liquidation payment of \$1,000 per share, plus accrued and unpaid dividends, and will be entitled to an aggregate payment of 1,000 times the payment made per share of our common stock. Each share of series A preferred stock will have 1,000 votes, voting together with our common stock. In the event of any merger, consolidation or other transaction in which our common stock is changed or exchanged, each share of series A preferred stock will be entitled to receive 1,000 times the amount received per share of our common stock. These rights are protected by customary antidilution provisions.

Because of the nature of the series A preferred stock's dividend, liquidation and voting rights, the value of one one thousandth of a share of series A preferred stock purchasable upon exercise of each right should approximate the value of one share of common stock.

Redemption of rights. At any time until ten business days following the date of a public announcement that a person or group, other than an exempted person, has acquired or obtained the right to acquire beneficial ownership of 15% or more of the outstanding shares of our common stock, or such later date upon which one of our executive officers first has actual knowledge of such event or such later date as our board of directors may determine, we may redeem the rights in whole, but not in part, at a price of \$.001 per right, payable in cash or stock. Immediately upon the redemption of the rights or such earlier time as established by our board of directors, the rights will terminate and the only right of the holders of rights will be to receive the redemption price.

Status of rights holder and tax affects. Until a right is exercised, the holder of the right, as such, will have no rights as a stockholder of ours, including no right to vote or to receive dividends. Although the distribution of the rights should not be taxable to stockholders or to us, stockholders may, depending upon the circumstances, recognize taxable income in the event that the rights become exercisable for our common stock, or other consideration, or for common stock of the acquiring company as described above.

Board's authority to amend. Our board of directors may amend any provision of the rights agreement, other than the redemption price, prior to the date on which the rights are no longer redeemable. Once the rights are no longer redeemable, our board's authority to amend the rights agreement is limited to correcting ambiguities or defective or inconsistent provisions in a manner that does not adversely affect the interest of holders of rights.

Effects of the rights. The rights are intended to protect our stockholders in the event of an unfair or coercive offer to acquire our company and to provide our board of directors with adequate time to evaluate unsolicited offers. The rights may have anti takeover effects. The rights will cause substantial dilution to a person or group that attempts to acquire us without conditioning the offer on a substantial number of rights being acquired. The rights, however, should not affect any prospective offeror willing to make an offer at a fair price and otherwise in the best interests of us and our stockholders, as determined by our board of directors. The rights should not interfere with any merger or other business combination approved by our board of directors.

# Registration rights

Upon the completion of this offering, holders of 7,752,001 shares of our common stock as of July 31, 2006 will have the right to require us to register these shares of common stock under the Securities Act under specified circumstances, including any additional shares issued or distributed by way of a dividend, stock split or other distribution in respect of these shares.

In connection with our acquisition of Microscience, we granted to Microscience Investments registration rights with respect to the shares of our common stock that we issued to Microscience Investments in the acquisition. We also have granted registration rights with respect to shares of our common stock to the holders of our existing class A common stock, in addition to Microscience Investments.

Registration rights held by Microscience Investments may be transferred to the following parties if they become holders of the shares covered by the registration rights: APAX Funds Nominees Limited, The Merlin BioSciences Funds, The Merlin Fund L.P., Advent Private Equity Funds, JPMorgan Partners LLC, Merlin Equity Limited, or any subsidiary, affiliate, parent or general partner of any of these parties.

# Demand registration rights

Subject to specified limitations and to the lock-up agreements with the underwriters for this offering, holders of these registrations rights may, beginning 90 days after this offering, require that we register all or part of our common stock subject to the registration rights for sale under the Securities Act. These holders may demand registration of our common stock so long as the offering price to the public of the shares requested to be registered is at least \$25,000,000. We are required to effect only one demand registration, subject to specified exceptions for each of Microscience and the holders of our existing class A common stock.

# Incidental registration rights

If, after the completion of this offering, we propose to register any of our common stock under the Securities Act, subject to specified exceptions, either for our own account or for the account of other security holders, holders of registration rights are entitled to notice of the registration and to include shares of common stock subject to the registration rights in the registered offering.

# Limitations and expenses

With specified exceptions, the right to include shares in a registration is subject to the right of underwriters for the offering to limit the number of shares included in the offering. We are required to pay one-half of all fees, costs and expenses of any demand registration, other than underwriting discounts and commissions.

# Transfer agent and registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company.

# **NASDAQ Global Market**

We have applied to have our common stock listed on The NASDAQ Global Market under the symbol "EBSI."

# Shares eligible for future sale

Prior to this offering, there has been no market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of common stock, including shares issued upon exercise of outstanding options or in the public market after this offering, or the anticipation of those sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of our equity securities. We have applied to have our common stock listed on The NASDAQ Global Market under the symbol "EBSI."

Upon the completion of this offering, we will have outstanding

shares of common stock, after giving effect to the issuance of

shares of common stock in this offering.

Of the shares to be outstanding after the completion of this offering, the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining shares of our common stock are "restricted securities" under Rule 144. Substantially all of these restricted securities will be subject to the 180-day lock-up period described below.

After the 180-day lock-up period, these restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act.

# **Rule 144**

In general and subject to the lock-up agreements described below, under Rule 144, beginning 90 days after the date of this prospectus, a person who has beneficially owned shares of our common stock for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; and
- the average weekly trading volume in our common stock on The NASDAQ Global Market during the four calendar weeks preceding the date of filing of a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale.

Sales under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. Upon expiration of the 180-day lock-up period described below, 7,782,016 shares of our common stock will be eligible for sale under Rule 144, including shares eligible for resale under Rule 144(k) as described below. We cannot estimate the number of shares of common stock that our existing stockholders will elect to sell under Rule 144.

# Rule 144(k)

Subject to the lock-up agreements described below, shares of our common stock eligible for sale under Rule 144(k) may be sold immediately upon the completion of this offering. In general, under Rule 144(k), a person may sell shares of common stock acquired from us immediately upon the completion of this offering, without regard to manner of sale, the availability of public information about us or volume, if:

• the person is not our affiliate and has not been our affiliate at any time during the three months preceding the sale; and

the person has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an affiliate.

Upon the expiration of the 180-day lock-up period described below, approximately 30,015 shares of common stock will be eligible for sale under Rule 144(k).

# **Rule 701**

In general, under Rule 701 of the Securities Act, any of our employees, consultants or advisors who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement is eligible to resell those shares 90 days after the effective date of this offering in reliance on Rule 144, but without compliance with the various restrictions, including the holding period, contained in Rule 144. Subject to the 180-day lock-up period described below, approximately 30,015 shares of our common stock will be eligible for sale in accordance with Rule 701.

# Lock-up agreements

We expect that the holders of substantially all of our currently outstanding capital stock will agree that, without the prior written consent of J.P. Morgan Securities Inc., they will not, during the period ending 180 days after the date of this prospectus, subject to exceptions specified in the lock-up agreements, offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock. Further, these holders have agreed that, during this period, they will not make any demand for, or exercise any right with respect to, the registration of our common stock or any security convertible into or exercisable or exchangeable for our common stock. The 180-day lock-up period may be extended under specified circumstances. The lock-up restrictions, specified exceptions and the circumstances under which the 180-day lock-up period may be extended are described in more detail under "Underwriting."

# Registration rights

Subject to the lock-up agreements described above, upon the completion of this offering, holders of 7,752,001 shares of our common stock as of July 31, 2006, will have the right to require us to register these shares of common stock under the Securities Act under specified circumstances. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. See "Description of capital stock—Registration rights" for additional information regarding these registration rights.

#### Stock options

As of July 31, 2006, we had outstanding options to purchase 1,062,779 shares of class B common stock, of which options to purchase 813,347 shares of class B common stock were vested as of July 31, 2006. As of July 31, 2006, options to purchase shares of common stock will be vested and eligible for sale within 180 days after the date of this prospectus. Immediately prior to the completion of this offering, each of these options automatically will become an option to purchase an equal number of shares of our common stock. Following this offering, we intend to file registration statements on Form S-8 under the Securities Act to register all of the shares subject to outstanding options and options and other awards issuable pursuant to our employee stock option plan and 2006 stock incentive plan. See "Management—Stock option add other compensation plans" for additional information regarding these plans. Accordingly, shares of our common stock registered under the registration statements will be available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements applicable to these shares.

# Underwriting

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities Inc., Cowen and Company, LLC and HSBC Securities (USA) Inc. are acting as representatives of the underwriters. We and the selling stockholders have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the initial public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of shares
J.P. Morgan Securities Inc.	
Cowen and Company, LLC	
HSBC Securities (USA) Inc.	
Total	

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the shares of common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to \$ per share from the initial public offering price. After the initial public offering of the shares, the offering price and other selling terms may be changed by the underwriters. The representatives have advised us that the underwriters do not intend to confirm discretionary sales in excess of 5% of the shares of common stock offered in this offering.

The underwriters have an option to buy up to additional shares of common stock from the selling stockholders to cover sales of shares by the underwriters that exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this over-allotment option. If any shares are purchased with this over-allotment option, the underwriters will purchase shares from the selling stockholders in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the initial public offering price per share of common stock less the amount paid by the underwriters to us and the selling stockholders per share of common stock. The underwriting fee is \$ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

Underwriting discounts and commissions	Without over- allotment exercise	With full over- allotment exercise
Per share	\$	\$
Total	\$	\$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will

be approximately \$ . Of this total, approximately \$ is payable by us and approximately \$ is payable by the selling stockholders

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed, with limited exceptions, that we will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, or file with the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing, without the prior written consent of J.P. Morgan Securities Inc. for a period of 180 days after the date of this prospectus. Notwithstanding the foregoing, if (1) during the last 17 days of the 180-day restricted period, we issue an earnings release or material news or a material event relating to us occurs; or (2) prior to the expiration of the 180-day period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period, the restrictions described above will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

Our directors and executive officers and substantially all of our stockholders have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for a period of 180 days after the date of this prospectus, may not, without the prior written consent of J.P. Morgan Securities Inc., (1) offer, pledge, announce the intention to sell, sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or such other securities, in cash or otherwise. Notwithstanding the foregoing, if (1) during the last 17 days of the 180-day restricted period, we issue an earnings release or material news or a material event relating to us occurs; or (2) prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day period, the restrictions described above will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

The restrictions imposed by these lock-up agreements will not apply to the transfer or disposition of shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (1) as a bona fide gift, (2) to any trust for the direct or indirect benefit of the stockholder or the immediate family of the stockholder in a transaction not involving a disposition for value, (3) to any corporation, partnership, limited liability company or other entity all of the beneficial ownership interests of which are held by the stockholder or the immediate family of the stockholder in a transaction not involving a disposition for value, (4) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the stockholder, (5) as a distribution to partners, members or stockholders of the stockholder in a transaction not involving a disposition for value or (6) to any affiliate of the stockholder or any investment fund or other entity controlled or managed by the stockholder in a transaction not involving a disposition for value; provided that the transferee, distributee or donee agrees in writing to be bound by the terms of the lock-up agreement to the same extent as if a party thereto; and, provided further that, in the case of (3), (5) and

(6) above, no filing pursuant to Section 16(a) of the Exchange Act, reporting a reduction in the beneficial ownership of common stock shall be required or shall be voluntarily made in connection with such transfer, other than a filing on a Form 5 made after the expiration of the 180-day restricted period or any extension thereof pursuant to the lock-up agreement. In addition, the restrictions imposed by the lock-up agreement do not apply to the sale of common stock by the stockholder pursuant to the underwriting agreement. Furthermore, notwithstanding the restrictions imposed by the lock-up agreement, the stockholder may, without the prior written consent of J.P. Morgan Securities Inc., (1) exercise an option to purchase shares of common stock granted under any stock incentive plan or stock purchase plan, (2) establish a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of common stock, provided that such plan does not provide for any transfers of common stock during the 180-day restricted period or any extension thereof pursuant to the lock-up agreement and (3) transfer shares of common stock acquired in this offering or on the open market following this offering.

We and the selling stockholders have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

We have applied to have our common stock listed on The NASDAQ Global Market under the symbol "EBSI."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' over-allotment option referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their over-allotment option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the over-allotment option. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on The NASDAQ Stock Market, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In

determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors, including:

- · the information set forth in this prospectus and otherwise available to the representatives;
- · our prospects and the history and prospects for the industry in which we compete;
- · an assessment of our management;
- · our prospects for future earnings;
- · the general condition of the securities markets at the time of this offering;
- · the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- · other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common stock, or that the shares of common stock will trade in the public market at or above the initial public offering price.

J.P. Morgan Partners, LLC, an affiliate of J.P. Morgan Securities Inc., through its ownership of various entities, owns approximately 10.9% of the voting securities of Microscience Investments Limited, which owns 16.2% of our common stock prior to this offering. Because J.P. Morgan Securities Inc. may be deemed an affiliate under the National Association of Securities Dealers, Inc.'s Conduct Rules, or the NASD Rules, as a result of J.P. Morgan Partners, LLC's ownership of more than 10% of the voting securities of Microscience Investments Limited, J.P. Morgan Securities Inc. may be deemed to have a "conflict of interest" with us under Rule 2720 of the NASD Rules. When an NASD member with a conflict of interest participates as an underwriter in a public offering, the NASD Rules require that the initial public offering price can be no higher than that recommended by a "qualified independent underwriter," as defined by the NASD Rules. In accordance with Rule 2720 of the NASD Rules, Cowen and Company, LLC will assume the responsibility of acting as qualified independent underwriter. In this role, Cowen and Company, LLC will perform a due diligence investigation and review and participate in the preparation of the registration statement, of which this prospectus is a part.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. HSBC Realty Credit Corporation, an affiliate of HSBC Securities (USA) Inc., is the lender under a mortgage loan that we entered into in April 2006 in the original principal amount of \$8.5 million in connection with the purchase of a building in Frederick, Maryland. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

# Legal matters

The validity of the common stock offered hereby will be passed upon by Wilmer Cutler Pickering Hale and Dorr LLP, Washington, D.C. Dechert LLP, Philadelphia, Pennsylvania is acting as counsel for the underwriters in connection with this offering.

# **Experts**

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2005 and 2004, and for each of the three years in the period ended December 31, 2005, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

# Where you can find more information

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract or any other document are not necessarily complete, and, and in each instance, we refer you to the copy of the contract or other documents filed as an exhibit to the registration statement. Each of theses statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the Securities and Exchange Commission's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. You can request copies of the registration statement by writing to the Securities and Exchange Commission and paying a fee for the copying cost. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for more information about the operation of the Securities and Exchange Commission's public reference room. In addition, the Securities and Exchange Commission maintains an Internet website, which is located at http://www.sec.gov, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the Securities and Exchange Commission. You may access the registration statement of which this prospectus is a part at the Securities and Exchange Commission's Internet website. Upon completion of this offering, we will be subject to the information reporting requirements of the Securities Exchange Act of 1934, and we will file reports, proxy statements and other information with the Securities and Exchange

This prospectus includes statistical data that were obtained from industry publications. These industry publications generally indicate that the authors of these publications have obtained information from sources believed to be reliable but do no guarantee the accuracy and completeness of their information. While we believe these industry publications to be reliable, we have not independently verified their data.

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# Report of independent registered public accounting firm

The Board of Directors and Stockholders Emergent BioSolutions Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. and Subsidiaries as of December 31, 2004 and 2005, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Emergent BioSolutions Inc. and Subsidiaries at December 31, 2004 and 2005, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

May 23, 2006 McLean, VA

# Emergent BioSolutions Inc. and subsidiaries Consolidated balance sheets

						As of March 31.
(in thousands, except share and per share data)		2004	Dece	ember 31, 2005	(1	2006 unaudited)
·					\$ \$	
ASSETS Current assets:						
Cash and cash equivalents	\$	6.821	\$	36,294	•	14.774
Accounts receivable	Ψ	18,637	Ψ	2.530	Ψ	2.470
Inventories		13.253		16.441		21,102
Income tax receivable		15,255		763		5,243
Deferred tax assets		978		1.989		5,245
Restricted cash		1,250		1,909		_
Prepaid expenses and other current assets		756		1.099		1,902
				,		,
Total current assets		41,695		59,116		45,491
Property, plant and equipment, net		27,269		30,645		32,527
Deferred tax assets, net of current		24		9,981		11,362
Other assets		68		590		1,193
Total assets	\$	69,056	\$	100,332	\$	90,573
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current liabilities:						
Accounts payable, related party	\$	15	\$	22	S	46
Accounts payable, operations	•	5.505	•	10.403	•	8.086
Accrued compensation		3,710		6,177		5,705
Long-term indebtedness, current portion		572		902		973
Notes payable to employees, current portion		474		506		520
Income taxes payable		3,761		2,134		- 020
Deferred tax liabilities		5,701		2,104		27
Deferred revenue		18,256		7.340		7,340
Other current liabilities		1,893		2.609		2.746
		,		,		, .
Total current liabilities		34,186		30,093		25,443
Long-term indebtedness, net of current portion		11,347		10,471		10,225
Notes payable to employees, net of current portion		474		31		
Other liabilities		100				
Total liabilities		46,107		40,595		35,668
Stockholders' equity:						
Preferred Stock \$0.01 par value; 3,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2004 and 2005 and March 31, 2006		_		_		_
Common Stock, Class A, \$0.01 par value; 10,000,000 shares authorized, 6,487,950, 7,752,001 and 7,752,001 shares issued and outstanding at December 31, 2004 and 2005 and March 31, 2006,						
respectively		65		78		78
Common Stock, Class B, \$0.01 par value; 2,000,000 shares authorized, 0, 7,400 and 16,800 shares issued and outstanding at December 31, 2004 and 2005 and March 31, 2006, respectively		_		_		_
Additional paid-in capital		7,564		34,539		34,637
Accumulated other comprehensive loss		- ,,,,,		(276)		(370)
Retained earnings		15.320		25.396		20,560
Total stockholders' equity		22,949		59,737		54,905
Total liabilities and stockholders' equity	\$	69,056	\$	100,332	\$	90,573
Total national dead of the state of the stat	Ψ	00,000	Ψ	100,002	Ψ	50,575

The accompanying notes are an integral part of these consolidated financial statements.

# Emergent BioSolutions Inc. and subsidiaries Consolidated statements of operations

(in thousands, except	Thr ended Year ended December 31, (											
share and per share data)		2003		2004	2005			2005		2006		
Revenues:										_		
Product sales	\$	55,536	\$	81,014	\$	127,271	\$	14,782	\$	12,196		
Milestones and grants		233		2,480		3,417		480		27		
Total revenues		55,769		83,494		130,688		15,262		12,223		
Operating expense (income):												
Cost of product sales		22,342		30,102		31,603		4,136		2,861		
Research and development		6,327		10,117		18,381		1,852		8,173		
Selling, general and administrative		19,547		30,323		42,793		8,849		10,587		
Purchased in-process research and development		1,824		_		26,575		_		_		
Settlement of State of Michigan obligation		_		(3,819)		_		_		_		
Litigation settlement						(10,000)						
Income (loss) from operations		5,729		16,771		21,336		425		(9,398)		
Other income (expense):												
Interest income		100		65		485		77		203		
Interest expense		(293)		(241)		(767)		(189)		(170)		
Other income (expense), net		168		6		55		(13)		7		
Total other income (expense)		(25)		(170)		(227)		(125)		40		
Income (loss) before provision for income taxes		5,704		16,601		21,109		300		(9,358)		
Provision for (benefit from) income taxes		1,250		5,129		5,325		76		(4,722)		
Net income (loss)	\$	4,454	\$	11,472	\$	15,784	\$	224	\$	(4,636)		
Earnings (loss) per share — basic	\$	0.68	\$	1.74	\$	2.21	\$	0.03	\$	(0.60)		
Earnings (loss) per share — diluted	\$	0.63	\$	1.61	\$	2.00	\$	0.03	\$	(0.60)		
Weighted average number of shares — basic		6,570,856		6,576,019		7,136,866		6,494,604		7,767,859		
Weighted average number of shares — diluted		7,061,537		7,104,172		7,908,023		7,102,822		7,767,859		
Cash dividends per share — basic	\$	_	\$	_	\$	0.76	\$	_	\$	_		

The accompanying notes are an integral part of these consolidated financial statements.

# Emergent BioSolutions Inc. and subsidiaries Consolidated statement of changes in stockholders' equity

(in thousands, except share and per share data)	com Shares	Class A no-par mon stock Amount	comr Shares	Class B no-par non stock Amount	\$0.01 par value com Shares	Class A mmon stock Amount	\$0.01 par valu Shares	Class B ue common stock Amount	Additional paid-in capital	Retained earnings	Accumulated other comprehensive loss	stockh	Total nolders' equity
Balance at December 31, 2002	6,262,554	\$ 2,940	\$ 254,384	\$ 69	<b>–</b> \$	· –	_	\$ —	\$ —	\$ 1,146	\$ —	\$	4,155
Redemption of common stock	_	_	(25,000)	(7)	_	_	_	_	_	(193)	_		(200)
Issuance of common stock	_	_	152,676	39	_	_	_	_	_	· —	_		39
Net Income (loss)		_	_	_	_	_	_	_	_	4,454	_		4,454
Balance at December 31, 2003	6,262,554	2,940	382,060	101	_	_	_	_	_	5,407	_		8,448
Redemption of common stock		_	(199,271)	(53)	_	_	_	_	_	(1,559)	_		(1,612)
Issuance of common stock	_	_	42,607	12	_	_	_	_	_		_		12
Conversion of class A no-par common stock to class A \$.01 par value common stock	(6,262,554)	(2,940)	_	_	6,262,554	63	_	_	2,877	_	_		_
Conversion of class B no-par common stock to class A \$.01 par value common stock	_	_	(225,396)	(60)	225,396	2	_	_	58	_	_		_
Stock-based compensation expense	_	_	(,,			_	_	_	4,310	_	_		4,310
Tax benefit related to the disqualifying disposition	_	_	_	_	_	_	_	_	319	=	_		319
Net income (loss)									_	11,472			11,472
Balance at December 31, 2004					6,487,950	65			7,564	15,320			22,949
Issuance of common stock to acquire Microscience Limited	_	_	_	_	1,264,051	13	_	_	26,988	_	_	:	27,001
Exercise of stock options	_	_	_	_	_	_	46,384	_	33	_	_		33
Redemption of common stock							(38,984)		(29)	(308)			(337)
Forfeiture of stock options	_	_	_	_	_	_	_	_	(17)		_		(17)
Payment of dividend									_	(5,400)			(5,400)
Net income (loss)	_	_	_	_	_	_	_	_	_	15,784	(070)		15,784
Foreign currency translation		_				_	_	_	_		(276)	_	(276)
Comprehensive income													15,508
Balance at December 31, 2005		_		_	7,752,001	78	7,400		34,539	25,396	(276)		59,737
Redemption of common stock Issuance of common stock	_		_	=	_		9.400	=	_ 2	(200)			(200)
Stock-based compensation expense	_	_	_	_	_	_		_	96	_	_		96
Net income (loss)	_	_	_	_	_	_	_	_	_	(4,636)	_		(4,636)
Foreign currency translation	_	_	_	_	_	_	_	_	_	(1,000)	(94)		(94)
Comprehensive loss	_	_	_	_	_	_	_	_	_	_	_		(4,730)
Balance at March 31, 2006 (unaudited)		\$ —		\$ —	7.752.001 \$	78	16.800	\$ —	\$ 34.637	\$ 20.560	\$ (370)		54.905

The accompanying notes are an integral part of these consolidated financial statements.

# Emergent BioSolutions Inc. and subsidiaries Consolidated statements of cash flows

								d Ma	months arch 31,
(in thousands)		2003		ded D 004	ecember 31, 2005	_	2005	(una	udited) 2006
(·····									
Cash flows from operating activities:									
Net income (loss)	\$	4,454	\$ 11,	472	\$ 15,784	\$	224	\$	(4,636
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities (net of effects of acquisitions):									
Stock-based compensation expense (credit)		_		310	(17)		_		96
Non-cash gain on settlement		_		819)	_		_		_
Depreciation and amortization		1,214		867	3,549		841		968
Deferred income taxes		(467)		418)	(10,968)		96		63
Other obligations		_		200	_				
Loss on disposal of property and equipment		13		43	32		15		4
Purchased in-process research and development		1,824		_	26,575				
Cash payment on State of Michigan obligation		540		_	_		_		-
Changes in operating assets and liabilities:  Accounts receivable		(528)	/15	664)	16.107		13.625		59
Inventories		(4,656)		609)	-, -		(4,318)		(4,66
Income taxes		(1,713)		794	(3,189) (2,390)		(4444)		(6.61
Prepaid expenses and other assets		(244)	J,	50	(865)		(181)		(1,40
Accounts payable		983	2	472	5,463		(456)		(2,29
Accrued compensation		(583)		585	2,466		88		(47
Other current liabilities		(1,617)		44	619		113		13
Deferred revenue		11,852	3	869	(10,916)		(10,916)		
Net cash provided by (used in) operating activities	_	11,072		196	42,250		(1,313)		(18,18
Cash flows from investing activities:	_	,,		-	,		(1,010)	_	(10,10
Purchases of property, plant and equipment		(4,123)	(17	072)	(6,532)		(379)		(2,85
Acquisitions, net of cash received		(3,794)	(		(559)		(ö. ö)		(2,00
Restricted cash deposits		(0,.0.)	(1.	250)	1,250		_		_
Proceeds from investment maturities		_		147	´ —		_		_
Net cash used in investing activities		(7,917)	(18.	175)	(5,841)		(379)		(2,85
Cash flows from financing activities:	_	,			, , ,				
Proceeds from notes payable		172	10.	992	31		70		_
Proceeds from notes payable to employees		_		947	123		_		_
Repayments on product supply and royalty obligations		(900)	(2,	351)	_		_		_
Issuance of Class B common stock		39		12	33		_		
Redemption of Class B common stock		(200)		665)	(337)		(106)		(20
Principal payments on notes payable		(38)	(	184)	(1,110)		(102)		(19
Debt issuance costs		_		(70)	_		_		-
Payment of dividend	_	_		_	(5,400)				
Net cash provided by (used in) financing activities		(927)	8,	681	(6,660)		(138)		(39
Effect of exchange rate changes on cash and cash equivalents		_		_	(276)		_		(9
Net increase (decrease) in cash and cash equivalents		2.228	(	298)	29.473		(1,830)		(21,52
Cash and cash equivalents at beginning of period		4,891		119	6,821		6,821		36,29
Cash and cash equivalents at end of period	\$	7,119	\$ 6,	821	\$ 36,294	\$	4,991	\$	14,774
Supplemental disclosure of cash flow information:									
Cash paid during the year for interest	\$	99	\$	170	\$ 696	\$	144	\$	14
Cash paid during the year for income taxes	\$	4,280	\$	_	\$ 17,985	\$	500	\$	1,200
	φ	7,200	Ψ		Ψ 17,905	φ	500	Ψ	1,200
Supplemental information on non cash investing and financing activities:	_		•		0.07.001	_			
ssuance of common stock to acquire Microscience Limited	\$	_	\$	_	\$ 27,001	\$	_	\$	_

The accompanying notes are an integral part of these consolidated financial statements

# **Emergent BioSolutions Inc. and subsidiaries Notes to consolidated financial statements**

(dollars in thousands, except per share data)

# 1. Nature of the business and organization

Emergent Biosolutions (the Company or Emergent) is a biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics. The Company operates in two business segments: biodefense and commercial. The Company commenced operations as BioPort Corporation (BioPort) in September 1998 through an acquisition from the Michigan Biologic Products Institute of rights to the marketed product, BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how. Following this acquisition, the Company completed renovations at the Lansing facilities that had been initiated by the State of Michigan. In December 2001, the U.S. Food and Drug Administration (FDA) approved a supplement to the Company's manufacturing facility license for the manufacture of BioThrax at the renovated facilities. In June 2004, the Company completed a corporate reorganization (Reorganization) in which:

- Emergent issued 6,487,950 shares of Class A Common Stock in exchange for 6,262,554 shares of BioPort class A common stock and 225,396 shares of BioPort class B common stock;
- all other issued and outstanding shares of BioPort class B common stock were repurchased and retired; and
- all outstanding stock options to purchase BioPort class B common stock were assumed by Emergent and option holders were granted replacement stock options to purchase an equal number of shares of Class B Common Stock of Emergent.

As a result of the Reorganization, BioPort became a wholly owned subsidiary of Emergent. The Company acquired its portfolio of commercial vaccine candidates through an acquisition of Microscience Limited (Microscience) in a share exchange in June 2005 and an acquisition of substantially all of the assets of Antex Biologics Inc. (Antex) for cash in May 2003. The Company has renamed Microscience as Emergent Product Development UK Limited.

# 2. Summary of significant accounting policies

# Basis of presentation and consolidation

The accompanying consolidated financial statements include the accounts of Emergent and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

# Unaudited interim financial information

The accompanying interim consolidated balance sheet as of March 31, 2006, the statements of operations and cash flows for the three months ended March 31, 2005 and 2006 and the statement of changes in stockholders' equity for the three months ended March 31, 2006 are unaudited. These unaudited interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. In the opinion of the Company's management, the unaudited interim consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and include all adjustments necessary for the fair presentation of the Company's statement of financial position, results of operations and its cash flows for the three months ended March 31, 2005 and 2006. The results for the three months ended March 31, 2006 are not necessarily indicative of the results to be expected for the year ending December 31, 2006. All references

to March 31, 2006 or to the three months ended March 31, 2005 and 2006 in the notes to the consolidated financial statements are unaudited.

#### Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

# Cash and cash equivalents

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions and high-quality corporate bonds. Also, the Company maintains cash balances with financial institutions in excess of insured limits. The Company does not anticipate any losses with such cash balances. At December 31, 2004 and 2005 and March 31, 2006, the Company maintained all of its cash and cash equivalents in three financial institutions.

# Fair value of financial instruments

The carrying amounts of the Company's short term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair values due to their short maturities. The carrying value and fair value of long-term indebtedness were \$11,821 and \$11,409, respectively, at December 31, 2004 and \$10,502 and \$10,089, respectively, at December 31, 2005. The carrying value and fair value of long-term indebtedness were \$10,225 and \$9,556, respectively, at March 31, 2006.

# Restricted cash

Restricted cash at December 31, 2004 consists of a certificate of deposit held by a bank as collateral for a letter of credit acting as a security deposit on a loan. This certificate of deposit was redeemed by the Company in October 2005.

# Significant customers and accounts receivable

The Company's primary customers are the U.S. Department of Defense (DoD) and U.S. Department of Health and Human Services (HHS). For the years ended December 31, 2003, 2004 and 2005 and the three months ended March 31, 2005 and 2006, sales of BioThrax to the DoD and HHS comprised 100%, 99% and 96% and 97% and 95% of total revenues, respectively. As of December 31, 2004 and 2005 and March 31, 2006, the Company's receivable balances were comprised of 96% and 38% and 23%, respectively, from these customers. Unbilled accounts receivable, included in accounts receivable, totaling \$3,772 and \$1,418 and \$1,690 as of December 31, 2004 and 2005 and March 31, 2006, respectively, relate to various service contracts for which product has been delivered or work has been performed, though invoicing has not yet occurred. Accounts receivable are stated at invoice amounts and consist primarily of amounts due from the DoD and HHS as well as amounts due under reimbursement contracts with other government entities and non-government and philanthropic organizations. If necessary, the Company records a provision for doubtful receivables to allow for any amounts which may be unrecoverable. This provision is based upon an analysis of the Company's prior collection experience, customer creditworthiness and current economic trends. As of December 31, 2004 and 2005 and March 31, 2006, an allowance for doubtful accounts was not recorded, as the prior collection history from these customers indicates collection is likely.

#### Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company places its cash and cash equivalents with high quality financial institutions. Management believes that the financial risks associated with its cash and cash equivalents are minimal. Because accounts receivable consist of amounts due from the U.S. federal government for product sales and from government agencies under government grants, management deems there to be minimal credit risk.

# Inventories

Inventories are stated at the lower of cost or market, with cost being determined using a standard cost method, which approximates average cost. Average cost consists primarily of material, labor and manufacturing overhead expenses and includes the services and products of third party suppliers. The Company analyzes its inventory levels quarterly and writes down, in the applicable period, inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand. The Company also writes off in the applicable period the costs related to expired inventory.

# Property, plant and equipment

Property, plant and equipment are stated at cost. Depreciation is computed using the straight-line method over the following estimated useful lives:

Buildings	39 years
Furniture and equipment	3-7 years
Internal-use software	Lesser of 3 years or product life
Leasehold improvements	Lesser of the asset life or life of lease

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

The Company capitalizes purchased software from the time the preliminary project stage is completed until the software is ready for use. Under the provisions of the Statement of Positions (SOP) No. 98-1, *Accounting for the Costs of Computer Software Developed or Obtained for Internal Use*, the Company capitalizes costs associated with software developed or obtained for internal use when the preliminary project stage is completed. Capitalized costs include only: (1) external direct costs of materials and services consumed in developing or obtaining internal use software and (2) payroll and payroll-related costs for employees who are directly associated with and who devote time to the internal use software project during the development stage. Capitalization of such costs ceases before training and other post implantation software activities occur. Computer software maintenance costs related to software development are expensed as incurred.

#### Income taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities, and their respective tax bases and operating loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled.

The Company records valuation allowances to reduce deferred tax assets to the amounts that it anticipates will be realized. The Company considers future taxable income and ongoing tax planning

strategies in assessing the need for valuation allowances. In general, if the Company determines that it is able to realize more than the recorded amounts of net deferred tax assets in the future, net income will increase in the period in which the determination is made. Likewise, if the Company determines that it is not able to realize all or part of the net deferred tax asset in the future, net income will decrease in the period in which the determination is made. The Company applies any reversals of valuation allowance related to an acquired deferred tax asset against other intangibles before impacting net income.

Under sections 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of net operating losses and deductions that are available. Due to the acquisition of Microscience in 2005, the Company believes the use of the operating losses will be significantly limited.

The Company's ability to realize deferred tax assets depends upon future taxable income as well as the limitations discussed above. For financial reporting purposes, a deferred tax asset must be reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized prior to expiration.

# Revenue recognition

The Company recognizes revenues from product sales in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB No. 104). SAB No. 104 requires recognition of revenues from product sales that require no continuing performance by the Company if four basic criteria have been met:

- there is persuasive evidence of an arrangement;
- · delivery has occurred and title has passed to the Company's customer;
- · the fee is fixed and determinable and no further obligation exists; and
- · collectibility is reasonably assured.

All revenues from product sales are recorded net of applicable allowances for sales returns, rebates, special promotional programs, and discounts. For arrangements where the risk of loss has not passed to the customer, the Company defers the recognition of revenue until such time that risk of loss has passed. Also, the cost of revenue associated with amounts recorded as deferred revenue is recorded in inventory until such time as risk of loss has passed.

In December 2005, the Securities and Exchange Commission released an interpretation with respect to the accounting for sales of vaccines and bioterror countermeasures to the federal government for placement into the strategic national stockpile. This interpretation provides for revenue recognition for specifically identified products purchased for the strategic national stockpile in the event that all requirements for revenue recognition, as specified in Statement of Financial Accounting Concepts No. 5, Recognition and Measurement in Financial Statements of Business Enterprises, are not met.

The Company recognizes revenue from milestone payments in accordance with Emerging Issues Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF No. 00-21), which addresses whether, for revenue recognition purposes, there is one or several elements in an arrangement. The Company recognizes revenue from milestone payments upon achievement of pre-defined scientific events that require substantive effort if achievement of the milestone was not readily assured at the inception of the agreement.

Payments received by the Company for the reimbursement of expenses for research and development activities are recorded in accordance with EITF Issue 99-19, *Reporting Revenue Gross as Principal Versus Net as an Agent* (EITF No. 99-19). Pursuant to EITF No. 99-19, for transactions in which the Company acts as principal, with discretion to choose suppliers, bears credit risk and performs a substantive part of

the services, revenue is recorded at the gross amount of the reimbursement. Costs associated with these reimbursements are reflected as a component of research and development expenses.

#### Impairment of long-lived assets

In accordance with Statement of Financial Accounting Standards No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144), the Company assesses the recoverability of its long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value. The Company has recorded no impairment losses for the years ended December 31, 2003, 2004 and 2005 and the three months ended March 31, 2006.

# Research and development

Research and development costs are expensed as incurred. Research and development costs primarily consist of salaries, materials and related expenses for personnel and facility expenses. Other research and development expenses include fees paid to consultants and outside service providers and the costs of materials used in clinical trials and research and development.

## Purchased in-process research and development

The Company accounts for purchased in-process research and development in accordance with the Statement of Financial Accounting Standards No. 2, Accounting for Research and Development Costs (SFAS No. 2) and along with Financial Accounting Standards Board (FASB) Interpretation No. 4, Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method — an interpretation of FASB Statement No. 2 (FIN 4). Under these standards, the Company is required to determine whether the technology relating to a particular research and development project acquired through an acquisition has an alternative future use. If the determination is that the technology has no alternative future use, the acquisition amount not directly attributed to fixed assets is expensed. Otherwise, the Company capitalizes and amortizes the costs incurred over their estimated useful lives of the technology acquired.

#### Comprehensive income (loss)

Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income (SFAS No. 130), requires the presentation of the comprehensive income (loss) and its components as part of the financial statements. Comprehensive income is comprised of net income (loss) and other changes in equity that are excluded from net income (loss). The Company includes gains and losses on intercompany transactions with foreign subsidiaries that are considered to be long-term investments and translation gains and losses incurred when converting its subsidiaries' financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income (loss).

# Foreign currencies

The local currency is the functional currency for the Company's foreign subsidiaries and, as such, assets and liabilities are translated into U.S. dollars at year-end exchange rates. Income and expense items are translated at average exchange rates during the year. Translation adjustments resulting from this process are charged or credited to other comprehensive income (loss).

#### Certain risks and uncertainties

The Company has derived substantially all of its revenue from sales of BioThrax under contracts with the DoD and HHS. The Company's ongoing U.S. government contracts do not necessarily increase the likelihood that it will secure future comparable contracts with the U.S. government. The Company

expects that a significant portion of the business that it will seek in the near future, in particular for BioThrax, will be under government contracts that present a number of risks that are not typically present in the commercial contracting process. U.S. government contracts for BioThrax require annual funding decisions by the government and are subject to unilateral termination by the government. The Company may fail to achieve significant sales of BioThrax to customers in addition to the U.S. government, which would harm its growth opportunities. The Company may not be able to sustain or increase profitability. The Company is spending significant amounts for the expansion of its manufacturing facilities. The Company may not be able to manufacture BioThrax consistently in accordance with FDA specifications. Other than BioThrax, all of the Company's product candidates are undergoing clinical trials or are in early stages of development, and failure is common and can occur at any stage of development. None of the Company's product candidates other than BioThrax has received regulatory approval.

# Earnings per share

Basic net income (loss) attributable to common stockholders per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income (loss) attributable to common stockholders by the weighted average number of shares outstanding for the period. Diluted net income (loss) attributable to common stockholders per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock.

The following table presents the calculation of basic and diluted net income per share:

			Ye	ar en	nded December 31,		Three months	ende	d March 31,
	2003	2004	2004			2005		2006	
Numerator:									
Net income (loss)	\$ 4,454	\$	11,472	\$	15,784	\$	224	\$	(4,636)
Denominator:									
Weighted-average number of shares — basic	 6,570,856		6,576,019		7,136,866		6,494,604		7,767,859
Dilutive securities — stock options	 490,681		528,152		771,157		608,218		
Weighted-average number of shares — diluted	7,061,537		7,104,172		7,908,023		7,102,822		7,767,859
Earnings (loss) per share — basic	\$ 0.68	\$	1.74	\$	2.21	\$	0.03	\$	(0.60)
Earnings (loss) per share — diluted	\$ 0.63	\$	1.61	\$	2.00	\$	0.03	\$	(0.60)

The Company has taken into consideration the disclosure required by the Participating Securities and the Two-Class Method under FASB Statement No. 128 (EITF No. 03-6).

# Accounting for stock-based compensation

As of March 31, 2006, the Company has one stock-based employee compensation plan, the Emergent BioSolutions Employee Stock Option Plan (the Emergent Plan), described more fully in Note 10 — Stockholders' Equity. Through December 31, 2005, the Company accounted for grants under the

Emergent Plan using the intrinsic value method in accordance with the provisions of Accounting Principles Board (APB), Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25) and has provided the pro forma disclosures of net income (loss) and net income (loss) per share in accordance with SFAS No. 123, Accounting for Stock-Based Compensation (SFAS No. 123) using the fair value method. Under APB No. 25, compensation expense is based on the difference, if any, on the date of the grant between the fair value of the Company's stock and the exercise price of the option and is recognized ratably over the vesting period of the option. The Company accounted for equity instruments issued to non-employees in accordance with SFAS No. 123 and EITF Issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services (EITF No. 96-18).

Effective January 1, 2006, the Company adopted the fair value provisions of SFAS No. 123 (revised 2004), *Share Based Payment* (SFAS No. 123(R)), using the modified prospective method. Under the fair value recognition provisions of SFAS No. 123(R), the Company recognizes stock-based compensation net of an estimated forfeiture rate.

Under the modified prospective method, compensation cost recognized in 2006 includes: (1) compensation cost for all share-based payments granted prior to but not yet vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and (2) compensation cost for all share-based payments granted subsequent to December 31, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). As a result of adopting SFAS No. 123(R) on January 1, 2006, the Company's loss before income taxes and net loss for the three month period ended March 31, 2006 is approximately \$96 higher than if it had continued to account for share-based compensation under APB No. 25. Both basic and diluted losses per share for the three months ended March 31, 2006 are \$0.02 lower than if the Company had continued to account for share-based compensation under APB No. 25. Results for prior periods have not been restated. Based on options granted to employees as of March 31, 2006, total compensation expense not yet recognized related to unvested options is approximately \$612. The Company expects to recognize that expense over a weighted average period of 3.5 years.

The Company has utilized the Black-Scholes valuation model for estimating the fair value of all stock options granted. No options were granted for the three months ended March 31, 2006. The fair value of each option is estimated on the date of grant. Set forth below are the weighted-average assumptions used in valuing the stock options granted and a discussion of the Company's methodology for developing each of the assumptions used:

	Yea	ır ended Dece	mber 31,	Three mor	nths ended March 31,
	2003	2004	2005	2005	2006
Expected dividend yield	0%	0%	0%	0%	_
Expected volatility	100%	52%	50%	50%	_
Risk-free interest rate	3.15%	2.93%	3.68%	3.44%	_
Expected average life of options (years)	2.7	2.5	3.4	3.5	_
Forfeiture rate	0%	0%	0%	0%	_

Expected dividend yield — The Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the
foreseeable future.

- Expected volatility Volatility is a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company uses the historical volatility of similar companies over the preceding three-year period to estimate expected volatility. Since 2003, the annual volatility of these similar companies has ranged from 18.4% to 29.4%, with an average of 23.4%.
- Risk-free interest rate This is the average U.S. Treasury rate with a term that most closely resembles the expected life of the option for the quarter in which the option was granted.
- Expected average life of options This is the period of time that the options granted are expected to remain outstanding. This estimate is based primarily on the employee position profile of option holders and the trading lock out periods that result from the employees access to stock price sensitive information.
- Forfeiture rate This is the estimated percentage of options granted that are expected to be forfeited or cancelled on an annual basis before becoming fully vested. The Company estimates the forfeiture rate based on past turnover data with further consideration given to the level of the employees to whom the options were granted.

Prior to the adoption of SFAS No. 123(R), the Company presented all tax benefits of deductions resulting from the exercise of stock options as operating cash flows in the statement of cash flows. SFAS No. 123(R) requires the cash flows resulting from the tax benefits resulting from tax deductions in excess of the compensation cost recognized for those options (excess tax benefits) to be classified as financing cash flows. There were no excess tax benefits classified as a financing cash inflow in the period ended March 31, 2008

The following table illustrates the effect on net income (loss) and net income (loss) per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation for the three years ended December 31, 2003, 2004 and 2005 and for the three months ended March 31, 2005 and 2006. The reported and pro forma net income (loss) and net income (loss) per share for the three month period ended March 31, 2006 are the same because stock-based compensation expense is recorded under the provisions of SFAS No. 123(R) for that period.

		Year end	ed Decer	nber 31,	TI		ths ended March 31,
	2003	2004		2005	200	5	2006
Net income, as reported	\$ 4,454	\$ 11,472	\$	15,784	\$ 224	1 \$	(4,636)
Add: Stock-based compensation in reported net income, net of taxes		2,801		_	_	-	96
Deduct: Total stock-based compensation expense determined under the fair value based method							
for all awards, net of taxes	(133)	(3,185)		(258)	(32	2)	(96)
Pro forma net income	\$ 4,321	\$ 11,088	\$	15,526	\$ 192	2 \$	(4,636)
Net income (loss) attributable to common stockholders per common share — basic	\$ 0.68	\$ 1.74	\$	2.21	\$ 0.03	3 \$	(0.60)
Net income (loss) attributable to common stockholders per common share — diluted	\$ 0.63	\$ 1.61	\$	2.00	\$ 0.03	3 \$	(0.60)
Pro forma net income (loss) attributable to common stockholders per common share — basic	\$ 0.66	\$ 1.69	\$	2.18	\$ 0.03	3 \$	(0.60)
Pro forma net income (loss) attributable to common stockholders per common share — diluted	\$ 0.61	\$ 1.56	\$	1.96	\$ 0.03	3 \$	(0.60)

#### Recent accounting pronouncements

In June 2005, the FASB issued Statement No. 154, Accounting Changes and Error Corrections — a replacement of APB Opinion No. 20 and FASB Statement No. 3 (SFAS No. 154). SFAS No. 154 requires retrospective application to prior periods' financial statements for all voluntary changes in accounting principle, unless impracticable. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. SFAS No. 154 will have no immediate impact on the Company's consolidated financial statements, though it would impact the Company's presentation of future voluntary accounting changes, should such changes occur.

In June 2005, the EITF reached consensus on EITF Issue No. 05-06, *Amortization Periods for Leasehold Improvements Purchased after Lease Inception or Acquired in a Business Combination*, (EITF No. 05-06). EITF No. 05-06 provides that leasehold improvements acquired in a business combination should be amortized over the lesser of the useful life of the assets or a term that includes renewals that are reasonably assured at the date of acquisition. The EITF also concluded that leasehold improvements placed in service significantly after and not contemplated at or near the beginning of the lease term should be amortized over the lesser of the useful life of the assets or a term that includes renewals that are reasonably assured at the date the leasehold improvements are purchased. EITF No. 05-06 is effective prospectively for leasehold improvements purchased or acquired in periods beginning after June 29, 2005. The Company does not believe that the adoption of this new standard will have a material impact on its financial position.

In November 2004, the FASB issued SFAS No. 151 — *Inventory Costs*, an amendment of Accounting Research Bulletin No. 43, Chapter 4 (SFAS No. 151). No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption did not have a material impact on the Company's financial position for the year ending December 31, 2005. The Company adopted this policy effective January, 2006.

In June 2006, the FASB also issued FASB Interpretation 48 — *Accounting for Uncertainty in Income Taxes*, an interpretation of FASB Statement No. 109, Accounting for Income Taxes (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 requires that the Company recognize in the financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. The Company is currently evaluating the impact of adopting FIN 48 on the financial statements.

#### Reclassifications

Certain prior period amounts have been reclassified to conform to the current year presentation.

#### 3. Acquisitions

#### Microscience Limited

On June 23, 2005, Emergent Europe, Inc., (EEI), a wholly-owned subsidiary of the Company incorporated in Delaware, completed the acquisition of Microscience pursuant to the terms and conditions of the Share Exchange Agreement dated June 23, 2005 (Exchange Agreement) by and among EEI and Microscience Holdings plc, a public limited liability company incorporated in England. At the closing date, the Company, through EEI, issued Microscience shareholders 1,264,051 shares of the Company's Class A

Common Stock in exchange for all of the outstanding stock of Microscience. Shares of Class A Common Stock of the Company were valued for financial statement purposes at \$21.36 per share. The Company's board of directors determined the fair value of the shares issued after taking into account the recommendation of management and the assessments provided by a third party valuation specialist. The results of operations for Microscience from June 23, 2005 are included in the accompanying consolidated statements of operations.

Total purchase consideration consisted of:

Fair value of common stock	\$ 27,001
Direct acquisition costs	<u>1,194</u>
Total purchase consideration	\$ 28,195

The acquisition was accounted for using the purchase method of accounting, as required by SFAS No. 141, *Business Combinations (SFAS No. 141)*. All of the acquired assets and assumed liabilities of Microscience were recorded at their estimated fair market values on the acquisition date, which approximated net book value.

The purchase price was allocated as follows:

Current assets	\$ 1,441
Property and equipment	863
Current liabilities	(684)
Net assets acquired	1,620
In-process research and development	26,575
Total purchase consideration	\$ 28,195

In connection with the transaction, the Company recorded a charge of \$26,575 for acquired research projects associated with products in development for which, at the acquisition date, technological feasibility had not been established and no alternative future use existed. Because Microscience was a development stage company that had not commenced its planned principal operations, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded.

Unaudited pro forma results of operations are as follows. The amounts are shown as if the acquisition had occurred on January 1, 2004 and 2005:

		Year ended	December 31,
	2004		2005
Pro forma revenue	\$ 83,571	\$	131,411
Pro forma net income (loss)	\$ (5,243)	\$	10,875
Pro forma earnings (loss) per share — basic	\$ (0.80)	\$	1.52
Pro forma earnings (loss) per share — diluted	\$ (0.80)	\$	1.38

This information is not necessarily indicative of the operational results that would have occurred if the acquisition had been consummated on the dates indicated nor is it necessarily indicative of future

operating results of the combined enterprise. The unaudited proforma combined condensed financial information does not reflect any adjustments to conform accounting practices or to reflect any cost savings or other synergies anticipated as a result of the acquisition.

### Antex Biologics Inc.

On May 31, 2003, BioPort completed the acquisition of assets from Antex, a subsidiary of Antex Pharma Inc. (Pharma and, together with Antex, Sellers), pursuant to the terms and conditions of the Asset Purchase Agreement dated April 10, 2003 (the Purchase Agreement) by and among BioPort and Sellers. Pursuant to the Purchase Agreement, BioPort acquired from Sellers all of the assets and assumed certain liabilities for cash of \$3,400 and transaction costs of \$394. The amount of consideration was determined on the basis of arm's length negotiations between BioPort and Sellers. The results of operations for Antex from May 31, 2003 are included in the accompanying consolidated statements of operations.

Total purchase consideration consisted of:

Purchase price	\$ 3,400
Direct acquisition costs	 394
Total purchase consideration	\$ 3,794

The acquisition was accounted for using the purchase method of accounting, as required by SFAS No. 141. All of the acquired assets and assumed liabilities of Antex were recorded at their estimated fair market value on the acquisition date, which approximated book value.

The purchase price was allocated as follows:

Current assets	\$ 279
Property and equipment	1,691
In-process research and development consideration	 1,824
Total purchase consideration	\$ 3,794

In connection with the transaction, the Company recorded a charge of \$1,824 for acquired research projects associated with products in development for which, at the acquisition date, technological feasibility had not been established and no alternative future use existed. Because Antex was a development stage company that had not commenced its planned principal operations, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded.

#### 4. Accounts receivable

Accounts receivable consist of the following:

			Dec	cember 31,	March 31,
	_	2004		2005	2006
Billed	\$	14,865	\$	1,112	\$ 780
Unbilled		3,772		1,418	1,690
Total	\$	18,637	\$	2,530	\$ 2,470

# 5. Inventories

Inventories consist of the following:

		De	ecember 31,	March 31,
	2004		2005	 2006
Raw materials and supplies	\$ 1,947	\$	2,229	\$ 2,245
Work-in-process	6,674		9,547	17,124
Finished goods	4,632		4,665	1,733
Inventories	\$ 13,253	\$	16,441	\$ 21,102

# 6. Property, plant and equipment

Property, plant and equipment consist of the following:

		December 31,	March 31,
	2004	2005	2006
Land and improvements	\$ 2,963	\$ 2,995	\$ 2,998
Buildings and leasehold improvements	13,496	14,143	14,340
Furniture and equipment	10,563	12,520	13,635
Internal-use software	3,818	3,937	4,208
Construction in-progress	2,086	6,197	7,467
	32,925	39,792	42,648
Less: Accumulated depreciation and amortization	(5,657	(9,147)	(10,121)
Property, plant and equipment, net	\$ 27,269	\$ 30,645	\$ 32,527

Depreciation and amortization expense was \$1,214, \$1,867 and \$3,549 for the years ended December 31, 2003, 2004 and 2005, respectively, and \$841 and \$968 for the three months ended March 31, 2005 and 2006, respectively. For the years ended December 31, 2003, 2004 and 2005, depreciation and amortization expense included approximately \$0, \$209 and \$1,257, respectively, related to internally developed software. For the three months ended March 31, 2005 and 2006, depreciation and amortization expense included approximately \$314 and \$314, respectively, related to internally developed software.

### 7. Other assets

In connection with the acquisition of Microscience in 2005 as further described in Note 3 — Acquisitions, the Company acquired a facility lease deposit totaling \$430. The deposit remains in effect as of March 31, 2006.

# 8. Other current liabilities

Other current liabilities consist of the following:

		Dec	ember 31,	March 31,
	2004		2005	2006
Contract costs	\$ 3	\$	445	\$ 1,072
Professional fees	1,462		1,390	1,089
Interest payable	71		146	168
Property taxes and other	357		628	417
	\$ 1,893	\$	2,609	\$ 2,746

# 9. Long-term debt and related party notes payable

The components of long term-debt and related party notes payable are as follows:

		De	cember 31, M
	2004	2005	2006
Term Loan dated October 2004; 6.625%, due October 2011	\$ 7,000	\$ 7,000	\$ 7,000
Forgivable Loan dated October 2004; 3.0%, due March 2013	2,500	2,500	2,500
ERP Term Loan; prime less 0.375%, due September 2007	2,280	1,760	1,600
Employee notes payable for stock redemption; 6%, due 2006	947	537	520
Other	140	113	98
Total notes payable	12,867	11,909	11,718
Less current portion of notes payable	(1,046)	(1,408)	(1,493)
Long-term portion of notes payable	\$ 11,821	\$ 10,502	\$ 10,225

In October 2004, the Company entered into a Secured Conditional Loan with the Maryland Economic Development Assistance Fund for \$2.5 million. The proceeds of the loan were used to reimburse the Company for eligible costs it incurred to purchase a building in Frederick, Maryland. The loan is secured by a \$1,250 letter of credit and a security interest in the building. The Company is required to pay an annual fee of 1% to maintain the letter of credit. The borrowing bears interest at 3% per annum, and the term of the loan ends March 31, 2013. The principal and related accrued interest may be forgiven if specified employment levels are achieved and maintained through December 2012, at least \$42,900 in project costs are expended prior to December 2009 and the Company occupies the building through December 2012. The loan requires the Company to employ at least 280 full-time employees at the Company's facilities in Frederick, Maryland as of December 31, 2009 and maintain at least 280 full-time employees through December 31, 2012. If as of December 31, 2009, 2010, 2011 or 2012 the Company employs fewer than 280 and more than 225 full-time employees at the Company's facilities in Frederick, Maryland, then the Company will be required to repay \$9 of principal plus accrued interest for each position not filled below the target level of 280 employees. If as of December 31, 2009, 2010, 2011 or 2012 the Company employs fewer than 225 full-time employees at the Company's facilities in Frederick, Maryland, then the Company will be required to repay the entire outstanding principal amount of the loan plus accrued interest. This loan is quaranteed by all of the subsidiaries of the Company.

In connection with the purchase of the building in Frederick, Maryland discussed above, the Company entered into a loan agreement for \$7,000 with a bank to finance the remaining portion of the purchase

price. The borrowing accrues interest at 6.625% per annum through October 2006. The Company is required to make interest only payments through that date. Beginning in November 2006, the Company will begin to make monthly payments of \$62, based upon a 15 year amortization schedule. In November 2009, the monthly payments will be adjusted based upon a 12 year amortization schedule. All unpaid principal and interest is due in full in October 2011. The Company is required to maintain certain financial and non-financial covenants' including a minimum tangible net worth of not less than \$5,000 and a debt coverage ratio of not less than 1.1 to 1. This loan is guaranteed by all of the subsidiaries of the Company.

During 2004, the Company implemented an Enterprise Resource Planning (ERP) system. The Company financed \$2,280 of the costs through the issuance of a term loan. The loan bears interest at prime less 0.375% (7.38% as of March 31, 2006) and is due in September 2007. Monthly payments escalate from \$40 to \$106 over the term. The ERP system provides security for the loan.

In 2004, the Company issued notes as consideration for the repurchase of outstanding class B common stock of BioPort. These notes were issued to various current and past employees who were issued equity as a result of earlier stock option exercises. Amounts are payable in annual installments, through 2006, and bear interest at 6%.

Scheduled principal repayments and maturities on long-term debt as of December 31, 2005 are as follows:

2006	\$ 1,408
2007	1,302
2008 2009	317
	2,838
2010 and thereafter	6,045
	\$ 11,910

#### Line of credit

On April 1, 2005, the Company, through BioPort, obtained a line of credit that provides for borrowings of up to \$10,000. The line of credit initially expired on May 1, 2006, but has been extended to October 1, 2006. The line of credit is secured by accounts receivable and bears interest at the prime rate less 0.375%. BioPort is subjected to certain covenants, including maintenance of specified equity levels on a quarterly basis. BioPort is currently in compliance with those covenants. There was no outstanding balance for this line of credit as of March 31, 2006.

# 10. Stockholders' equity

#### Preferred stock

The Company is authorized to issue up to 3,000,000 shares of preferred stock, \$0.01 par value per share (Preferred Stock). Any preferred stock issued may have dividend rates, voting rights, conversion privileges, redemption characteristics, and sinking fund requirements as approved by the Company's board of directors. As of March 31, 2006, no preferred stock has been issued.

### Common stock

The Company currently has two classes of common stock authorized and outstanding: class A common stock, \$0.01 par value per share (Class A Common Stock), and class B common stock, \$0.01 par value per share (Class B Common Stock). The Company is authorized to issue up to 10,000,000 shares of the Class A Common Stock and 2,000,000 shares of the Class B Common Stock. Holders of Class A Common Stock are entitled to one vote for each share of Class A Common Stock held on all matters as

may be provided by law. Holders of Class B Common Stock are not entitled to vote the shares of Class B Common Stock, except as otherwise required by

Holders of Class A Common Stock and Class B Common Stock are entitled to receive ratably dividends payable as and when declared by the Company's board of directors. On June 15, 2005, the Company's board of directors declared a special cash dividend to the holders of outstanding shares of Class A Common Stock and Class B Common Stock in an aggregate amount of \$5,400. The Company's board of directors declared this special dividend in order to distribute the net proceeds of a payment received as a result of the settlement of litigation initiated in 2002 by BioPort against Elan Pharmaceuticals, Inc., Athena Neurosciences, Inc. and Solstice Neurosciences, Inc. in an effort to clarify intellectual property rights, including the recovery of royalties and other costs and fees, to which BioPort believed it was entitled under a series of agreements regarding the development of botulinum toxin products. The Company paid the special cash dividend on July 13, 2005 to stockholders of record as of June 15, 2005. No regular dividends have been declared or paid.

Each share of Class B Common Stock will automatically convert into one share of Class A Common Stock immediately prior to the closing of the first underwritten sale of the Company's securities pursuant to an effective registration statement under the Securities Act of 1933, as amended. Following conversion, the Class B Common Stock will be eliminated and no further shares may be issued.

Prior to the formation of the Company, BioPort issued class A no-par voting common stock (BioPort Class A Common Stock) and class B no-par non-voting common stock (BioPort Class B Common Stock) to fund operations. BioPort, at its sole discretion, elected to redeem 25,000 shares of BioPort Class B Common Stock for \$200 during the year ended December 31, 2003.

In June 2004, in the Reorganization, the Company issued 6,487,950 shares of Class A Common Stock in exchange for 6,262,551 shares of BioPort Class A Common Stock and 225,396 shares of BioPort Class B Common Stock held by BioPharm, L.L.C. The Company repurchased and retired the remaining issued and outstanding shares of BioPort Class B Common Stock from former employees. Approximately 189,000 shares of BioPort were repurchased at \$7.89 per share and 9,800 shares of BioPort were repurchased at \$11.84 per share. Shares were repurchased for \$665 in cash and the issuance of \$947 in notes payable. See Note 9 — Long-term debt and related party notes payable, for additional information related to the former employee notes payable.

During the year ended December 31, 2005, the Company repurchased 38,984 shares of Class B Common Stock with an original weighted average cost of \$.76 per share, for \$337.

#### Stock options

As of March 31, 2006, the Company has one stock-based employee compensation plan, the Emergent Plan, under which the Company has granted options to purchase shares of Class B Common Stock.

Prior to the Reorganization, BioPort had a separate stock option plan (BioPort plan) under which options were granted to purchase BioPort Class B Common Stock. The exercise price and vesting schedule for options were determined by BioPort's board of directors, or a committee thereof, which was established to administer the BioPort plan options.

As of June 30, 2004, options to purchase 677,381 shares of BioPort Class B Common Stock were outstanding under the BioPort plan. Pursuant to the Reorganization, all outstanding BioPort plan options were assumed by Emergent and option holders were granted replacement stock options to purchase an equal number of shares of Class B Common Stock of Emergent. The exercise period for the replacement options was extended to June 30, 2007. The BioPort options were scheduled to expire on June 30, 2004.

In connection with the Reorganization, the Company recorded stock-based compensation expense as a result of the issuance of the stock options to purchase Class B Common Stock. Based upon the guidance

in APB No. 25, because the stock options granted for Class B Common Stock provided for an extended term over that of the cancelled BioPort plan options, a new measurement date was created and the Company recorded as stock-based compensation expense the excess of the intrinsic value of the modified options over the intrinsic value of the BioPort plan options when originally issued. This resulted in stock-based compensation expense of \$2,801, net of taxes, for the year ended December 31, 2004.

Outside of the reorganization, options to purchase an additional 112,000 shares of Class B common stock of Emergent under the Emergent Plan were granted during the year ended December 31, 2004.

The terms and conditions of stock options (including price, vesting schedule, term and number of shares) under the Emergent plan are determined by the Company's compensation committee, which administers the Emergent Plan.

Each option granted under the Emergent Plan becomes exercisable as specified in the relevant option agreement, and no option can be exercised after ten years from the date of grant, beginning one year after the date of grant.

The Emergent Plan has both incentive and non qualified stock option features. Under the plan, the Company may grant options totaling up to 1,250,000 shares of Class B Common Stock. The exercise price of each incentive option must be not less than 100% of the fair market value of the shares on the date of grant, except in the case of the incentive stock options being granted to a 10% stockholder, in which case the exercise price must be not less than 110% of the fair market value of the shares on the date of grant.

The following is a summary of stock option plan activity:

		Е	BioPort Plan		·	•	Emergent Plan
	Number of shares		Weighted average exercise price	Number of shares		Weighted average exercise price	Aggregate intrinsic value
Outstanding at December 31, 2002	803,242	\$	0.25	_	\$	_	_
Granted	103,500		13.05	_		_	_
Exercised	(152,676)		0.26	_		_	_
Forfeited	(77,235)		0.80	_		_	
Outstanding at December 31, 2003	676,831		2.17	_		_	_
Exercisable at December 31, 2003	458,696		0.58	_		_	
Granted	47,391		3.11	281,898		7.89	_
Exercised	(42,607)		0.27	_		_	_
Converted from BioPort to Emergent Plan	(677,381)		1.24	677,381		1.24	_
Forfeited	(4,234)		1.36	(57,784)		3.44	
Outstanding at December 31, 2004			_	901,495	\$	3.27	_
Exercisable at December 31, 2004			_	860,279		2.95	_
Granted			_	280,000		11.19	_
Exercised	_		_	(46,384)		0.91	_
Forfeited	_		_	(43,032)		7.57	_
Outstanding at December 31, 2005			_	1,092,079	\$	5.11	
Exercisable at December 31, 2005			_	852,481	\$	3.50	
Granted (unaudited)			_			_	
Exercised (unaudited)	_		_	(9,400)		0.25	_

		BioPort Plan					Emergent Plan
	Number of shares	Weighted average exercise price	Number of shares		Weighted average exercise price		Aggregate intrinsic value
Forfeited (unaudited)	_	_	(18,000)		4.70		_
Outstanding at March 31, 2006		_	1,064,679	\$	5.16	\$	20,612,185
Exercisable at March 31, 2006	_		836,081	\$	3.70	\$	17,407,206

The weighted average remaining contractual term of options outstanding and exercisable as of March 31, 2006 was 2.05 years and 1.40 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2003, 2004 and 2005 was \$7.97, \$2.73 and \$4.28, respectively. No options were granted during the three months ended March 31, 2006. The total intrinsic value of options exercised during the years ended December 31, 2003, 2004 and 2005 and during the three months ended March 31, 2006 was \$1,165, \$325 and \$563 and \$197, respectively.

At December 31, 2005, stock options outstanding and vested by exercise price were as follows:

_			Options	outstanding		Options exercisable			
Range of exercise prices	Number outstanding	Weighted average remaining contractual life (years)		Weighted average exercise price	Number exercisable		Weighted average exercise price		
\$ 0.25	342,879	1.50	\$	0.25	342,879	\$	0.25		
0.28	162,500	1.50		0.28	162,500		0.28		
4.43	16,100	1.50		4.43	16,100		4.43		
7.89	400,600	2.69		7.89	279,002		7.89		
10.06	135,000	4.96		10.06	48,000		10.06		
24.52	35,000	4.65		24.52	4,000		24.52		
	1,092,079	2.46	\$	5.11	852,481	\$	3.50		

The Company's board of directors considered the assessments of valuation specialists in determining the fair value of the Class B Common Stock underlying stock options granted during 2005 and as of December 31, 2003, 2004 and 2005. The assessments of these valuation specialists were based upon the application of the income and market approaches consistent with the practice aid issued by the American Institute of Certified Public Accountants entitled Valuation of Privately Held Company Equity Securities Issued as Compensation. Under the income approach, the valuation specialists used a discounted cash flow analysis based on projections of future cash flow to determine an estimated value. Under the market approach, the valuation specialists analyzed comparable public companies and developed an estimated value for the Class B Common Stock based on revenues, earnings and enterprise values. The values derived by each of these methods were adjusted for lack of voting rights, minority interest and lack of marketability of the Class B Common Stock.

Options granted from April 1, 2005 through March 31, 2006 are as follows:

Month of grant	Number of options granted	Weighted average exercise price	Weighted average fair value of common stock	Weighted average intrinsic value(1)
April 2005	25,000	\$ 7.89	\$ 7.89	_
May 2005	115,000	10.06	10.06	_
June 2005	30,000	14.88	14.88	_
July 2005	10,000	24.52	24.52	_
September 2005	5,000	24.52	24.52	_
November 2005	10,000	24.52	24.52	_

<sup>(1)</sup> Intrinsic value reflects the amount by which the value of the shares as of the grant date exceeds the exercise price of the options.

# 11. Income taxes

Significant components of the provision for income taxes attributable to operations consist of the following:

		Year ended	d December 31,		Three months led March 31,
	2003	2004	2005	2005	2006
Current					
Federal	\$ 1,717	\$ 5,547	\$ 16,093	\$ (20)	\$ (5,155)
State	_	_	200	<u>'—</u> '	100
Total current	1,717	5,547	16,293	(20)	(5,055)
Deferred					
Federal	(416)	(372)	(9,769)	(39)	301
State	(51)	(46)	(1,199)	135	32
Total deferred	(467)	(418)	(10,968)	96	333
Total provision (benefit) for income taxes	\$ 1,250	\$ 5,129	\$ 5,325	\$ 76	\$ (4,722)

The Company's net deferred tax asset consists of the following:

		Decem	ber 31,	March 31,
	 2004		2005	2006
Net operating loss carryforward	\$ 666	\$	2,242	\$ 2,901
Purchased in-process research and development	645		721	_
Stock compensation	1,457		1,696	1,689
Foreign deferrals	_		10,114	9,666
Other	883		3,198	5,080
Deferred tax asset	 3,651		17,971	19,336
Fixed assets	(1,859)		(1,387)	(1,238)
Other	(124)		(393)	(609)
Deferred tax liability	 (1,983)		(1,780)	(1,847)
Valuation allowance	 (666)		(4,221)	(6,154)
Net deferred tax asset	\$ 1,002	\$	11,970	\$ 11,335

Net operating loss carryforwards of approximately \$63 million will begin to expire in the year 2018 if unused. The use of the Company's net operating loss carryforwards may be restricted due to changes in Company ownership. The Company paid \$4,280, \$0, and \$17,985 in income taxes in 2003, 2004, and 2005, respectively. For the three months ended March 31, 2005 and March 31, 2006, the company paid \$500 and \$1,200 in income taxes, respectively.

The provision for income taxes differs from the amount of taxes determined by applying the U.S. federal statutory rate to loss before provision for income taxes as a result of the following:

				Three m	onths ended	
		Year ended [	December 31,	March 31,		
	2003	2004	2005	2005	2006	
Federal tax at statutory rates	\$ 1,996	\$ 5,863	\$ 7,388	\$ 105	\$ (3,181)	
State taxes, net of federal benefit	(230)	(714)	(2,329)	(160)	(27)	
Impact of foreign operations	` <del>_</del>	` —	(2,278)	` —	(1,467)	
Change in valuation allowance	187	479	3,558	237	1,915	
Tax credits	(441)	(492)	(474)	(120)	_	
Other differences	(255)	11	(214)	80	(1,993)	
Permanent differences	(7)	(18)	(326)	(66)	31	
Federal tax at statutory rates	\$ 1,250	\$ 5,129	\$ 5,325	\$ 76	\$ (4,722)	

The Company is the subject of an ongoing federal income tax audit for the tax year ended December 31, 2004. The potential financial statement impact of the audit cannot be estimated at this time. Accordingly, the Company has not recorded any reserve relating to this audit.

### 12. 401(k) savings plan

During 1999, the Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers substantially all employees. Under the 401(k) Plan, employees may make elective salary deferrals. The Company provides for matching of qualified deferrals up to 50% of the first 6% of the employee's salary. During the years ended December 31, 2003, 2004 and 2005, the Company made matching contributions of approximately \$182, \$452 and \$520, respectively. During the three months ended March 31, 2005 and 2006, the Company made matching contributions of approximately \$107 and \$128, respectively.

### 13. Commitments and settlement gains

#### Leases

The Company leases laboratory and office facilities, office equipment and vehicles under various operating lease agreements. The Company leases office and laboratory space in Gaithersburg, Maryland under a noncancelable operating lease that contains a 3% annual escalation and expires on November 30, 2008. For the years ended December 31, 2003, 2004 and 2005 and the three months ended March 31, 2005 and 2006, total rent expense was \$890, \$1,334 and \$2,526 and \$482 and \$721, respectively. During 2005 and the three months ended March 31, 2006, the Company leased a building in Frederick, Maryland under a lease with an option to purchase. In April 2006, the Company exercised this option and purchased the building.

Future minimum payments under operating lease obligations as of December 31, 2005 are as follows:

2006	\$ 1,6	689
2007	1,2	249
2008	1,1	188
2009		56
Total minimum lease payments	\$ 4,1	182

#### Vendor contracts

In accordance with a recently signed research contract, the Company is committed to spending a minimum of \$200 in research and development activities by September 2007. To date, the Company has incurred minimal expenditures under this contract.

#### Litigation

In June 2002, BioPort initiated a lawsuit against Élan Pharmaceuticals and related entities in an effort to clarify intellectual property rights, including the recovery of royalties and other costs and fees, to which BioPort believed it was entitled under a set of 1991 agreements and to clarify intellectual property rights associated with those agreements. BioPort sought damages, injunctive relief and declaratory relief. On June 27, 2005, the Company obtained a settlement pursuant to which Élan and related entities agreed to pay the Company \$10,000. Payment of such settlement was received by the Company in July 2005. The agreement also clarified the parties' intellectual property rights. Upon receipt of the settlement from Élan Pharmaceuticals and related entities, the Company distributed a net settlement amount (total proceeds from the settlement less reserves for applicable federal and state income taxes, legal expenses related to the suit and other miscellaneous expenses) of \$5,400 to all Company stockholders of record as of June 15, 2005.

In 1998, the Company recorded obligations related to the initial purchase agreement of Michigan Biologic Products Institute of \$10,119. During 2004, the Company settled its entire remaining purchase obligations to the State of Michigan for \$6,300, resulting in a gain of \$3,819, which is reflected as a component of operations on the accompanying statement of operations.

From time to time, the Company is involved in product liability claims and other litigation considered normal in the nature of its business. The Company does not believe that any such proceedings would have a material, adverse effect on the results of its operations.

### 14. Related party transactions

Simba LLC, a Maryland based limited liability company 100% owned by the Company's Chief Executive Officer and his wife, provides chartered air transportation. Simba offers its services to the Company on a discount from Simba's normal commercial rate. For the years ended December 31, 2003, 2004 and 2005

and the three months ended March 31, 2005 and 2006, the Company paid approximately \$0, \$32 and \$34 and \$0 and \$13, respectively, for transportation on an as needed basis for business purposes. As of May 2006, this arrangement has been terminated.

The Company has entered into marketing and sales contracts with family members of the Chief Executive Officer to market and sell BioThrax in certain international territories if certain conditions are met. A consulting arrangement with the Chief Executive Officer's sister requires a payment of 4% of net sales, not to exceed \$2.00 per dose, under the agreement. A marketing arrangement with an entity affiliated with the Chief Executive Officer and his family requires a payment of 40% of gross sales in countries in the Middle East and North Africa, except Israel. No royalty payments under these agreements have been triggered for the years ended December 31, 2003, 2004 and 2005 and the three months ended March 31, 2005 and 2006. Some of these arrangements have terminated.

For the years ended December 31, 2003, 2004 and 2005 and the three months ended March 31, 2005 and 2006, the Company paid approximately \$116, \$494 and \$794, and \$188 and \$170, respectively, in consulting and lease and transportation arrangements with various persons or entities affiliated with the Chief Executive Officer or two members of the board of directors. Accounts payable for these services was \$15 and \$22 as of December 31, 2004 and 2005, respectively. Accounts payable for these services as of March 31, 2006 was \$46. Some of these arrangements have terminated.

### 15. Segment information

The Company operates in two business segments: biodefense and commercial. In the biodefense business, the Company develops and commercializes products for use against biological agents that are potential weapons of bioterrorism. Revenues in this segment relate to the Company's FDA approved product, BioThrax. In the commercial business, the Company develops products for use against infectious diseases with significant unmet or underserved medical needs. Revenues in this segment consist primarily of development and grant revenues received under collaboration and grant arrangements. The all other segment relates to the general operating costs of the business and includes costs of the centralized services departments, which are not allocated to the other segments. The assets in this segment consist of cash and fixed assets.

				Repo	rtable	segments	
	 Biodefense Commercial		ommercial	All other			Total
Year Ended December 31, 2005							
External revenue	\$ 128,219	\$	2,469	\$	_	\$	130,688
Research and development	10,327		6,962		1,092		18,381
Interest revenue	_		_		485		485
Interest expense	_		_		(767)		(767)
Depreciation and amortization	2,911		411		226		3,548
Net income (loss)	58,632		(40,325)		2,523		15,784
Assets	40,502		5,489		54,341		100,332
Expenditures for long-lived assets	\$ 3,286	\$	3,052	\$	194	\$	6,532

				Reportable segme			
	 Biodefense Commercial		All other			Total	
Year Ended December 31, 2004							
External revenue	\$ 82,585	\$	909	\$	_	\$	83,494
Research and development	6,279		1,136		2,702		10,117
Interest revenue	_		_		65		65
Interest expense	_		_		(241)		(241)
Depreciation and amortization	1,685		169		10		1,867
Net income (loss)	21,776		(5,428)		(4,876)		11,472
Assets	51,626		3,491		13,939		69,056
Expenditures for long-lived assets	\$ 8,320	\$	668	\$	8,084	\$	17,072
Year Ended December 31, 2003							
External revenue	\$ 55,536	\$	233	\$	_	\$	55,769
Research and development	4,352		477		1,498		6,327
Interest revenue	_		_		100		100
Interest expense	_		_		(293)		(293)
Depreciation and amortization	1,153		61		· -		
Net income (loss)	6,106		(1,459)		(193)		(4,454)
Asset	28,266		2,462		7,119		37,847
Expenditures for long-lived assets	\$ 4,020	\$	103	\$	_	\$	4,123

The accounting policies of the segments are the same as those described in the summary of significant accounting policies in Note 2 — Summary of significant accounting policies. There are no inter-segment transactions.

### 16. Quarterly financial data (unaudited)

Quarterly financial information for the years ended December 31, 2005 and 2004 is presented in the following tables:

					Three months ended
		March 31	June 30	September 30	December 31
Fiscal year 2005				000000000000000000000000000000000000000	2000
Revenues	\$	15,261	\$ 44,058	\$ 27.581	\$ 43,788
Income (loss) from operations	,	425	3,699	 4,498	 12,714
Net income (loss)		225	2,616	3,410	9,533
Net income (loss) per share, basic		0.03	0.40	0.44	1.23
Net income (loss) per share, diluted		0.03	0.37	0.40	1.11
Fiscal year 2004					
Revenues	\$	20,360	\$ 13,044	\$ 22,241	\$ 27,848
Income (loss) from operations		3,758	(7,632)	8,063	12,582
Net income (loss)		2,582	(5,271)	5,580	8,560
Net income (loss) per share, basic		0.39	(0.79)	0.86	1.32
Net income (loss) per share, diluted		0.37	(0.79)	0.79	1.22

### 17. Subsequent events

On April 25, 2006, the Company completed the acquisition of a 150,000 square foot facility in Frederick, Maryland. This facility was previously under a lease which contained an option to purchase the facility. The Company paid \$1,250 in cash and financed the balance with cash and with a bank loan in the amount of \$8,500. This loan requires principal and interest payments from May 2006 through April 2011. The interest rate is a floating rate based on LIBOR plus 3%, equaling 8.1% on the closing date.

On May 4, 2006, HHS modified its supply contract with the Company to purchase an additional 5 million doses of BioThrax to be delivered between May 4, 2006 and May 5, 2007. The value of this contract modification is \$120,000 and will be reflected in the financial results upon acceptance of shipment by HHS, which is expected to occur during 2006 and 2007.

In May 2006, the Company entered into a collaboration agreement with Sanofi Pasteur relating to the development and commercialization of its meningitis B vaccine candidate and received a \$3,800 upfront license fee. This agreement also provides for a series of milestone payments upon the achievement of specified development and commercialization objectives, payments for development work under the collaboration and royalties on net sales of this product.

In July 2006, the Company executed a lease agreement for approximately 23,000 square feet of office space in Rockville, Maryland. Annual rent begins at \$600 per year and escalates at approximately 3% per year over the ten year term of the lease. The Company has a five year renewal option at the end of the initial term.



**JPMorgan** 

# **Cowen and Company**

**HSBC** 

, 2006

Until , 2006 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

#### PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

### Item 13. Other Expenses of Issuance and Distribution

The following table indicates the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by the Registrant. All amounts are estimated except the Securities and Exchange Commission registration fee and the National Association of Securities Dealers Inc. filing fee.

	Ar	mount
Securities and Exchange Commission registration fee	\$	9,229
National Association of Securities Dealers Inc. fee		9,125
Nasdaq Stock Market listing fee		*
Accountants' fees and expenses		*
Legal fees and expenses		*
Blue Sky fees and expenses		*
Transfer Agent's fees and expenses		*
Printing and engraving expenses		*
Miscellaneous		*
Total Expenses	\$	*

<sup>\*</sup> To be filed by amendment.

#### Item 14. Indemnification of Directors and Officers

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. The Registrant's restated certificate of incorporation provides that no director of the Registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as director, notwithstanding any provision of law imposing such liability, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability

but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnify for such expenses which the Court of Chancery or such other court shall deem proper.

The Registrant's restated certificate of incorporation provides that the Registrant will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Registrant) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of the Registrant, or is or was serving, or has agreed to serve, at the Registrant's request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, including any employee benefit plan, (all such persons being referred to hereafter as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Registrant, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The Registrant's restated certificate of incorporation provides that the Registrant will indemnify any Indemnitee who was or is a party to or threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Registrant to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer of the Registrant, or is or was serving, or has agreed to serve, at our request, as a director, officer, partner, employee or trustee of or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, (including any employee benefit plan), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Registrant, except that no indemnification shall be made with respect to any claim, issue or matter as to which Indemnitee shall have been adjudged to be liable to the Registrant, unless, and only to the extent, that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnity for such expense (including attorney's fees) which the Court of Chancery of Delaware or the court in which such action or suit was brought shall deem proper. Notwithstanding the foregoing, to the extent that an Indemnitee has been successful, on the merits or otherwise, in defense of any action, suit or proceeding, Indemnitee shall be indemnified by the Registrant against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

The Registrant has entered into agreements to indemnify the Registrant's directors and executive officers. These agreements, among other things, provide that the Registrant will indemnify the director or executive officer to the fullest extent permitted by law for claims arising in his or her capacity as a director, officer, manager, employee, agent or representative of the Registrant. The indemnification agreements also establish the procedures that will apply in the event a director or officer makes a claim for indemnification.

The Registrant maintains a general liability insurance policy which covers certain liabilities of directors and officers of the Registrant arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement the Registrant enters into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, the Registrant, the Registrant's directors, the Registrants officers and persons who control the Registrant with the meaning of the Securities Act of 1933, as amended, against certain liabilities.

#### Item 15. Recent Sales of Unregistered Securities

Set forth below is information regarding shares of class A and class B common stock issued, and options granted, by the Registrant for class B common stock within the past three years. Also included is the consideration, if any, received by the Registrant for such shares, options and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

#### (a) Issuance of Securities

- (1) On June 30, 2004, the Registrant issued an aggregate of 6,487,950 shares of class A common stock to stockholders of BioPort Corporation in exchange for an equal number of outstanding shares of common stock of BioPort. All other issued and outstanding shares of common stock of BioPort were repurchased and retired. As a result of this exchange, BioPort became a wholly owned subsidiary of the Registrant.
- (2) On June 23, 2005, the Registrant issued an aggregate of 1,264,051 shares of class A common stock to Microscience Investments Limited, formerly Microscience Holdings plc, in connection with the acquisition of all the outstanding shares of capital stock of Microscience Limited.

No underwriters were involved in the foregoing issuances of securities. The securities described in this section (a) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All stockholders to whom shares of class A common stock described above were issued represented to the Registrant in connection with such issuances that they were acquiring the shares for their own account, for investment, and not with a view to the sale or distribution, and that they had sufficient knowledge and experience in financial matters so as to be capable of evaluating the merits and risks of purchasing the shares. The stockholders received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

#### (b) Stock Option Grants

Since inception, we have issued options to certain employees and directors to purchase an aggregate of 1,271,229 shares of our class B common stock as of July 31, 2006. As of July 31, 2006, options to purchase 68,999 shares of class B common stock had been exercised, options to purchase 139,451 shares of class B common stock had been forfeited and options to purchase 1,062,779 shares of class B common stock remained outstanding at a weighted average exercise price of \$6.38 per share.

The issuance of stock options and the common stock issuable upon the exercise of such options as described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Section 3(b) of the Securities Act and Rule 701 promulgated thereunder. All recipients either received adequate information about the Registrant or had access, through employment or other relationships, to such information

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of common stock described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

#### Item 16. Exhibits

The exhibits to the registration statement are listed in the Exhibit Index to this registration statement and are incorporated by reference herein.

#### Item 17. Undertakings

- (a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.
- (b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.
- (c) The undersigned registrant hereby undertakes that:
  - (i) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of the registration statement as of the time it was declared effective.
  - (ii) For purposes of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

#### SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Gaithersburg, State of Maryland on the 14th day of August 2006.

EMERGENT BIOSOLUTIONS INC.

By: /s/ Fuad El-Hibri

Fuad El-Hibri

President, Chief Executive Officer and Chairman of the Board of Directors

### POWER OF ATTORNEY

We, the undersigned directors and officers of Emergent BioSolutions Inc., hereby severally constitute and appoint Fuad El-Hibri, Daniel J. Abdun-Nabi and R. Don Elsey, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and any subsequent registration statements pursuant to Rule 462 of the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that each of said attorney-in-fact or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	<u>T</u> itle	Date
/s/ Fuad El-Hibri Fuad El-Hibri	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	August 14, 2006
/s/ R. Don Elsey R. Don Elsey	Vice President Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	August 14, 2006
/s/ Joe M. Allbaugh Joe M. Allbaugh	Director	August 14, 2006
/s/ Zsolt Harsanyi Zsolt Harsanyi, Ph.D	Director	August 14, 2006
/s/ Jerome M. Hauer Jerome M. Hauer	Director	August 14, 2006
	W.5	

<u>Signature</u>	Title	Date
/s/ Shahzad Malik Shahzad Malik, M.D.	Director	August 14, 2006
/s/ Ronald B. Richard Ronald B. Richard	Director	August 14, 2006
/s/ Louis Sullivan Louis Sullivan, M.D.	Director	August 14, 2006
	II-6	

# EXHIBIT INDEX

Exhibit Number	Description
1.1*	Form of Underwriting Agreement
3.1	Amended and Restated Certificate of Incorporation of the Registrant
3.2*	Form of Restated Certificate of Incorporation of the Registrant to be effective upon completion of the offering
3.3	Bylaws of the Registrant
3.4*	Form of Amended and Restated By-laws of the Registrant to be effective upon the completion of the offering
4.1*	Specimen certificate evidencing shares of common stock
4.2	Registration Rights Agreement, dated June 23, 2005, between the Registrant and Microscience Investments Limited, formerly Microscience Holdings plc
4.3*	Registration Rights Agreement, dated , 2006, among the Registrant and the entities listed on Schedule 1 thereto
4.4*	Rights Agreement, dated , 2006, between the Registrant and the Rights Agent
5.1*	Opinion of Wilmer Cutler Pickering Hale and Dorr LLP
9.1	Voting and Right of First Refusal Agreement, dated October 21, 2005 between the William J. Crowe, Jr. Revocable Living Trust and Fuad El-Hibri
9.2	Voting Agreement, dated June 30, 2004, between BioPharm, L.L.C. and Michigan Biologics Products, Inc.
9.3	Voting Agreement, dated June 30, 2004, between BioPharm, L.L.C. and Biologika, L.L.C.
9.4	Voting Agreement, dated June 30, 2004, by and among the stockholders named therein
9.5*	Voting Agreement, dated , 2006, between BioPharm, L.L.C. and Microscience Investments Limited, formerly Microscience Holdings plc
10.1 10.2	Employee Stock Option Plan, as amended and restated
10.2	Form of Director Stock Option Agreement 2006 Stock Incentive Plan
10.3	Form of Incentive Flan Form of Incentive Stock Option Agreement under 2006 Stock Incentive Plan
10.5*	Form of Nonstatutory Stock Option Agreement under 2006 Stock Incentive Plan
10.6*	Severance Plan and Termination Protection Program
10.7	Form of Indemnity Agreement
10.8†	Contract No. W9113M-04-D-0002, dated January 3, 2004, between BioPort Corporation and U.S. Army Space and Missile Defense Command, as amended
10.9†	Contract No. 200-2005-11811, dated May 5, 2005, between BioPort Corporation and Department of Health and Human Services, Office of
10.51	Public Health Emergency Preparedness and Office of Research and Development Coordination, as amended
10.10 <del>†</del>	Filling Services Agreement, dated March 18, 2002, between BioPort Corporation and Hollister-Stier Laboratories LLC, as amended
10.11†	BT Vaccine License Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency
10.12†	BT Vaccine Development Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency
10.13 <del>†</del>	rBot Vaccine License Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency
10.14 <del>†</del>	rBot Vaccine Development Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency
10.15 <del>†</del>	Exclusive Distribution Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency

Exhibit Number	<u>D</u> escription
10.16†	Investment Agreement relating to Microscience Holdings plc, dated March 18, 2005, among the Wellcome Trust, Microscience Investments Limited, formerly Microscience Holdings plc, and Emergent Product Development UK Limited, formerly Microscience Limited, as amended
10.17	Standard Employment Contract, dated December 22, 2005, between Emergent Product Development UK Limited, formerly Emergent Europe Limited, and Steven N. Chatfield
10.18	Letter Agreement, dated July 11, 2006, between the Registrant and Steven N. Chatfield
10.19†	Consulting Services Agreement, dated March 1, 2006, between the Registrant and The Hauer Group
10.20	Amended and Restated Marketing Agreement, dated January 1, 2000, between BioPort Corporation and Intergen N.V.
10.21	Lease, dated December 1, 1998, between ARE-QRS, Corp. and Antex Biologics Inc., as amended
10.22	Lease (540 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire), dated December 13, 1996, between Slough Properties Limited and Azur Environmental Limited, as assigned to Emergent Product Development UK Limited, formerly Microscience Limited
10.23	Lease (545 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire), dated December 13, 1996, between Slough Properties Limited and Azur Environmental Limited, as assigned to Emergent Product Development UK Limited, formerly Microscience Limited
10.24*	Lease Agreement, dated June 27, 2006, between Brandywine Research LLC and the Registrant
10.25	Amended and Restated Loan Agreement, dated July 29, 2005, between BioPort Corporation and Fifth Third Bank, as amended
10.26	Loan and Security Agreement, dated October 14, 2004, among the Registrant, Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., Antex Biologics Inc., BioPort Corporation and Mercantile Potomac Bank
10.27	Promissory Note, dated October 14, 2004, from Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., to Mercantile Potomac Bank
10.28	Loan Agreement, dated October 15, 2004, between Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., and the Department of Business and Economic Development
10.29	Deed of Trust Note, dated October 14, 2004, between Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., and the Department of Business and Economic Development
10.30+	Term Note, dated August 10, 2004, from BioPort Corporation to Fifth Third Bank
10.31	Loan Agreement, dated April 25, 2006, among the Registrant, Emergent Frederick LLC and HSBC Realty Credit Corporation (USA)
10.32	Bond Purchase Agreement, dated March 31, 2005, between the County Commissioners of Frederick County, Emergent Commercial Operations Frederick Inc., formerly Emergent Biologics Inc., and Mercantile Potomac Bank
10.33†	License and Co-development Agreement, dated May 6, 2006, between Emergent Product Development UK Limited, formerly Emergent Europe Limited, and Sanofi Pasteur, S.A.
10.34*	Product Supply Agreement, dated June 12, 2006, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics, Inc.
10.35*	Election of Fuad El-Hibri to Participate in the Severance Plan and Termination Protection Program
10.36*	Services Agreement, dated August 1, 2006, between East West Resources Corporation and the Registrant
10.37*	Director Compensation Program
21.1*	Subsidiaries of the Registrant
23.1	Consent of Independent Registered Public Accounting Firm
23.2*	Consent of Wilmer Cutler Pickering Hale and Dorr LLP (included in Exhibit 5.1)
24.1	Powers of Attorney (included on signature page)
	Lby amandment

<sup>\*</sup> To be filed by amendment.

† Confidential treatment requested. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

### AMENDED AND RESTATED

### CERTIFICATE OF INCORPORATION

OF

# EMERGENT BIOSOLUTIONS INC.

\*\*\*\*\*

(Incorporated December 19, 2003)

- I, the undersigned, sole incorporator of Emergent BioSolutions Inc. (the "Corporation"), hereby certify:
- 1. That the current name of the Corporation and the name under which the Corporation was originally incorporated is Emergent BioSolutions Inc.
- 2. That the original Certificate of Incorporation of the Corporation (the "Original Certificate of Incorporation") was filed with the Secretary of State of the State of Delaware on December 19, 1003.
- 3. That the Original Certificate of Incorporation of the Corporation is hereby amended and restated and integrated into the single instrument which is hereinafter set forth, and which is captioned the Amended and Restated Certificate of Incorporation of Emergent BioSolutions Inc.
- 4. That the Corporation has not received any payment for any of its stock and that the amendment and restatement set forth herein has been duly approved by the sole incorporator of the Corporation in accordance with Section 241 of the General Corporation Law of the State of Delaware and has been duly adopted in accordance with Sections 241 and 245 of the General Corporation Law of the State of Delaware.
  - 5. That the sole incorporator of the Corporation executed a written consent wherein, it was:

RESOLVED, that the Certificate of Incorporation of the Corporation be amended and restated in its entirety as follows:

- 1. Name. The name of the corporation (the "Corporation") is: Emergent BioSolutions Inc.
- 2. Registered Office. The address of its registered office in the State of Delaware is 2711 Centerville Road, Suite 400, City of Wilmington 19808, County of New Castle; and the

name of the registered agent of the Corporation in the State of Delaware at such address is Corporation Service Company.

3. <u>Purpose</u>. The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

#### 4. Capital Stock

- a. <u>Total Number of Shares of Stock.</u> The total number of shares of capital stock of all classes that the Corporation shall have the authority to issue is Fifteen Million (15,000,000) shares. The authorized capital stock is divided into (i) Three Million (3,000,000) shares of preferred stock, with par value of \$0.01 per share (the "Preferred Stock"); (ii) Ten Million (10,000,000) shares of class A voting common stock (the "Class A Common Stock"), with par value of \$0.01 per share; and (iii) Two Million (2,000,000) shares of class B non-voting common stock (the "Class B Common Stock"), with par value of \$0.01 per share.
- b. <u>Preferred Stock</u>. The board of directors of the Corporation is authorized, subject to limitations prescribed by law and the provisions of this Article 4, to provide for the issuance of the shares of Preferred Stock in series, and by filing a certificate pursuant to the applicable law of the State of Delaware, to establish from time to time the number of shares to be included in each such series, and to fix the voting rights, designations, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof.

The authority of the board of directors with respect to each series shall include, but not be limited to, determination of the following:

- (i) The number of shares constituting that series and the distinctive designation of that series;
- (ii) The dividend rate on the shares of that series, whether dividends shall be cumulative, and, if so, from which date or dates, and the relative rights of priority, if any, of payment of dividends on shares of that series;
- (iii) Whether that series shall have voting rights, in addition to the voting rights provided by law, and, if so, the terms of such voting rights;
- (iv) Whether that series shall have conversion privileges, and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as the board of directors shall determine;
- (v) Whether or not the shares of that series shall be redeemable, and, if so, the terms and conditions of such redemption, including the date or dates upon or after which they shall be redeemable, and the amount per share

- payable in case of redemption, which amount may vary under different conditions and at different redemption dates;
- (vi) Whether that series shall have a sinking fund for the redemption or purchase of shares of that series, and, if so, the terms and amount of such sinking fund;
- (vii) The rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the corporation, and the relative rights of priority, if any, of payment of shares of that series; and
- (viii) Any other relative rights, preferences and limitations of that series.
- c. <u>Class A Common Stock</u>. Each holder of Class A Common Stock shall be entitled to one (1) vote for each share of Class A Common Stock held of record by such holder on all matters, and in such manner, as may be provided by law. Each holder of Class A Common Stock shall be entitled to notice of any stockholders' meeting in accordance with the by-laws of the Corporation.
- d. <u>Class B Common Stock</u>. No holder of shares of Class B Common Stock shall be entitled to vote any of the shares of Class B Common Stock so held, nor shall such holders be entitled to notice of any meeting of the Corporation's stockholders convened in accordance with the Corporation's bylaws, except as otherwise required by law.

### e. Conversion.

- (i) Class A Common Stock is not convertible. Each share of Class B Common Stock shall automatically convert into one (1) share of Class A Common Stock, without any action by the Corporation or further action by the holder thereof, immediately prior to the closing of the first underwritten sale of the Corporation's securities pursuant to an effective registration statement under the Securities Act of 1933, as amended.
- (ii) In the case of a conversion as a result of the occurrence of the event described in Section 4(e)(i) above, such conversion shall be deemed effective at the time immediately prior to the closing of the underwritten sale of securities pursuant to such registration statement.
- (iii) Following a conversion pursuant to this Section 4(e), the Class B Common Stock shall be eliminated, and the Corporation shall from time to time take such appropriate action as may be necessary to prohibit the reissuance thereof in accordance with the General Corporation Law of the State of Delaware.

- (iv) The Corporation shall reserve and at all times keep available out of its authorized but unissued shares of Class A Common Stock a sufficient number of shares of Class A Common Stock to satisfy the conversion requirements contemplated by this Section 4(e).
- f. <u>Dividend Rights</u>. Holders of Class A Common Stock and Class B Common Stock shall be entitled to receive ratably dividends payable in cash, in stock or otherwise, as and when declared by the board of directors of the Corporation out of assets legally available therefor, subject to any preferential rights of any outstanding Preferred Stock.
- g. Other Rights. Upon liquidation, dissolution or winding up of the Corporation, after payment in full of the amounts required to be paid to the holders of any outstanding Preferred Stock, all holders of Class A Common Stock and Class B Common Stock are entitled to receive ratably any assets available for distribution to holders thereof after the payment of all debts and other liabilities of the Corporation.
- 5. Amendment of Bylaws; Election of Directors. The board of directors of the Corporation is authorized to make, alter or repeal the bylaws of the Corporation. Election of directors need not be by written ballot
- 6. Exculpation. No director shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director notwithstanding any provision of law imposing such liability; provided, however, that to the extent provided by applicable law, this provision shall not eliminate the liability of a director (i) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the General Corporation Law of Delaware, or (iv) for any transaction from which the director derived an improper personal benefit. No amendment to or repeal of this provision shall apply to or have any effect on the liability or alleged liability of any director for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal.
- 7. (a) Actions, Suits and Proceedings Other Than by or in the Right of the Corporation. The Corporation shall indemnify each person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation), by reason of the fact that the person is or was, or has agreed to become, a director or officer of trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) (all such persons being referred to hereafter as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person or the person's appeal therefrom, if the person acted in good faith and in a manner the person reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's

conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his conduct was unlawful. Notwithstanding anything to the contrary in this Article, except as set forth in Section (f) below, the Corporation shall not indemnify an Indemnitee seeking indemnification in connection with a proceeding (or part thereof) initiated by the Indemnitee unless the initiation thereof was approved by the board of directors of the Corporation.

(b) Actions or Suits by or in the Right of the Corporation. The Corporation shall indemnify any Indemnitee who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that the person is or was, or has agreed to become, a director or officer of the Corporation, or is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and amounts paid in settlement actually and reasonably incurred by the person or on the person's behalf in connection with such action, suit or proceeding and any appeal therefrom, if he acted in good faith and in a manner he reasonably believed to be in, or not opposed to, the best interests of the Corporation, except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Corporation unless and only to the extent that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses (including attorneys' fees) which the Court of Chancery of Delaware or such other court shall deem proper.

(c) <u>Indemnification for Expenses of Successful Party.</u> Notwithstanding the other provisions of this Article, to the extent that an Indemnitee has been successful, on the merits or otherwise, in defense of any action, suit or proceeding referred to in Sections (a) and (b) of this Article, or in defense of any claim, issue or matter therein, or on appeal from any such action, suit or proceeding, he shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by him or on his behalf in connection therewith. Without limiting the foregoing, if any action, suit or proceeding is disposed of, on the merits or otherwise (including a disposition without prejudice), without (i) the disposition being adverse to the Indemnitee, (ii) an adjudication that the Indemnitee was liable to the Corporation, (iii) a plea of guilty or *nolo contendere* by the Indemnitee, (iv) an adjudication that the Indemnitee did not act in good faith and in a manner he reasonably believed to be in, or not opposed to, the best interests of the Corporation, and (v) with respect to any criminal proceeding, an adjudication that the Indemnitee had reasonable cause to believe his conduct was unlawful, the Indemnitee shall be considered for the purpose hereof to have been wholly successful with respect thereto.

- (d) Notification and Defense of Claim. As a condition precedent to an Indemnitee's right to be indemnified, the Indemnitee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or investigation involving the Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to the Indemnitee. After notice from the Corporation to the Indemnitee of its election so to assume such defense, the Corporation shall not be liable to the Indemnitee for any legal or other expenses subsequently incurred by the Indemnitee in connection with such claim, other than as provided below in this Section (d). The Indemnitee shall have the right to employ the Indemnitee's own counsel in connection with such claim, but the fees and expenses of such assumption of the defense thereof shall be at the expense of the Indemnitee unless (i) the employment of counsel by the Indemnitee has been authorized by the Corporation, (ii) counsel to the Indemnitee shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Corporation and the Indemnitee in the conduct of the defense of such action, or (iii) the Corporation shall not in fact have employed counsel to assume the defense of such action, in each of which cases the fees and expenses of counsel for the Indemnitee shall be at the expense of the Corporation, except as otherwise expressly provided by this Article. The Corporation shall not be entitled, without the consent of the Indemnitee, to assume the defense of any claim brought by or in the right of the Corporation or as to which counsel for the Indemnitee shall have reasonably made the conclusion provided for in clause (ii) above.
- (e) Advance of Expenses. Subject to the provisions of Section (f) below, in the event that the Corporation does not assume the defense pursuant to Section (d) of this Article of any action, suit, proceeding or investigation of which the Corporation receives notice under this Article, any expenses (including attorneys' fees) incurred by an Indemnitee in defending a civil or criminal action, suit proceeding or investigation or any appeal therefrom shall be paid by the Corporation in advance of the final disposition of such matter, provided, however, that the payment of such expenses incurred by an Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of the Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined that the Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article. Such undertaking may be accepted without reference to the financial ability of such person to make such repayment.
- (f) <u>Procedure for Indemnification</u>. In order to obtain indemnification or advancement of expenses pursuant to Section (a), (b), (c) or (e) of this Article, the Indemnitee shall submit to the Corporation a written request, including in such request such documentation and information as is reasonably available to the Indemnitee and is reasonably necessary to determine whether and to what extent the Indemnitee is entitled to indemnification or advancement of expenses. Any such indemnification or advancement of expenses shall be made promptly, and in any event within sixty (60) days after receipt by the Corporation of the written request of the Indemnitee, unless with respect to requests under Section (a), (b) or (e) the Corporation determines, by clear and convincing evidence, within such sixty (60) day period that

the Indemnitee did not meet the applicable standard of conduct set forth in Section (a) or (b), as the case may be. Such determination shall be made in each instance by (i) a majority vote of a quorum of the directors of the Corporation consisting of persons who are not at that time parties of the action, suit or proceeding in question ("disinterested directors"), (ii) if no such quorum is obtainable, a majority vote of a committee of two or more disinterested directors, (iii) a majority vote of a quorum of the outstanding shares of stock of all classes entitled to vote for directors, voting as a single class, which quorum shall consist of stockholders who are not at that time parties to the action, suit or proceeding in question, (iv) independent legal counsel (who may be regular legal counsel to the Corporation), or (v) a court of competent jurisdiction.

- (g) Remedies. The right to indemnification or advances as granted by this Article shall be enforceable by the Indemnitee in any court of competent jurisdiction if the Corporation denies such request, in whole or in part, or if no disposition thereof is made within the sixty (60) day period referred to above in Section (f). Unless otherwise provided by law, the burden of proving that the Indemnitee is not entitled to indemnification or advancement of expenses under this Article shall be on the Corporation. Neither the failure of the Corporation to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because Indemnitee has not met the applicable standard of conduct, nor an actual determination by the Corporation pursuant to Section (f) that the Indemnitee has not met such applicable standard of conduct. The Indemnitee's expenses (including attorneys' fees) incurred in connection with successfully establishing his right to indemnification, in whole or in part, in any such proceeding shall also be indemnified by the Corporation.
- (h) <u>Subsequent Amendment</u>. No amendment, termination or repeal of this Article or of the relevant provisions of the General Corporation Law of the State of Delaware or any other applicable laws shall affect or diminish in any way the rights of any Indemnitee to indemnification under the provisions hereof with respect to any action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal.
- (i) Other Rights. The indemnification and advancement of expenses provided by this Article shall not be deemed exclusive of any other rights to which an Indemnitee seeking indemnification or advancement of expenses may be entitled under any law (common or statutory), agreement or vote of stockholders or disinterested directors or otherwise, both as to action in his official capacity and as to action in any other capacity while holding office for the Corporation, and shall continue as to an Indemnitee who has ceased to be a director or officer, and shall inure to the benefit of the estate, heirs, executors and administrators of the Indemnitee. Nothing contained in this Article shall be deemed to prohibit, and the Corporation is specifically authorized to enter into, agreements with officers and directors providing indemnification rights and procedures different from those set forth in this Article. In addition, the Corporation may, to the extent authorized from time to time by its board of directors, grant indemnification rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in this Article.

- (j) <u>Partial Indemnification</u>. If an Indemnitee is entitled under any provision of this Article to indemnification by the Corporation for some or a portion of the expenses (including attorneys' fees), judgments, fines or amounts paid in settlement actually and reasonably incurred by him or on his behalf in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify the Indemnitee for the portion of such expenses (including attorneys' fees), judgments, fines or amounts paid in settlement to which the Indemnitee is entitled.
- (k) <u>Insurance</u>. The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) against any expense, liability, or loss incurred by him in any such capacity, or arising out of his status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the General Corporation Law of the State of Delaware.
- (1) Merger or Consolidation. If the Corporation is merged into or consolidated with another corporation and the Corporation is not the surviving corporation, the surviving corporation shall assume the obligations of the Corporation under this Article with respect to any action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the date of such merger or consolidation.
- (m) Savings Clause. If this Article or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Indemnitee as to any expenses (including attorneys' fee), judgments, fines and amounts paid in settlement in connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including an action by or in the right of the Corporation, to the fullest extent permitted by an applicable portion of this Article that shall not have been invalidated and to the fullest extent permitted by applicable law.
- (n) <u>Definitions</u>. Terms used herein and defined in Section 145(h) and Section 145(i) of the General Corporation Law of the State of Delaware shall have the respective meanings assigned to such terms in such Section 145(h) and Section 145(i).
- (o) <u>Subsequent Legislation</u>. If the General Corporation Law of the State of Delaware is amended after adoption of this Article to expand further the indemnification permitted to Indemnitees, then the Corporation shall indemnify such persons to the fullest extent permitted by the General Corporation Law of the State of Delaware, as so amended.
- 8. <u>Creditor and/or Stockholder Compromise or Arrangement</u>. Whenever a compromise or arrangement is proposed between the Corporation and its creditors or any class of them and/or between the Corporation and its stockholders or any class of them, any court of equitable jurisdiction within the State of Delaware may, on the application in a summary way of the Corporation or of any creditor or stockholder thereof or on the application of any receiver or

receivers appointed for the Corporation under §291 of Title 8 of the Delaware Code or on the application of trustees in dissolution or of any receiver or receivers appointed for the Corporation under §279 of Title 8 of the Delaware Code order a meeting of the creditors or class of creditors, and/or of the stockholders or the Corporation, as the case may be, to be summoned in such manner as the said court directs. If a majority in number representing three fourths in value of the creditors or class of creditors, and/or of the stockholders or class of stockholders or the Corporation, as the case may be, agree to any compromise or arrangement and to any reorganization of the Corporation as consequence of such compromise or arrangement, the said compromise or arrangement and the said reorganization shall, if sanctioned by the court to which the said application has been made, be binding on all the creditors or class of creditors, and/or on all the stockholders, of the Corporation, as the case may be, and also on the Corporation.

- 9. The Board of Directors of the Corporation, when evaluating any offer of another party (a) to make a tender or exchange offer for any equity security of the Corporation or (b) to effect a business combination, shall, in connection with the exercise of its judgment in determining what is in the best interests of the Corporation as a whole, be authorized to give due consideration to any such factors as the Board of Directors determines to be relevant, including, without limitation:
  - (i) the interests of the Corporation's stockholders, including the possibility that these interests might be best served by the continued independence of the Corporation;
  - (ii) whether the proposed transaction might violate federal or state laws;
- (iii) not only the consideration being offered in the proposed transaction, in relation to the then current market price for the outstanding capital stock of the Corporation, but also to the market price for the capital stock of the Corporation over a period of years, the estimated price that might be achieved in a negotiated sale of the Corporation as a whole or in part or through orderly liquidation, the premiums over market price for the securities of other corporations in similar transactions, current political, economic and other factors bearing on securities prices and the Corporation's financial condition and future prospects; and
- (iv) the social, legal and economic effects upon employees, suppliers, customers, creditors and others having similar relationships with the Corporation, upon the communities in which the Corporation conducts its business and upon the economy of the state, region and nation.

In connection with any such evaluation, the Board of Directors is authorized to conduct such investigations and engage in such legal proceedings as the Board of Directors may determine.

[signature page follows]

IN WITNESS WHEREOF, EMERGENT BIoSOLUTIONS INC. has caused this Amended and Restated Certificate of Incorporation to be signed by Louis A. Bevilacqua, its Sole Incorporator, this 30th day of January, 2004.

EMERGENT BIOSOLUTIONS INC.

By: /s/ Louis A. Bevilacqua

Louis A. Bevilacqua Incorporator

Address of Incorporator: Louis A. Bevilacqua Thelen Reid & Priest LLP 701 Pennsylvania Ave., N.W. Suite 800 Washington, D.C. 20004-2608

# BYLAWS

OF

# EMERGENT BIOSOLUTIONS INC.

(the "Corporation")

Adopted on January 30, 2004; and Amended on June 15, 2005

# ARTICLE I

## OFFICES

SECTION 1.01. Registered Office. The registered office of the Corporation in the State of Delaware shall be in the City of Wilmington, County of New Castle.

SECTION 1.02. Other Offices. The Corporation may also have offices at such other places both within and without the State of Delaware as the Board of Directors may from time to time determine or the business of the Corporation may require.

### ARTICLE II

# MEETINGS OF STOCKHOLDERS

SECTION 2.01. Place of Meeting. All meetings of stockholders for the election of directors shall be held at such place, either within or without the State of Delaware, as shall be designated from time to time by the Board of Directors and stated in the notice of the meeting.

SECTION 2.02. Annual Meeting. The annual meeting of stockholders shall be held at such date and time as shall be designated from time to time by the Board of Directors and stated in the notice of the meeting.

SECTION 2.03. Voting List. The officer who has charge of the stock ledger of the Corporation shall prepare and make, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least 10 days prior to the meeting, either at a place within the city where the meeting is to be held, which place shall be specified in the notice, or if not so specified, at the place where the meeting is to be held. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present.

SECTION 2.04. Special Meeting. Special meetings of the stockholders, for any purpose or purposes, unless otherwise proscribed by statute or by the Certificate of Incorporation, may be called by the Chairman of the Board or by the Chief Executive Officer of the Corporation or by the Board of Directors or by written order of a majority of the directors or shall be called by the Chief Executive Officer or the Secretary at the request in writing of stockholders holding not less than 20% of the entire capital stock of the Corporation issued and outstanding and entitled to vote. Such request shall state the purposes of the proposed meeting. The Chairman of the Board or the Chief Executive Officer of the Corporation or directors so calling, or the stockholders so requesting, any such meeting shall fix the time and any place, either within or without the State of Delaware, as the place for holding such meeting.

SECTION 2.05. Notice of Meeting. Written notice of the annual, and each special meeting of stockholders, stating the time, place, and purpose or purposes thereof, shall be given to each stockholder entitled to vote thereat, not less than 10 nor more than 60 days before the meeting.

SECTION 2.06. Quorum. The holders of a majority of the shares of the Corporation's capital stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, shall constitute a quorum at any meeting of stockholders for the transaction of business, except as otherwise provided by statute or by the Certificate of Incorporation. Notwithstanding the other provisions of the Certificate of Incorporation or these bylaws, the holders of a majority of the shares of the Corporation's capital stock entitled to vote thereat, present in person or represented by proxy at the meeting, whether or not a quorum is present, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present or represented. If the adjournment is for more than 30 days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. At such adjourned meeting at which a quorum shall be present or represented, any business may be transacted which might have been transacted at the meeting as originally notified.

SECTION 2.07. *Voting*. When a quorum is present at any meeting of the stockholders, the vote of the holders of a majority of the shares of the Corporation's capital stock having voting power present in person or represented by proxy shall decide any question brought before such meeting, unless the question is one upon which, by express provision of the statutes, of the Certificate of Incorporation or of these bylaws, a different vote is required, in which case such express provision shall govern and control the decision of such question. Every stockholder having the right to vote shall be entitled to vote in person, or by proxy appointed by an instrument in writing subscribed by such stockholder and filed with the Secretary of the Corporation before, or at the time of, the meeting. A vote may be cast either orally or in writing.

SECTION 2.08. Consent of Stockholders. Whenever the vote of stockholders at a meeting thereof is required or permitted to be taken for or in connection with any corporate action by any provision of the statutes, the meeting and vote of stockholders may be dispensed with if all the stockholders who would have been entitled to vote upon the action if such meeting were held shall consent in writing to such corporate action being taken; or on the written consent of the holders of shares of the Corporation's capital stock having not less than the minimum percentage of the vote required by

statute for the proposed corporate action, and provided that prompt notice must be given to all stockholders of the taking of corporate action without a meeting and by less than unanimous written consent

SECTION 2.09. Voting of Stock of Certain Holders. Shares of the Corporation's capital stock standing in the name of another corporation, domestic or foreign, may be voted by such officer, agent, or proxy as the bylaws of such corporation may prescribe, or in the absence of such provision, as the Board of Directors of such corporation may determine. Shares standing in the name of a deceased person may be voted by the executor or administrator of such deceased person, either in person or by proxy. Shares standing in the name of a guardian, conservator, or trustee may be voted by such fiduciary, either in person or by proxy, but no such fiduciary shall be entitled to vote shares held in such fiduciary capacity without a transfer of such shares into the name of such fiduciary. Shares standing in the name of a receiver may be voted by such receiver. A stockholder whose shares are pledged shall be entitled to vote such shares, unless in the transfer by the pledger on the books of the Corporation, he has expressly empowered the pledgee to vote thereon, in which case only the pledgee, or his proxy, may represent the stock and vote thereon.

SECTION 2.10. Treasury Stock. The Corporation shall not vote, directly or indirectly, shares of its own capital stock owned by it; and such shares shall not be counted in determining the total number of outstanding shares of the Corporation's capital stock.

SECTION 2.11. Fixing Record Date. The Board of Directors may fix in advance a date, which shall not be more than 60 days nor less than 10 days preceding the date of any meeting of stockholders, nor more than 60 days preceding the date for payment of any dividend or distribution, or the date for the allotment of rights, or the date when any change, or conversion or exchange of capital stock shall go into effect, or a date in connection with obtaining a consent, as a record date for the determination of the stockholders entitled to notice of, and to vote at, any such meeting and any adjournment thereof, or entitled to receive payment of any such dividend or distribution, or to receive any such allotment of rights, or to exercise the rights in respect of any such change, conversion or exchange of capital stock, or to give such consent, and in such case such stockholders and only such stockholders as shall be stockholders of record on the date so fixed, shall be entitled to such notice of, and to vote at, any such meeting and any adjournment thereof, or to receive payment of such dividend or distribution, or to receive such allotment of rights, or to give such consent, as the case may be, notwithstanding any transfer of any stock on the books of the Corporation after any such record date fixed as aforesaid.

SECTION 2.12. Organization. Meetings of stockholders shall be presided over by the Chairman of the Board, or in his absence by the Chief Executive officer, or in his absence by the President, or in the absence of the foregoing persons by a chairman designated by the Board of Directors, or in the absence of such designation by a chairman chosen at the meeting. The Secretary shall act as secretary of the meeting, but in his absence the chairman of the meeting may appoint any person to act as secretary of the meeting.

SECTION 2.13. Telephonic Meetings Permitted. Unless otherwise restricted by the Certificate of Incorporation or these bylaws, any stockholder may participate in a meeting of the

stockholders by means of a conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting pursuant to this bylaw shall constitute presence in person at such meeting.

SECTION 2.14. *Proxies.* A stockholder entitled to vote at a meeting of stockholders or entitled to express consent or dissent without a meeting may authorize other persons to act for him or her by a proxy. A proxy shall be signed by the stockholder or his or her authorized agent or other representative. A proxy is not valid after the expiration of 3 years from its date unless otherwise provided in the proxy.

# ARTICLE III

#### BOARD OF DIRECTORS

SECTION 3.01. *Powers*. The business and affairs of the Corporation shall be managed by its Board of Directors, which may exercise all such powers of the Corporation and do all such lawful acts and things as are not by statute or by the Certificate of Incorporation or by these bylaws directed or required to be exercised or done by the stockholders.

SECTION 3.02. *Number, Election and Term.* The number of directors that shall constitute the whole Board of Directors shall be not less than 3 nor more than 9 as established by a majority of the holders of the Corporation's Class A voting common stock from time to time. The directors shall be elected at the annual meeting of stockholders, except as provided in Section 3.03 or in the Certificate of Incorporation, and each director elected shall hold office until his death, resignation, retirement, disqualification, removal from office, or until his successor shall be elected and shall qualify. Directors need not be residents of Delaware or stockholders of the Corporation.

SECTION 3.03. Vacancies, Additional Directors, and Removal From Office. If any vacancy occurs in the Board of Directors caused by death, resignation, retirement, disqualification, or removal from office of any director, or otherwise, or if any new directorship is created by an increase in the authorized number of directors, a majority of the directors then in office, though less than a quorum, or a sole remaining director, may choose a successor or fill the newly created directorship; and a director so chosen shall hold office until the next applicable election and until his successor shall be duly elected and shall qualify, unless sooner displaced. Any director may be removed either for or without cause at any special meeting of stockholders duly called and held for such purpose.

SECTION 3.04. Regular Meeting. A regular meeting of the Board of Directors shall be held each year, without other notice than this bylaw, at the place of, and immediately following, the annual meeting of stockholders, or within 10 days of such time if such later time is deemed advisable; and other regular meetings of the Board of Directors shall be held each year, at such time and place as the Board of Directors may provide, by resolution, either within or without the State of Delaware, without other notice than such resolution. At his discretion, the Chairman may invite other persons as appropriate to attend any regular meeting of the Board of Directors.

SECTION 3.05. Special Meeting. A special meeting of the Board of Directors may be called by the Chairman of the Board of Directors or by the Chief Executive Officer of the Corporation and shall be called by the Secretary on the written request of any two directors. The Chairman or Chief Executive Officer so calling, or the directors so requesting, any such meeting shall fix the time and any place, either within or without the State of Delaware, as the place for holding such meeting. At his discretion, the Chairman may invite other persons as appropriate to attend any special meeting of the Board of Directors.

SECTION 3.06. Notice of Special Meeting. Written notice of special meetings of the Board of Directors shall be given to each director at least 48 hours prior to the time of such meeting. Any director may waive notice of any meeting. The attendance of a director at any meeting shall constitute a waiver of notice of such meeting, except where a director attends a meeting for the purpose of objecting to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any special meeting of the Board of Directors need be specified in the notice or waiver of notice of such meeting, except that notice shall be given of any proposed amendment to the bylaws if it is to be adopted at any special meeting or with respect to any other matter where notice is required by statute.

SECTION 3.07. *Quorum.* A majority of the Board of Directors shall constitute a quorum for the transaction of business at any meeting of the Board of Directors, and the act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board of Directors, except as may be otherwise specifically provided by statute, by the Certificate of Incorporation or by these bylaws. If a quorum shall not be present at any meeting of the Board of Directors, the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present.

SECTION 3.08. Action Without Meeting. Unless otherwise restricted by the Certificate of Incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board of Directors, or of any committee thereof as provided in Article IV of these bylaws, may be taken without a meeting, if a written consent thereto is signed by all members of the Board of Directors or of such committee, as the case may be, and such written consent is filed with the minutes of proceedings of the Board of Directors or such committee.

SECTION 3.09. Compensation. Directors, as such, shall not be entitled to any stated salary for their services unless voted by the stockholders or the Board of Directors; but by resolution of the Board of Directors, a fixed sum and expenses of attendance, if any, may be allowed for attendance at each regular or special meeting of the Board of Directors or any meeting of a committee of directors. No provision of these bylaws shall be construed to preclude any director from serving the Corporation in any other capacity and receiving compensation therefor.

SECTION 3.10. Telephonic Meetings Permitted. Unless otherwise restricted by the Certificate of Incorporation or these bylaws, any member of the Board of Directors, or any committee designated by the Board, may participate in a meeting of the Board or of such committee, as the case may be, by means of a conference telephone or similar communications equipment by means of which

all persons participating in the meeting can hear each other, and participation in a meeting pursuant to this bylaw shall constitute presence in person at such meeting.

SECTION 3.11. Organization. Meetings of the Board of Directors shall be presided over by the Chairman of the Board, or in his absence by the Chief Executive Officer, or in his absence by the President, or in their absence by a chairman chosen at the meeting. The Secretary shall act as secretary of the meeting, but in his absence the chairman of the meeting may appoint any person to act as secretary of the meeting.

SECTION 3.12. Dissent. A director who is present at a meeting of the Board of Directors, or of any committee thereof, of which he or she is a member, at which action on a corporate matter is taken is presumed to have concurred in that action unless his or her dissent is entered in the minutes of the meeting or unless he or she files his or her written dissent to the action with the person acting as secretary of the meeting before or promptly after the adjournment thereof. The right to dissent shall not apply to a director who voted in favor of the action. A director who is absent from a meeting of the Board of Directors, or of any committee thereof, of which he or she is a member, at which any such action is taken is presumed to have concurred in the action unless he or she files a dissent with the Secretary of the Corporation within a reasonable time after he or she has knowledge of the action.

### ARTICLE IV

#### COMMITTEES OF DIRECTORS

SECTION 4.01. Designation of Committees. The Board of Directors may, by resolution passed by a majority of the whole Board of Directors, designate one or more committees, each such committee to consist of one or more of the directors of the Corporation or such other persons as the Board of Directors deems appropriate. The Board of Directors may designate one or more directors or other persons as alternate members of any committee, who may replace any absent or disqualified member at any meeting of such committee; provided, however, that in the absence or disqualification of any member of such committee or committees, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the Board of Directors or other person to act at the meeting in the place of any such absent or disqualified member. Without limiting the generality of the foregoing, the Board of Directors may appoint one or more directors of the Corporation or such other persons as the Board of Directors deems appropriate to serve on an Executive Committee to perform such functions and to have such authority as determined by the Board of Directors. The Executive Committee may, in turn, appoint one or more directors or such other persons as the Executive Committee deems appropriate to serve on a Compensation Committee to determine appropriate levels of compensation and other benefits for employees of the Corporation.

SECTION 4.02. *Authority*. Subject to the Delaware General Corporation Law, each committee shall have and may exercise such of the powers conferred or authorized by the Board of Directors or of any duly authorized committee thereof, as the case may be.

SECTION 4.03. Minutes. Each committee of directors shall keep regular minutes of its proceedings and report the same to the Board of Directors when required.

SECTION 4.04. Compensation. Members of special or standing committees may be allowed compensation for attending committee meetings if, and in such amounts or such manner as, the Board of Directors shall so determine.

SECTION 4.05. Committee Rules. Unless the Board of Directors otherwise provides, each committee designated by the Board may adopt, amend and repeal rules for the conduct of its business. In the absence of a provision by the Board or a provision in the rules of such committee to the contrary, a majority of members of such committee shall constitute a quorum for the transaction of business, the vote of a majority of such members present at a meeting shall be the act of such committee, and in other respects each committee shall conduct its business pursuant to Article III of these bylaws.

# ARTICLE V

#### NOTICE

SECTION 5.01. *Methods of Giving Notice*. Whenever under the provisions of applicable statutes, the Certificate of Incorporation or these bylaws, notice is required to be given to any director, member of any committee, or stockholder, such notice shall be in writing and delivered personally or mailed to such director, member, or stockholder; provided that in the case of a director or a member of any committee such notice may be given orally or by telephone or facsimile. If mailed, notice to a director, member of a committee, or stockholder shall be deemed to be given when deposited in the United States mail first class in a sealed envelope, with postage thereon prepaid, addressed, in the case of a stockholder, to the stockholder at the stockholder's address as it appears on the records of the Corporation or, in the case of a director or a member of a committee, to such person at his business address.

SECTION 5.02. Written Waiver. Whenever any notice is required to be given under the provisions of an applicable statute, the Certificate of Incorporation, or these bylaws, a waiver thereof in writing, signed by the person or persons entitled to said notice, whether before or after the time stated therein, shall be deemed equivalent thereto and attendance at a meeting shall be deemed to be waiver of notice unless attendance is for the purpose of contesting notice.

# ARTICLE VI

#### OFFICERS

SECTION 6.01. Officers. The officers of the Corporation shall be a Chairman of the Board, a Chief Executive Officer, a President, a Chief Operating Officer, a Chief Financial Officer, a Treasurer and a Secretary. The Corporation may also have, at the discretion of the Board of Directors, one or more Executive Vice Presidents, Senior Vice Presidents or Vice Presidents, one or more Assistant Treasurers or Secretaries and such other officers and assistant officers, as may be elected from time to time by the Board of Directors. The Board of Directors may delegate to any officer or committee the

power to appoint any subordinate officers, committees or agents; to specify their duties and authority; and to determine their compensation. Any two or more offices may be held by the same person. No officer shall execute, acknowledge, verify or countersign any instrument on behalf of the Corporation in more than one capacity, if such instrument is required by law, by these bylaws or by any act of the Corporation to be executed, acknowledged, verified, or countersigned by two or more officers. The Chairman of the Board shall be elected from among the directors. With the foregoing exceptions, none of the other officers need be a director, and none of the officers need be a stockholder of the Corporation.

SECTION 6.02. *Election and Term of Office*. The officers of the Corporation shall be elected annually by the Board of Directors at its first meeting held after the annual meeting of stockholders or as soon thereafter as conveniently possible. Each officer shall hold office until his successor shall have been chosen and shall have qualified or until his death or the effective date of his resignation or removal, or until he shall cease to be a director in the case of the Chairman.

SECTION 6.03. Removal and Resignation. Any officer or agent elected or appointed by the Board of Directors may be removed without cause by the affirmative vote of a majority of the Board of Directors whenever, in its judgment, the best interests of the Corporation shall be served thereby, but such removal shall be without prejudice to the contractual rights, if any, of the person so removed. Any officer may resign at any time by giving written notice to the Corporation. Any such resignation shall take effect at the date of the receipt of such notice or at any later time specified therein, and unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

SECTION 6.04. Vacancies. Any vacancy occurring in any office of the Corporation by death, resignation, removal, or otherwise, may be filled by the Board of Directors for the unexpired portion of the term.

SECTION 6.05. Salaries. The salaries of all officers and agents of the Corporation shall be fixed by the Board of Directors or pursuant to its direction; and no officer shall be prevented from receiving such salary by reason of his also being a director.

SECTION 6.06. Bonds. The Board of Directors may require any and all of the officers to have bonds in favor of the Corporation, with sufficient surety or sureties, and in such amounts as the Board of Directors may fix, conditioned for the faithful performance of the duties of their respective offices.

SECTION 6.07. Chairman of the Board. The Chairman of the Board, subject to the direction of the Board of Directors, shall perform such executive, supervisory and management functions and duties as from time to time may be assigned to him or her by the Board of Directors. The Chairman of the Board shall preside at all meetings of the stockholders of the Corporation and all meetings of the Board of Directors.

SECTION 6.08. Chief Executive Officer. The Chief Executive Officer shall have general and active management of the business of the Corporation and shall see that all orders and resolutions of the Board of Directors are carried into effect. The Chief Executive Officer shall preside at

all meetings of the stockholders of the Corporation and all meetings of the Board of Directors in the absence of the Chairman of the Board. The Chief Executive Officer shall execute all authorized conveyances, contracts, or other obligations in the name of the Corporation except where required by law to be otherwise signed and executed and except where the signing and execution shall be expressly delegated by the Board of Directors to some other officer or agent of the Corporation or reserved to the Board of Directors or any committee thereof.

SECTION 6.09. President. The President shall be subject to the direction of the Board of Directors and the Chief Executive Officer, and shall have general charge of the business, affairs and property of the Corporation and general supervision over its other officers and agents. The President shall see that the officers carry all other orders and resolutions of the Board of Directors into effect. The President shall execute all authorized conveyances, contracts, or other obligations in the name of the Corporation except where required by law to be otherwise signed and executed and except where the signing and execution shall be expressly delegated by the Board of Directors to some other officer or agent of the Corporation or reserved to the Board of Directors or any committee thereof. The President shall preside at all meetings of the stockholders of the Corporation and all meetings of the Board of Directors in the absence of the Chairman of the Board and the Chief Executive Officer.

SECTION 6.10. Chief Operating Officer. The Chief Operating Officer shall be subject to the direction of the Chief Executive Officer, President and the Board of Directors and shall have day-to-day managerial responsibility for the operation of the Corporation.

SECTION 6.11. Chief Financial Officer. The Chief Financial Officer shall be subject to the direction of the Chief Executive Officer, President and the Board of Directors and shall have day-to-day managerial responsibility for the finances of the Corporation.

SECTION 6.12. Executive Vice Presidents, Senior Vice Presidents or Vice Presidents. Any Vice Presidents in the order designated by the Board of Directors or, lacking such a designation, by the President, shall, in the absence or disability of the President, perform the duties and exercise the powers of the President and shall perform such other duties as the Board of Directors shall prescribe.

SECTION 6.13. Treasurer. The Treasurer shall have the custody of the corporate funds, securities, or similar valuable effects, and evidences of indebtedness, shall keep full and accurate accounts of receipts and disbursements in books belonging to the Corporation and shall deposit all moneys and other valuable effects in the name and to the credit of the Corporation in such depositories as from time to time may be designated by the Board of Directors. The Treasurer shall disburse the funds of the Corporation in such manner as may be ordered by the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President from time to time and shall render the Chairman of the Board and the Board of Directors, at meetings of the Board of Directors or whenever any of them may so require, an account of all transactions and of the financial condition of the Corporation.

SECTION 6.14. Secretary. At every meeting of the Board of Directors, the Secretary shall record the minutes of the proceedings of the Board and shall provide copies of such minutes to all of the Directors and to such officers as the Chairman of the Board may direct. The

Secretary shall give (or cause to be given) notice of all meetings of the Board of Directors and shall perform such other duties as from time to time may be proscribed by the Board of Directors, the Chairman of the Board, the Chief Executive Officer, the President or the Treasurer. The Secretary shall have custody of the seal of the Corporation and shall have authority to affix the same to any instrument requiring it, and to attest the seal by his or her signature. The Board of Directors may give general authority to officers other than the Secretary to affix the seal of the Corporation and to attest the affixing thereof by their signature.

SECTION 6.15. Assistant Secretary. At the request of the Secretary, or in his or her absence or disability, any Assistant Secretary, shall perform all the duties of the Secretary and be subject to all the restrictions upon the Secretary. The Assistant Secretary shall perform such other duties as may be assigned to him or her by the Board of Directors or the Secretary.

SECTION 6.16. Assistant Treasurer. At the request of the Treasurer, or in his or her absence or disability, any Assistant Treasurer, shall perform all the duties of the Treasurer and be subject to all the restrictions upon the Treasurer. The Assistant Treasurer shall perform such other duties as may be assigned to him or her by the Board of Directors or the Treasurer.

### ARTICLE VII

#### CONTRACTS, CHECKS AND DEPOSITS

SECTION 7.01. Contracts. Subject to the provisions of Section 6.01, the Board of Directors may authorize any officer, officers, agent, or agents, to enter into any contract or execute and deliver any instrument in the name of and on behalf of the Corporation, and such authority may be general or confined to specific instances.

SECTION 7.02. Checks. All checks, demands, drafts, or other orders for the payment of money, notes, or other evidences of indebtedness issued in the name of the Corporation, shall be signed by such officer or officers or such agent or agents of the Corporation, and in such manner, as shall be determined by the Board of Directors.

SECTION 7.03. Deposits. All funds of the Corporation not otherwise employed shall be deposited from time to time to the credit of the Corporation in such banks, trust companies, or other depositories as the Board of Directors may authorize.

#### ARTICLE VIII

### CERTIFICATES OF STOCK

SECTION 8.01. *Issuance*. Each stockholder of this Corporation shall be entitled to a certificate or certificates showing the number of shares of capital stock registered in his name on the books of the Corporation. The certificates shall be in such form as may be determined by the Board of Directors, shall be issued in numerical order and shall be entered in the books of the Corporation as they are issued. They shall exhibit the holder's name and number of shares and shall be signed by the

Chairman of the Board or the Chief Executive Officer or the President or a Vice President and by the Treasurer or an Assistant Treasurer, or Secretary or an Assistant Secretary. If such certificate is manually signed by one officer or manually countersigned by a transfer agent or by a registrar, any other signature on the certificate may be a facsimile. If the Corporation shall be authorized to issue more than one class of stock or more than one series of any class, the designations, preferences, and relative participating, optional, or other special rights of each class of stock or series thereof and the qualifications, limitations, or restrictions of such preferences and rights shall be set forth in full or summarized on the face or back of the certificate which the Corporation shall issue to represent such class of stock; provided that, except as otherwise provided by statute, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate which the Corporation shall issue to represent such class or series of stock, a statement that the Corporation will furnish to each stockholder who so requests the designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations, or restrictions of such preferences and rights. Certificates shall not be issued representing fractional shares of stock

SECTION 8.02. Lost Certificates. The Board of Directors may direct a new certificate or certificates to be issued in place of any certificates theretofore issued by the Corporation alleged to have been lost, stolen, or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen or destroyed. When authorizing such issue of a new certificates, the Board of Directors may, in its discretion and as a condition precedent to the issuance thereof, require such owner to give the Corporation a bond in such sum as it may direct as indemnity against any claim that may be made against the Corporation with respect to the certificate or certificates alleged to have been lost, stolen, or destroyed.

SECTION 8.03. *Rights, Options, Warrants*. Subject to the provisions of any stockholders' agreement, the Corporation may issue rights, options or warrants for the purchase of shares of the Corporation. Subject to the provisions of any stockholders' agreement, the Board of Directors shall determine the terms upon which the rights, options, or warrants are to be issued, their form and content, and the consideration for which the shares are to be issued.

SECTION 8.04. *Transfers*. Upon surrender to the Corporation or the transfer agent of the Corporation of a certificate for shares duly endorsed or accompanied by proper evidence of succession, assignment, or authority to transfer, it shall be the duty of the Corporation to issue a new certificate to the person entitled thereto, cancel the old certificate, and record the transaction upon its books. Transfers of shares shall be made only on the books of the Corporation by the registered holder thereof, or by his attorney thereunto authorized by power of attorney and filed with the Secretary of the Corporation or the Transfer Agent.

SECTION 8.05. Registered Stockholders. The Corporation shall be entitled to treat the holder of record of any share or shares of the Corporation's capital stock as the holder in fact thereof and, accordingly, shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of the State of Delaware.

SECTION 8.06. *Transfer Agents, Registrars*. The Board of Directors may make such rules and regulations as it may deem expedient concerning the issuance and transfer of certificates for shares of the Corporation, may appoint transfer agents or registers or both, and may require all certificates for shares to bear the signature of either or both. Nothing herein shall be construed to prohibit the Corporation from acting as its own transfer agent at any of its offices.

SECTION 8.07. Fractional Shares. The Corporation, with the approval of the Board of Directors, may issue certificates for fractions of a share where necessary to effect share transfers, share distributions or a reclassification, merger, consolidation or reorganization, which shall entitle the holders, in proportion to their fractional holdings, to exercise voting rights, receive dividends and participate in liquidating distributions. As an alternative, the Corporation, with the approval of the Board of Directors, may pay in cash the fair value of fractions of shares as of the time when those entitled to receive the fractions are determined. As another alternative, the Corporation, with the approval of the Board of Directors may issue scrip in registered or bearer form over the manual or facsimile signature of an officer of the Corporation or of its agent, exchangeable as therein provided for full shares; but such scrip shall not entitle the holder to any right of a stockholder, except as therein provided. The scrip shall be issued subject to the condition that it becomes void if not exchanged for certificates representing full shares before a specified date. The scrip may be subject to the condition that the shares for which the scrip is exchangeable may be sold by the Corporation and the proceeds thereof distributed to the holders of the scrip, or subject to any other condition which the Board of Directors may determine. The Corporation may provide reasonable opportunity for persons entitled to fractions of a share or scrip to sell them or to purchase additional fractions of a share or scrip needed to acquire a full share.

#### ARTICLE IX

### DIVIDENDS

SECTION 9.01. Declaration. Dividends with respect to the shares of the Corporation's capital stock, subject to the provisions of the Certificate of Incorporation, if any, may be declared by the Board of Directors at any regular or special meeting, pursuant to applicable law. Dividends may be paid in cash, in property, or in shares of capital stock, subject to the provisions of the Certificate of Incorporation

SECTION 9.02. Reserve. Before payment of any dividend, there may be set aside out of any funds of the Corporation available for dividends such sum or sums as the Board of Directors from time to time, in their absolute discretion, think proper as a reserve or reserves to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of the Corporation, or for such other purpose as the Board of Directors shall think conducive to the interest of the Corporation, and the Board of Directors may modify or abolish any such reserve in the manner in which it was created

#### ARTICLE X

INDEMNIFICATION

SECTION 10.01. Mandatory Indemnification. The Corporation shall indemnify any director or officer of the Corporation in accordance with the provisions set forth in the Certificate of Incorporation as well as any other person entitled to such indemnification pursuant to the provisions therein.

SECTION 10.02. Continuation of Indemnity. The indemnification and advancement of expenses provided or granted hereunder and under the Certificate of Incorporation shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee, or agent and shall inure to the benefit of the heirs, executors, and administrators of such a person.

# ARTICLE XI

# CORPORATE ACTIONS

SECTION 11.01. *Instruments*. All instruments of any nature shall be signed, executed, acknowledged or verified by such officer or officers or such agents or agents of the Corporation as the Board of Directors may determine, and such authority may be general or confined to specific instances. However, an officer may not sign, execute, acknowledge or verify an instrument in more than one capacity if the instrument is required to be signed, executed, acknowledged or verified by two or more officers.

SECTION 11.02. Conflict of Interest. A transaction in which a director or officer is determined to have an interest shall not, because of the interest, be enjoined, set aside, or give rise to an award of damages or other sanction, in a proceeding by a stockholders of the Corporation or by or in the right of the Corporation, if the person interested in the transaction establishes any of the following:

- (a) The transaction was fair to the Corporation at the time entered into; or
- (b) The material facts of the transaction and the director's or officer's interest were disclosed or known to the Board of Directors or a committee thereof, and the Board of Directors or the committee thereof, as applicable, authorized, approved or ratified the transaction by a vote of a majority of the directors on the Board or committee who had no interest in the transaction, though less than a quorum, who had no interest in the transaction. The presence of, or a vote cast by, a director with an interest in the transaction does not affect the validity of the action; or
- (c) The material facts of the transaction and the director's or officer's interest were disclosed or known to the stockholders of the Corporation entitled to vote and they authorized, approved, or ratified the transaction by a vote of the majority of the shares held by the stockholders of the Corporation who did not have an interest in the transaction. A majority of the shares held by the stockholders of the Corporation who did not have an interest in the transaction constitutes a quorum for the purpose of taking action under this Section.

## ARTICLE XII

#### MISCELLANEOUS

SECTION 12.01. Seal. The corporate seal, if one is authorized by the Board of Directors, shall have inscribed thereon the name of the Corporation, and the words "Corporate Seal, Delaware." The seal may be used by causing it or a facsimile thereof to be impressed or affixed or otherwise reproduced.

SECTION 12.02. *Books*. The books of the Corporation may be kept (subject to any provision contained in the statutes) outside the State of Delaware at the offices of the Corporation, or at such other place or places as may be designated from time to time by the Board of Directors.

SECTION 12.03. Conflicts. In the event of any conflict or potential conflict in the interpretation of any provision(s) under these bylaws and the terms of the stockholders' agreement (as the same maybe amended and/or restated from time to time) among the Corporation and the holders of the Corporation's Class A voting common stock, to the fullest extent permitted under Delaware law, the provisions of the stockholders' agreement shall prevail.

SECTION 12.04. Fiscal Year. The fiscal year of the Corporation shall be the calendar year.

### ARTICLE XIII

### AMENDMENT

SECTION 13.01. Amendment by Shareholders. These bylaws may be altered, amended or repealed by a majority of the stockholders of the Corporation; provided that, such bylaws are not in conflict with the Certificate of Incorporation, the Delaware General Corporation Law or other applicable law.

SECTION 13.02. Amendment by Directors. These bylaws may be altered, amended, or repealed by a majority of the number of directors then constituting the Board of Directors at any regular meeting of the Board of Directors without prior notice, or at any special meeting of the Board of Directors if notice of such alteration, amendment, or repeal be contained in the notice of such special meeting; provided that, such bylaws are not in conflict with the Certificate of Incorporation, the Delaware General Corporation Law or other applicable law.

# ARTICLE XIV

# OFF-SHORE OFFERINGS

In all offerings of securities pursuant to Regulation S of the Securities Act of 1933 (the "Act"), the Corporation shall require that its stock transfer agent refuse to register any transfer of securities not made in accordance with the provisions of Regulation S, pursuant to registration under the Securities Act of 1933 or an available exemption under the Act. Furthermore, the Corporation shall ensure that all certificates evidencing securities of the Corporation issued in a transaction that is

exempt from the registration requirements of Section 5 of the Act by reason of Regulation S promulgated thereunder bear the following legend (in addition to any other legends required by law or otherwise):

"TRANSFER OF THE SECURITIES EVIDENCED BY THIS CERTIFICATE IS PROHIBITED, EXCEPT IN ACCORDANCE WITH THE PROVISIONS OF REGULATION S OF THE SECURITIES ACT OF 1933, PURSUANT TO A REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933, OR PURSUANT TO AN AVAILABLE EXEMPTION FROM REGISTRATION. HEDGING TRANSACTIONS INVOLVING THE SECURITIES EVIDENCED BY THIS CERTIFICATE MAY NOT BE CONDUCTED UNLESS IN COMPLIANCE WITH THE SECURITIES ACT."

[SEAL]

### REGISTRATION RIGHTS AGREEMENT

THIS REGISTRATION RIGHTS AGREEMENT is made as of June 23, 2005, by and among EMERGENT BIOSOLUTIONS INC., a Delaware corporation (together with any successor thereto, the "Company"), and MICROSCIENCE HOLDINGS PLC, a public limited company organized under the laws of the United Kingdom ("PLC"). Each of the Company and PLC are referred to herein as a "Party" and collectively, as the "Parties".

WHEREAS, the Company's wholly-owned indirect subsidiary and PLC are simultaneously entering into a Share Exchange Agreement (the "Share Exchange Agreement") pursuant to which PLC is exchanging all of the issued and outstanding capital stock of its wholly-owned subsidiary Microscience Limited for 1,264,051 shares of the Company's Class A Common Stock;

WHEREAS, the Company and PLC desire to provide for certain arrangements with respect to the registration of shares of capital stock of the Company under the Securities Act (as defined herein); and

WHEREAS, the execution and delivery of this Agreement is a condition precedent to the transaction contemplated by the Share Exchange Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

- 1. Certain Definitions. Capitalized terms used in this Agreement and not otherwise defined shall have the following respective meanings:
  - "Agreement" shall mean this Registration Rights Agreement, as amended, restated, supplemented or otherwise modified from time to time
  - "Commission" shall mean the United States Securities and Exchange Commission or any other federal agency at the time administering the Securities Act and the Exchange Act.
  - "Common Stock" shall mean the Company's Class A Common Stock, \$0.01 par value per share.
- "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended, or any similar successor federal statute, and the rules and regulations of the Commission thereunder, all as the same shall be in effect at the time.
  - "Holder" shall mean PLC or another holder of Registrable Securities who was assigned registration rights hereunder in accordance with Section 7 hereof.
- "Initial Public Offering" means the first underwritten public offering of Common Stock for the account of the Company and offered on a "firm commitment" basis pursuant to an offering registered under the Securities Act with the Commission on Form S-1 or its then equivalent.

"Person" shall mean any individual, sole proprietorship, partnership, joint venture, trust, unincorporated organization, association, corporation, limited liability company, institution, public benefit corporation, other entity or government (whether federal, state, county, city, municipal, local, foreign, or otherwise, including any instrumentality, division, agency, body or department thereof).

"Registrable Securities" shall mean (a) the shares of Common Stock issued to PLC pursuant to the Share Exchange Agreement and (b) any additional shares of Common Stock issued or distributed by way of a dividend, stock split or other distribution in respect of any share of Class A Common Stock issued to PLC under the Share Exchange Agreement; provided, however, that notwithstanding anything to the contrary contained herein, "Registrable Securities" shall not at any time include any securities (i) registered and sold pursuant to the Securities Act, (ii) sold pursuant to Rule 144 or (iii) which could then be sold in their entirety pursuant to Rule 144 without limitation or restriction.

"Registration Date" means the date upon which the registration statement pursuant to which the Company shall have initially registered shares of Common Stock under the Securities Act for sale to the public shall have been declared effective.

"Rule 144" means Rule 144 promulgated under the Securities Act or any successor regulation.

"Securities Act" shall mean the Securities Act of 1933, as amended, or any similar successor federal statute, and the rules and regulations of the Commission thereunder, all as the same shall be in effect at the time.

# 2. Registrations.

### (a) Demand Registration.

(i) At any time after the expiration of ninety (90) days after the Registration Date, if the Company shall be requested in writing by Holders of Registrable Securities to file a registration statement for Registrable Securities having an aggregate offering price to the public of not less than \$25,000,000 under the Securities Act (a "Demand Notice") in accordance with this Section 2(a), then the Company shall use commercially reasonable efforts to effect, as soon as practicable, such a registration statement. Upon receipt of a Demand Notice, the Company shall give written notice of such proposed registration to all Holders and shall offer to include in such proposed registrable Securities requested to be included in such proposed registration by such Holders who respond in writing to the Company's notice within 30 days after delivery of such notice (which response shall specify the number of Registrable Securities Proposed to be included in such registration). The Company shall use commercially reasonable efforts to effect, as soon as practicable, such registration on an appropriate form, including Form S-2 or S-3, if available, under the Securities Act of the Registrable Securities which the Company has been so requested to register; provided, however, that the Company shall not be obligated to effect any registration under the Securities Act except in accordance with the following provisions:

- (A) The Company shall not be obligated to file more than one registration statement initiated by the Holders of Registrable Securities pursuant to this Section 2(a); provided, however, that the Company shall be obligated to file a second registration statement if at the time of the filing of the first registration statement referred to above any Registrable Securities remain subject to the Pledge Agreement (as defined in the Share Exchange Agreement);
- (B) The Company shall not be obligated to file a registration statement during the period following the Registration Date when the Holders are subject to any restrictions on disposition of Registrable Securities pursuant to any agreement described in Section 6(a); and
- (C) The Company shall not be obligated to file any registration statement during any period in which any other registration statement (other than on Form S-4 or Form S-8 promulgated under the Securities Act or any successor forms thereto) pursuant to which securities of the Company are to be or were sold has been filed and not withdrawn or has been declared effective within the prior 90 days.
- (ii) If the Holders requesting to be included in a registration pursuant to this Section 2(a) so elect, the offering of such Registrable Securities pursuant to such registration shall be in the form of an underwritten offering. The Holders of a majority of the Registrable Securities requested to be included in such registration shall select one or more nationally recognized firms of investment bankers reasonably acceptable to the Company to act as the lead managing underwriter or underwriters in connection with such offering and shall select any additional investment bankers and managers to be used in connection with the offering, which shall also be reasonably acceptable to the Company.
- (iii) With respect to any registration pursuant to this <u>Section 2(a)</u>, the Company may include in such registration any Common Stock; <u>provided</u>, <u>however</u>, that if a managing underwriter, if any, advises the Company that the inclusion of all Registrable Securities and Common Stock requested to be included by the Company in such registration would interfere with the successful marketing (including pricing) of all such securities, then the number of Registrable Securities and Common Stock proposed to be included in such registration shall be included in the following order:
  - (A) first, the Registrable Securities shall be included, pro rata based upon the number of Registrable Securities to be included at the time of such registration; and
  - (B) second, Common Stock requested to be included by the Company.
- (iv) At any time before the registration statement covering Registrable Securities becomes effective, Holders of a majority of the Registrable Securities requested to be included in such registration may request the Company to withdraw or

not to file the registration statement. In that event, if such request of withdrawal shall have been caused by, or made in response to, a material adverse effect or change in the Company's financial condition, operations, business or prospects, such Holders of Registrable Securities shall not be deemed to have used their demand registration rights under this Section 2(a).

(b) <u>Piggyback Registration</u>. If, at any time or times after (but not including) an Initial Public Offering, the Company shall seek to register any shares of its Common Stock under the Securities Act for sale to the public for its own account or on the account of others (except with respect to registration statements on Form S-4, S-8 or another form not available for registering the Registrable Securities for sale to the public), the Company will give written notice thereof to all Holders. If within fifteen (15) business days after their receipt of such notice one or more Holders request in writing the inclusion of some or all of the Registrable Securities owned by them in such registration, the Company will use commercially reasonable efforts to effect the registration under the Securities Act of such Registrable Securities. In the case of the registration of shares of capital stock by the Company in connection with any underwritten public offering, if the principal underwriter determines that the number of Registrable Securities to be offered must be limited, the Company shall not be required to register Registrable Securities of the Holders in excess of the amount, if any, of shares of the capital stock which the principal underwriter of such underwritten offering shall reasonably and in good faith agree to include in such offering in addition to any amount to be registered for the account of the Company.

# 3. Further Obligations of the Company.

- (a) Whenever the Company is required hereunder to register any Registrable Securities, it agrees that it shall also do the following:
- (i) Prepare and file, and use commercially reasonable efforts to cause to become effective, with the Commission a registration statement and such amendments and supplements to said registration statement and the prospectus used in connection therewith as may be necessary to keep said registration statement effective until the Holder or Holders have completed the distribution described in the registration statement relating thereto (but for no more than one hundred eighty (180) days or such lesser period until all such Registrable Securities are sold) and to comply with the provisions of the Securities Act with respect to the sale of securities covered by said registration statement for such period;
- (ii) Furnish to each selling Holder a draft copy of the registration statement and such copies of each preliminary and final prospectus as such Holder may reasonably request to facilitate the public offering of its Registrable Securities;
- (iii) Enter into and perform its obligations under any reasonable underwriting agreement required by the proposed underwriter, if any, in such form and containing such terms as are customary:
  - (iv) Use its commercially reasonable efforts to register or qualify the securities covered by said registration statement under the securities or "blue sky" laws of such

jurisdictions as any selling Holder may reasonably request provided the Company shall not be required to qualify to do business or file a general consent to service of process in connection therewith:

- (v) Cause upon or immediately after the effectiveness of a registration all such Registrable Securities to be listed on each securities exchange or quotation system on which the Common Stock of the Company is then listed or quoted;
- (vi) notify each Holder of Registrable Securities covered by a registration statement, at any time when a prospectus relating thereto is required to be delivered under the Securities Act, of (A) the issuance of any stop order by the Commission in respect of such registration statement, or (B) the happening of any event as a result of which the prospectus included in such registration statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing; and
- (vii) provide a transfer agent and registrar for all Registrable Securities registered pursuant hereunder and a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration.
  - (b) With a view to making available to the Holders the benefits of Rule 144, the Company agrees to:
    - (i) make and keep public information available, as those terms are understood and defined in Rule 144, at all times after the effective date of the Initial Public Offering;
    - (ii) file with the Commission in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act, if any; and
- (iii) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (A) a written statement by the Company that it has complied with the information and reporting requirements of Rule 144(c) and (B) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company.
- (c) From and after the date of this Agreement, the Company shall not, without the prior written consent of the Holders of a majority of the outstanding Registrable Securities, enter into any agreement with any holder or prospective holder of any securities of the Company that would allow such holder or prospective holder to include such securities in any registration statement filed under Section 2 hereof, unless under the terms of such agreement, such holder or prospective holder may include such securities in any such registration only to the extent that the inclusion of such securities will not reduce the amount of the Registrable Securities of the Holders that are included.

# 4. Payment of Expenses by; Cooperation by, and Obligations of, Prospective Sellers.

- (a) Notwithstanding any other provision in this Agreement to the contrary, the Company and the Holders shall each pay one-half of all expenses of any registration effected pursuant to Section 2(a) hereof and the Holders shall pay in full any incremental expenses of including the Holders' Registrable Securities in a Piggyback Registration pursuant to Section 2(b) hereof, including, without limitation, all legal and accounting fees, printing costs, listing fees and miscellaneous expenses, but excluding underwriters' commissions or discounts attributable to the Registrable Securities being offered and sold by the Holders, which shall be borne exclusively by the Holders.
- (b) Each prospective seller of Registrable Securities shall furnish to the Company in writing such information as the Company may reasonably request from such seller in connection with any registration statement with respect to such Registrable Securities.
- (c) The failure of any prospective seller of Registrable Securities to furnish any information or documents in accordance with any provision contained in this Agreement shall not affect the obligations of the Company under this Agreement to any remaining sellers who furnish such information and documents unless, in the reasonable opinion of counsel to the Company and/or the underwriters, such failure impairs or adversely affects the offering or the legality of the registration statement or causes the request not to meet the requirements of Section 2 of this Agreement.
- (d) Upon receipt of a notice (telephonic or written) from the Company or the underwriter of the happening of an event which makes any statement made in a registration statement or related prospectus covering Registrable Securities untrue or which requires the making of any changes in such registration statement or prospectus so that they will not contain any untrue statement of material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein in light of the circumstances under which they were made not misleading, the Holders of Registrable Securities included in such registration statement shall discontinue disposition of such Registrable Securities pursuant to such registration statement until such Holders' receipt of copies of the supplemented or amended prospectus or until advised by the Company or the underwriters that dispositions may be resumed.
  - (e) Each Holder of Registrable Securities included in any registration statement will effect sales of such securities in accordance with the plan of distribution given to the Company.
- (f) At the end of any period during which the Company is obligated to keep any registration statement current and effective as provided in this Agreement, the Holders of Registrable Securities included in such registration statement shall discontinue sales of shares pursuant to such registration statement, unless they receive notice from the Company of its intention to continue effectiveness of such registration statement with respect to such shares which remain unsold and such Holders shall notify the Company of the number of shares

registered which remain unsold promptly upon expiration of the period during which the Company is obligated to maintain the effectiveness of the registration statement.

(g) No Person may participate in any underwritten registration pursuant to this Agreement unless such Person (i) agrees to sell such Person's securities on the basis provided in any underwriting arrangements made with respect to such registration and (ii) completes and executes all questionnaires, powers of attorney, indemnities, underwriting agreements and other documents reasonably required by the terms of such underwriting arrangements.

### 5. Indemnification; Contribution.

(a) Incident to any registration of any Registrable Securities under the Securities Act pursuant to this Agreement, the Company will indemnify and hold harmless each Holder who offers or sells any such Registrable Securities in connection with such registration statement (including its partners (including partners of partners and stockholders of any such partners), and directors, officers, employees, representatives and agents of any of them, and each person who controls any of them within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act), from and against any and all losses, claims, damages, reasonable expenses and liabilities, joint or several (including any reasonable investigation, legal and other expenses incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, as the same are incurred), to which they, or any of them, may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities arise out of or are based on (i) any untrue statement or alleged untrue statement of a material fact contained in such registration statement (including any related preliminary or definitive prospectus, or any amendment or supplement to such registration statement or prospectus) or (ii) any omission or alleged omission to state in such document a material fact required to be stated in it or necessary to make the statements in it not misleading; provided, however, that the Company will not be liable to the extent that (1) such loss, claim, damage, expense or liability arises from and is based on an untrue statement or omission or alleged untrue statement or omission made in reliance on and in conformity with information furnished in writing to the Company by or on behalf of such Holder in accordance with Section 4(b) of this Agreement for use in such registration statement, or (2) in the case of a sale directly by such Holder (including a sale of Registrable Securities through any underwriter retained by such Holder to engage in a distribution solely on behalf of such Holder), such untrue statement or alleged untrue statement or omission or alleged omission was contained in a preliminary prospectus and corrected in a final or amended prospectus, and such Holder failed to deliver a copy of the final or amended prospectus at or prior to the confirmation of the sale of the Registrable Securities to the Person asserting any such loss, claim, damage or liability in any case where such delivery is required by the Securities Act or any state securities laws. With respect to such untrue statement or omission or alleged untrue statement or omission in the information furnished in writing to the Company by or on behalf of such Holder in accordance with Section 4(a) of this Agreement for use in such registration statement, such Holder, on a several and not joint basis, will indemnify and hold harmless the Company (including its directors, officers, employees, representatives and agents), each other Holder (including its partners (including partners of partners and stockholders of such partners) and directors, officers, employees, representatives and agents of any of them, and each person

within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act), from and against any and all losses, claims, damages, reasonable expenses and liabilities, joint or several (including any reasonable investigation, legal and other expenses incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, as the same are incurred), to which they, or any of them, may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise.

(b) If the indemnification provided for in Section 5(a) above for any reason is held by a court of competent jurisdiction to be unavailable to an indemnified party in respect of any losses, claims, damages, expenses or liabilities referred to therein, then each indemnifying party under this Section 5, in lieu of indemnifying such indemnified party thereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages, expenses or liabilities (i) in such proportion as is appropriate to reflect the relative benefits received by the Company and the other Holders from the offering of the Registrable Securities or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company and the other Holders in connection with the statements or omissions which resulted in such losses, claims, damages, expenses or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company and the Holders shall be deemed to be in the same respective proportions that the net proceeds from the offering received by the Company and the Holders, in each case as set forth in the table on the cover page of the applicable prospectus, bear to the aggregate public offering price of the Registrable Securities. The relative fault of the Company and the Holders shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by or on behalf of the Company or the Holders and the Parties' relative intent, knowledge and access to information.

The Company and the Holders agree that it would not be just and equitable if contribution pursuant to this <u>Section 5(b)</u> were determined by pro rata or per capita allocation or by any other method of allocation which does not take account of the equitable considerations referred to in the immediately preceding paragraph. No person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not found guilty of such fraudulent misrepresentation.

(c) The amount paid by an indemnifying party or payable to an indemnified party as a result of the losses, claims, damages and liabilities referred to in this Section 5 shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim, payable as the same are incurred. The indemnification and contribution provided for in this Section 5 will remain in full force and effect regardless of any investigation made by or on behalf of the indemnified parties or any officer, director, employee, agent or controlling person of the indemnified parties. No indemnifying party, in the defense of any such claim or litigation, shall enter into a consent of entry of any judgment or enter into a settlement without the consent of the indemnified party, which consent will not be unreasonably withheld. Any indemnified party that proposes to assert the right to be indemnified under this Section 5

will, promptly after receipt of notice of commencement or threat of any claim or action against such party in respect of which a claim is to be made against an indemnifying party under this Section 5 notify the indemnifying party in writing (such written notice, an "Indemnification Notice") of the commencement or threat of such action, enclosing a copy of all papers served or notices received (if applicable), but the omission so to notify the indemnifying party will not relieve the indemnifying party from any liability that the indemnifying party may have to any indemnified party under the foregoing provisions of this Section 5 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnified party. The indemnified party will have the right to retain its own counsel in any such action if (i) the employment of counsel by the indemnified party has been authorized by the indemnifying party; (ii) the indemnified party's counsel, with the concurrence of indemnifying party; counsel, shall have reasonably concluded that there is a substantial likelihood of a conflict of interest between the indemnifying party and the indemnified party in the conduct of the defense of such action or (iii) the indemnifying party shall not in fact have employed counsel to assume the defense of such action within a reasonable period of time following its receipt of the Indemnification Notice, in each of which cases the fees and expenses of the indemnified party's separate counsel shall be at the expense of the indemnifying party; provided, however, that the indemnified party shall agree to repay any expenses so advanced hereunder if it is ultimately determined by a court of competent jurisdiction that the indemnified party to whom such expenses are advanced is not entitled to be indemnified; and provided, further, that so long as the indemnified party has reasonably concluded that no conflict of interest exists, the indemnifying party may assume the defense of any action here

- (d) In the event of an underwritten offering of Registrable Securities under this Agreement, the Company and the Holders shall enter into standard indemnification and underwriting agreements with the underwriter thereof. To the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the provisions of this <u>Section 5</u>, the provisions in the underwriting agreement shall control.
- (e) The obligation of the Company and Holders under this Section 5 shall survive the completion of any offering of Registrable Securities in a registration statement under Section 2, and otherwise.

#### 6. Market Standoff Agreement

(a) In connection with the Initial Public Offering by the Company, each Holder, if requested by the Company and the managing underwriter of the Company's securities, shall agree not to, directly or indirectly, offer, sell, pledge, contract to sell (including any short sale), grant any option to purchase or otherwise dispose of any securities of the Company held by it (except for any securities sold pursuant to such registration statement) for a period of ninety (90) days (or such longer period, not to exceed one hundred eighty (180) days, that the managing underwriter specifies is required for successful completion of the Initial Public Offering) following the effective date of the registration statement as agreed to by such parties. Such agreement shall be in writing and in form and substance reasonably satisfactory to the Holders, the Company and such underwriter and pursuant to customary and prevailing terms

and conditions. The foregoing provisions of this Section 6(a) shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement, and shall only be applicable to the Holders if all officers and directors and five percent (5%) or greater stockholders of the Company enter into similar or more restrictive agreements with respect to any shares of common stock of the Company that are beneficially held by them and that are not being sold by them in connection with the Company's Initial Public Offering.

(b) Each Holder agrees that in the event the Company proposes to offer for sale to the public any of its equity securities after the Initial Public Offering, and if (i) such Holder holds beneficially or of record five percent (5%) or more of the outstanding equity securities of the Company, (ii) requested by the Company and the managing underwriter of Common Stock or other securities of the Company, and (iii) all other such five percent (5%) stockholders are requested by the Company and such underwriter to sign, and actually do sign, a similar or more restrictive agreement restricting the sale or other transfer of shares of the Company, then it will not directly or indirectly, offer, sell, pledge, contract to sell (including any short sale), grant any option to purchase or otherwise dispose of any securities of the Company held by it (except for any securities sold pursuant to such registration statement) for a period of ninety (90) days (or such longer period, not to exceed one hundred eighty (180) days, that the managing underwriter specifies is required for completion of the offering) following the effective date of the registration statement as agreed to by such parties. Such agreement shall be in writing and in form and substance reasonably satisfactory to the Holders, the Company and such underwriter and pursuant to customary and prevailing terms and conditions.

7. Transferability of Registration Rights. The registration rights set forth in this Agreement may not be transferred, except to the following Persons and then, only if such Persons become Holders of Registrable Securities: APAX Funds Nominees Limited; The Merlin BioSciences Funds; The Merlin Fund L.P.; Advent Private Equity Funds; JP Morgan Partners LLC; Merlin Equity Limited; or any subsidiary, affiliate, parent or general partner of any of the foregoing. All transfers of Registrable Securities are also subject to the transfer restrictions contained in the Class A Stockholders Agreement, dated June 30, 2004, among the Company and the Class A Stockholders of the Company. Each subsequent Holder of Registrable Securities must consent in writing to be bound by the terms and conditions of this Agreement in order to acquire the rights granted pursuant to this Agreement.

#### 8. Miscellaneous

(a) Notices. Except as otherwise expressly provided herein, all notices, requests, demands, claims, and other communications hereunder will be in writing. Any such notice, request, demand, claim, or other communication hereunder shall be deemed duly given (a) upon confirmation of facsimile, (b) one (1) business day following the date sent when sent by overnight delivery and (c) five (5) business days following the date mailed when mailed by registered or certified mail return receipt requested and postage prepaid at the following addresses (or such other address for a Party as shall be specified by such Party by like notice):

If to the Company: 300 Professional Drive

Suite 250

Gaithersburg, MD 20879 Fax: (301) 944-0173 Attn: Mr. Daniel J. Abdun-Nabi

If to PLC or any Holder:

To the address of PLC as set forth on the signature page hereto.

- (b) Entire Agreement. This Agreement, together with the instruments and other documents hereby contemplated to be executed and delivered in connection herewith, contains the entire agreement and understanding of the parties hereto, and supersedes any prior agreements or understandings between or among them, with respect to the subject matter hereof.
- (c) <u>Successors and Assigns</u>. The parties intend that this Agreement shall not benefit or create any right or cause of action in or on behalf of any person other than Parties hereto and their respective successors and permitted assigns.
- (d) <u>Amendments and Waivers</u>. Except as otherwise expressly set forth in this Agreement, any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), with the written consent of the Company and the Holders of at least a majority of the Registrable Securities. No waivers of or exceptions to any term, condition or provision of this Agreement, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such term, condition or provision.
- (e) <u>Counterparts</u>; <u>Facsimile Execution</u>. This Agreement may be executed in multiple counterparts, each of which shall constitute an original but all of which shall constitute but one and the same instrument. One or more counterparts of this Agreement may be delivered via telecopier, with the intention that they shall have the same effect as an original counterpart hereof. Facsimile execution and delivery of this Agreement is legal, valid and binding for all purposes.
  - (f) Captions. The captions of the sections, subsections and paragraphs of this Agreement have been added for convenience only and shall not be deemed to be a part of this Agreement.
- (g) <u>Severability</u>. Each provision of this Agreement shall be interpreted in such manner as to validate and give effect thereto to the fullest lawful extent, but if any provision of this Agreement is determined by a court of competent jurisdiction to be invalid or unenforceable under applicable law, such provision shall be ineffective only to the extent so determined and such invalidity or unenforceability shall not affect the remainder of such provision or the remaining provisions of this Agreement; provided, however, that the Company and a majority of the Holders shall negotiate in good faith to attempt to implement an equitable

adjustment in the provisions of this Agreement with a view toward effecting the purposes of this Agreement by replacing the provision that is invalid or unenforceable with a valid and enforceable provision the economic effect of which comes as close as possible to that of the provision that has been found to be invalid and unenforceable.

(h) Governing Law. This Agreement and the rights and obligations of the Parties hereunder shall be governed by, and construed in accordance with, the laws of the State of Delaware.

#### (i) Submission to Jurisdiction

- (iv) The Parties agree that any suit, action or proceeding with respect to any dispute, controversies or claims or any judgment entered by any court in respect thereof may be brought in any state or federal court in the state of Delaware and any appellate court thereof and irrevocably and unconditionally submits to the non-exclusive jurisdiction of such courts for the purpose of any such suit, action, proceeding or judgment. Each of the Parties hereto agrees that final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law. Each of the Parties further submits, for the purpose of any such suit, action, proceeding or judgment brought or rendered against it, to the appropriate courts of the jurisdiction of its domicile.
- (v) The Parties agree that any suit, action or proceeding with respect to the Agreement or any judgment entered by any court in respect thereof may be brought in the competent courts of the state of Delaware, and irrevocably submits to the non-exclusive jurisdiction of such courts for the purpose of any such suit, action, proceeding or judgment.
- (vi) Nothing herein shall in any way be deemed to limit the ability of any Party to serve any such process of summons, complaint and other legal process in any other manner permitted by applicable law or to obtain jurisdiction over, or bring any suit, action or proceeding against, any other Party in such other jurisdiction, and in such manner, as may be permitted by applicable law.
- (vii) The Parties also irrevocably consent, if for any reason any of the Party's authorized agent for service of process of summons, complaint and other legal process in any action, suit or proceeding is not present in Delaware, to the service of such papers being made out of those courts by mailing copies of the papers by registered United States air mail, postage prepaid, to the Party at its address specified in Section 8(a). In such a case, the relevant Party shall also send by facsimile, or have sent by facsimile, a copy of the papers to all Parties.
- (viii) Service in the manner provided in Section 8(h) in any action, suit or proceeding will be deemed personal service, will be accepted by each of the Parties as such and will be valid and binding upon such Party for all purposes of any such action, suit or proceeding.
- (j) <u>Appointment of Process Agent</u>. The Parties hereby irrevocably appoint Corporation Service Company (the "<u>Process Agent</u>"), with an office on the date hereof at 2711 Centerville Road, Wilmington, Delaware 19808, United States of America as its agent to receive

on behalf of each of the Parties service of copies of the summons and complaint and any other process which may be served in any suit, action or proceeding. Each Party agrees that the failure of the Process Agent to give any notice of any such service of process to such Party shall not impair or affect the validity of such service or, to the extent permitted by applicable law, the enforcement of any judgment based thereon. Such appointment shall be irrevocable as long as any amounts payable under this Agreement or the terms and conditions of this Agreement are outstanding, except that if for any reason the Process Agent appointed hereby ceases to be able to act as such, each Party shall, by an instrument reasonably satisfactory to the other Parties, appoint another Person in the State of Delaware as such Process Agent subject to the approval (which approval shall not be unreasonably withheld) of the other Parties. PLC covenants and agrees that it shall take any and all reasonable action, including the execution and filing of any and all documents, that may be necessary to continue the designation of a Process Agent pursuant to this Section 8(i) in full force and effect and to cause the Process Agent to act as such.

- (k) Other Methods of Service. Nothing herein shall in any way be deemed to limit the ability of any Party to serve any such process or summonses in any other manner permitted by applicable law or to obtain jurisdiction over, or bring any suit, action or proceeding against, the other Parties in such other jurisdictions, and in such manner, as may be permitted by applicable law.
- (1) Waiver of Inconvenient Forum, Etc. Each of the Parties hereby irrevocably waives any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Agreement brought in any state or federal court in the State of Delaware, United States of America, and hereby further irrevocably waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. A final judgment (in respect of which time for all appeals has elapsed) in any such suit, action or proceeding shall be conclusive and may be enforced in any court to the jurisdiction of which the Parties are or may be subject, by suit upon judgment.
- (m) EACH PARTY HERETO HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY HERETO (i) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (ii) ACKNOWLEDGES THAT IT AND THE OTHER PARTIES HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION.

[Signature page follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Registration Rights Agreement to be duly executed as of the date first set forth above.

# COMPANY: EMERGENT BIOSOLUTIONS INC.

By: /s/ Fuad El-Hibri

Name: Fuad El-Hibri

Title: Chairman, President and CEO

# PLC: MICROSCIENCE HOLDINGS PLC

By: /s/ [Illegible]
Name: [Illegible]
Title: Finance Director

Address:

MICROSCIENCE HOLDINGS PLC c/o Advent Venture Partners 25 Buckingham Gate London SW1E 6LD United Kingdom Fax: 44 20 7828 1474 Attention: Shahzad Malik

with a copy to:

Morrison & Foerster CityPoint One Ropemaker Street London EC2Y 9AW United Kingdom Fax: 44 20 7496 8500 Attention: James Gubbins

[Signature Page to Registration Rights Agreement]

### VOTING AND RIGHT OF FIRST REFUSAL AGREEMENT

VOTING AND RIGHT OF FIRST REFUSAL AGREEMENT, effective as of October 21, 2005 (this "Agreement"), by and among the William J. Crowe, Jr. Revocable Living Trust (the "Trust") and Mr. Fuad El-Hibri (the "Mr. El-Hibri").

#### BACKGROUND

The parties hereto own certain membership interests in Intervac, L.L.C. ("Intervac"), a Maryland limited liability company governed by the terms of an Amended and Restated Operating Agreement, dated as of July 1, 1998, among the members thereto, as amended and/or supplemented from time to time (the "Operating Agreement").

The Trust is the beneficial and record owner of an 18% Interest (as such term is defined in the Operating Agreement) in Intervac (together with any other Interest the Trust may hereafter hold, the "**Trust Interest**"). Mr. El-Hibri, together with Nancy El-Hibri, as tenants by the entirety, are the beneficial and record owners of a 32.5% Interest (as such term is defined in the Operating Agreement) in Intervac, four and a half percent (4.5%) of which was purchased pursuant to a Buy and Sell Agreement, dated as of the date hereof, by and between the Trust (as seller) and Fuad El-Hibri, and Nancy El-Hibri, as tenants by the entirety, and a Buy and Sell Agreement, dated as of the date hereof, by and between Fuad El-Hibri, as tenants by the entirety, and the United States Naval Academy Foundation, Inc. (as seller) (together, the "**Buy and Sell Agreements**").

In consideration of the above referenced purchases of Interest (as such term is defined in the Operating Agreement) under the Buy and Sell Agreements, the parties desire to enter into this Agreement in order to codify their mutual agreement regarding the voting of the Trust Interest and Mr. El-Hibri's right of first refusal to acquire certain Trust Interest in certain sales of Trust Interest.

### AGREEMENT

NOW THEREFORE, in consideration of the mutual agreements contained herein and other good and adequate consideration, the parties hereby agree as follows:

- $1. \ \underline{Definitions}. \ As \ used \ herein, the \ following \ terms \ shall \ have \ the \ following \ respective \ meanings:$ 
  - "Business Day" means any day that is not a Saturday, Sunday or day on which banking institutions in New York, New York are not required to be open.
  - "Person" means any individual, partnership, corporation, limited liability company, group, trust or other legal entity.
  - "Transfer" means any sale, assignment, transfer, pledge, bequest, hypothecation, mortgage, other disposition, grant of proxy with respect to, or any encumbrance, whether

voluntary or involuntary or whether by operation of law of a Trust Interest or portion thereof. The words "Transferred" and "Transfers" as used herein have correlative meanings

- 2. Representations and Warranties. Each of the Trust and Mr. El-Hibri hereby represent and warrant to the other that:
  - (a) it/he has the requisite power and authority to enter into and perform this Agreement;
  - (b) it/his execution, delivery and performance of this Agreement have been duly authorized by all necessary action;
  - (c) (with respect only to the trust) this Agreement has been duly executed by an authorized trustee of the Trust; and
- (d) the performance of this Agreement by it/he will not require it/him to obtain the consent, waiver or approval of any person and will not violate, result in a breach of, or constitute a default under any statute, regulation, agreement, judgment, consent, or decree by which it/him is bound.
- 3. <u>Voting</u>. The Trust shall, at any time that it owns any Trust Interest and such Trust Interest has rights to vote at any annual, special or other general meeting or pursuant to a written resolution of Intervac's members, vote such Trust Interest for and against and abstain from voting with respect to any proposal in the same manner and to the same extent as Mr. El-Hibri. The Trust hereby irrevocably grants to Mr. El-Hibri, a proxy, coupled with an interest, with full power of substitution, to vote all Trust Interest in the manner described in the preceding sentence.

#### Right of First Refusal

(a) In the event that the Trust receives a bona fide arms' length offer ("Offer") from a third party (the "Offeror") to acquire any Trust Interest for any compensation, including, but not limited to, cash or marketable securities, the value of which marketable securities shall be determined based on the trading price on the close of business on the date of such offer, the Trust shall first deliver to Mr. El-Hibri a written notice (the "First Refusal Notice"), which First Refusal Notice shall be irrevocable for a period of 14 Business Days after receipt thereof, offering all of the Trust Interest proposed to be Transferred by the Trust at the same economic terms (where possible) specified in the Offer (such First Refusal Notice shall include the foregoing information and all other terms of the Offer). Mr. El-Hibri shall have the right and option to notify the Trust, in a writing (the "Right Acceptance") delivered within 14 Business Days of receipt of the First Refusal Notice, of his intent to purchase all or any portion of the Trust Interest proposed to be Transferred by matching the economic terms (where possible) of the terms stated in the First Refusal Notice.

(b) Transfers of Trust Interest under the terms of Section 4(a) above shall be made at such location as Mr. El-Hibri may specify on a mutually satisfactory Business Day within 30 days after the delivery by Mr. El-Hibri of the Right Acceptance. Delivery of certificates or other instruments, documents, agreements or amendments evidencing such Transferred Trust Interest

(duly endorsed for Transfer, if required) shall be made on such date against payment of the purchase price therefor.

- (c) If effective Right Acceptance shall not be received pursuant to Section 3(a) above with respect to all of the Trust Interest offered for Transfer pursuant to a First Refusal Notice, then the Trust may Transfer to the Offeror (and no other Person) all but not less than all of the Trust Interest so offered and not so accepted at a price not less than the price, and on the same terms and conditions as stated in the First Refusal Notice at any time within 30 days after the expiration of the 14 Business Day period specified in Section 3(a) which commences upon Mr. El-Hibri's receipt of the First Refusal Notice; provided, however, that the Offerer agrees in writing to be bound by the terms of this Agreement as provided in Section 5(a) below.
- (d) In the event that such Trust Interest are not Transferred by the Trust to the Offeror during the 30 day period specified in Section 3(e), then the right of the Trust to Transfer such Trust Interest to the Offeror pursuant to the Offer shall expire and any Transfer of such Trust Interest shall be made in accordance with this Section 3.

#### 5. Transfer Restrictions: Legend

- (a) <u>Transfer Restrictions</u>. The Trust on behalf of itself, and each and any executor, administrator, heir, successors or permitted assigns, hereby agrees that all Transfers of Trust Interest made by it shall be made subject to this Agreement and any transferee, including, but not limited to, any Affiliate, heir, successors or permitted assigns, will agree in writing to be bound by the terms and provisions of this Agreement as a condition precedent to any such Transfer.
- (b) <u>Legend</u>. If at any time any certificate(s) is/are issued by Intervac representing any Interest held by the Trust, then each such certificate shall be endorsed with a legend in substantially the following form:

THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO CERTAIN VOTING REQUIREMENTS AND OTHER RESTRICTIONS SET FORTH IN A VOTING AND RIGHTS AGREEMENT BETWEEN THE HOLDER OF THIS CERTIFICATE AND CERTAIN OTHER PARTIES. TRANSFER OF THE SECURITIES IS SUBJECT TO THE RESTRICTIONS CONTAINED IN SUCH AGREEMENT.

6. Additional Interest. If, after the effective date hereof, the Trust, or any trustee thereof acquires beneficial or record ownership of any additional Interest in Intervac (any such Interest, "Additional Interest"), including, without limitation, upon exercise of any right to acquire Interest in Intervac, the provisions of this Agreement shall thereafter be applicable to such Additional Interest as if such Additional Interest had been held by such party as of the effective date hereof. The provisions of the immediately preceding sentence shall be effective with respect to Additional Interest without action by any Person immediately upon the acquisition by such party or its Affiliates of beneficial ownership of such Additional Interest. Such party shall cause

any Affiliate or trustee that acquires Additional Interest to enter into a written joinder to this Agreement in form and substance satisfactory to the other party.

7. <u>Termination</u>. This Agreement shall automatically terminate five (5) years from the effective date of this Agreement first written above. Upon the termination of this Agreement, except as otherwise set forth herein, the restrictions and obligations set forth herein shall terminate and be of no further effect, except that such termination shall not affect rights perfected or obligations incurred under this Agreement prior to such termination.

#### 8. Miscellaneous.

- (a) <u>Binding Effect</u>. This Agreement and all the provisions hereof shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, estates, successors and permitted assigns. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by any of the parties hereto without the prior written consent of the other parties. The parties hereto agree to cause their Affiliates to agree in writing to be bound by the terms of this Agreement prior to, or immediately upon, the acquisition of any Interests by such Affiliates.
- (b) <u>Amendments</u>. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by each of the parties hereto. However, any party may waive any condition to the obligations of any other party hereunder.
- (c) <u>Notices</u>. All notices, requests, demands and other communications required or permitted hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand, facsimile or mail, certified or registered mail (return receipt requested) with postage prepaid:
  - (i) If to Mr. Fuad El-Hibri, to:

Mr. Fuad El-Hibri 13340 Signal Tree Lane Potomac, MD 20854

(ii) If to the Trust, to:

William J. Crowe, Jr. Revocable Living Trust c/o William P. Daisley 10834 Brewer House Rd. Rockville, MD 20852

or to such other address as any party may have furnished to the others in writing in accordance herewith.

(d) Arbitration. Any controversy or claim arising out of or relating to this Agreement will be settled by arbitration in accordance with the following provisions:

- (i) <u>Disputes Covered</u>. The agreement of the parties to arbitrate covers all disputes of every kind relating to or arising out of this Agreement, <u>except</u> disputes determined not to be arbitratable by the arbitrator. Disputes include actions for breach of contract with respect to this Agreement or the related agreement. In addition, the arbitrator selected according to procedures set forth below will determine the arbitrability of any matter brought to them, including their authority to impose equitable remedies that may be requested in good faith by a party, and their decision will be final and binding on the parties.
  - (ii) Venue. The venue for the arbitration will be in Rockville, Maryland.
  - (iii) Law. The governing law for the arbitration will be the law of the State of Maryland without reference to its conflicts of laws provisions.
  - (iv) Selection. There will be a single arbitrator appointed by the American Arbitration Association.
  - (v) Administration. The arbitration will be administered by the American Arbitration Association.
- (vi) <u>Rules</u>. The rules of arbitration will be the Commercial Arbitration Rules of the American Arbitration Association, as modified by any other instructions that the parties may agree upon at the time. If there is any conflict between the Commercial Arbitration Rules and the provisions of this section, the provisions of this section will prevail.
- (vii) Substantive Law. The arbitrator will be bound by and shall strictly enforce the terms of this Agreement and may not limit, expand or otherwise modify its terms. The arbitrator will make a good faith effort to apply substantive applicable law, but an arbitration decision shall not be subject to review because of errors of law.
- (viii) <u>Decision</u>. The arbitrator's decision will provide a reasoned basis for the resolution of each dispute and for any award. The arbitrator will not have power to award damages in connection with any dispute in excess of actual compensatory damages.
- (ix) Fees; Expenses. Unless the arbitrator's decision otherwise directs each party will bear its own fees and expenses with respect to the arbitration and any proceeding related thereto and the parties will share equally the fees and expenses of the American Arbitration Association and the arbitrator.
- (x) Remedies; Award. The arbitrator will have power and authority to award any remedy or judgment that could be awarded by a court of law in Maryland, subject to the limitations set forth in this Agreement. The award rendered by arbitrator will be final and binding upon the parties, and judgment upon the award may be entered in any court of competent jurisdiction in the United States.
- (e) Equitable Relief. The parties agree that it is impossible to determine the monetary damages which would accrue to any party by reason of the failure of any party to perform any of its obligations under this Agreement. Each party shall be entitled to enforce its rights under this Agreement specifically and to exercise all other rights existing in its favor. The parties hereto

agree and acknowledge that money damages may not be an adequate remedy for any breach of the provisions of this Agreement. Accordingly, notwithstanding the agreement of the parties to arbitrate set forth in Section 8(d), in addition to any other right or remedy (including money damages) to which a party may be entitled, at law or in equity, each party shall be entitled in its sole discretion to apply to any court of law, or equity, of competent jurisdiction for specific performance, injunctive relief or such other relief as such court may deem just and proper in order to enforce any provision or prevent any breach or threatened breach of this Agreement and, to the extent permitted by applicable law, each party waives (a) any objection to the imposition of such relief and any claim or defense that there is an adequate remedy at law for such breach or threatened breach, and (b) any requirement to post any bond or make any other undertaking or other security. The availability of such remedies shall not prohibit any party from pursuing any other remedies for such breach or threatened breach, including the recovery of damages from a breaching party.

- (f) <u>Applicable Law</u>. This Agreement and the legal relations among the parties hereto arising from this Agreement shall be governed by and construed in accordance with the laws of the State of Maryland, without reference to or application of any conflicts of law principles.
- (g) Counterparts; Facsimile Execution. This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed original but all of which shall constitute one and the same instrument. Facsimile execution and delivery of this Agreement is legal, valid and binding for all purposes.
- (h) Entire Agreement. This Agreement constitutes the entire agreement and understanding of the parties hereto in respect of the subject matter contained herein. There are no restrictions, promises, warranties, covenants or undertakings, other than those expressly set forth or referred to herein. This Agreement supersedes all prior agreements and understandings among the parties with respect to such subject matter.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and made and entered into effective as of the date first set forth above.

William J. Crowe, Jr. Revocable Living Trust

By: /s/ William J. Crowe, Jr., Trustee

William J. Crowe, Jr., Trustee

/s/ Fuad El-Hibri

Mr. Fuad El-Hibri

### VOTING AGREEMENT

VOTING AGREEMENT, effective as of June 30, 2004 (this "Agreement"), by and between BIOPHARM, LLC, a Delaware limited liability company ("BioPharm") and Michigan Biologics Products, Inc., a Michigan corporation ("MBPI").

### BACKGROUND

BioPharm is the beneficial and record owner of 1,412,896 shares (the "BioPharm Shares") of the voting class A common stock ("Class A Stock") of Emergent BioSolutions Inc., a Delaware corporation (the "Company") and MBPI is the beneficial and record owner of 672,500 shares of Class A Stock. The parties desire to enter into this voting agreement in order to codify their mutual understanding regarding the voting of the Class A Stock (and any other voting capital stock of the Company that may hereafter be held by either party) and MBPI's right to participate in certain sales of securities by BioPharm.

### AGREEMENT

NOW THEREFORE, in consideration of the mutual agreements contained herein and other good and adequate consideration, the parties hereby agree as follows:

- 1. Representations and Warranties. Each of BioPharm and MBPI hereby represent and warrant to the other that:
  - (a) it has the requisite power and authority to enter into and perform this Agreement;
  - (b) its execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action;
  - (c) this Agreement has been duly executed by an authorized officer of such party; and
- (d) the performance of this Agreement by it will not require it to obtain the consent, waiver or approval of any person and will not violate, result in a breach of, or constitute a default under any statute, regulation, agreement, judgment, consent, or decree by which it is bound.
- 2. Quorum. MBPI shall, at any time it owns any capital stock of the Company and such capital stock has rights to vote at any annual, special or other general meeting of the Company's stockholders, and at any adjournment or adjournments thereof, cause all such capital stock to be present in person or by proxy at such meeting for purposes of determining whether a quorum is present at any such meeting.
- 3. <u>Voting</u>. MBPI shall, at any time it owns any capital stock of the Company and such capital stock has rights to vote at any annual, special or other general meeting or pursuant to a written resolution of the Company's stockholders, vote such shares for and against and abstain from voting with respect to any proposal in the same manner and to the same extent as

BioPharm. MBPI hereby irrevocably grants BioPharm a proxy, coupled with an interest, with full power of substitution, to vote all shares of the Company's capital stock owned by MBPI in the manner described in the preceding sentence.

4. <u>Co-Sale Right</u>. In the event that BioPharm receives a <u>bona fide</u> arms' length offer from an offeror to purchase a majority of the capital stock of the Company held by BioPharm for a specified price payable in cash or otherwise and on specified terms and conditions, BioPharm shall promptly forward a written notice to MBPI indicating the amount of shares to be sold, the purchase price for the shares and any other material terms of the offer. BioPharm shall not transfer any shares to the offeror unless the terms of the offer are extended to MBPI with respect to MBPI's proportionate percentage of the aggregate number of shares to which the offer relates; provided, however that in the event that MBPI does not accept the terms of the offer within ten (10) days of receipt of notice by BioPharm, then such co-sale right shall terminate. The proportionate percentage is equal to a fraction the numerator of which is the number of shares then held by BioPharm or MBPI, as the case may be, and the denominator of which, is the number of shares, in the aggregate, then held by BioPharm and MBPI MBPI shall be required to execute and deliver such documents and instruments and make such representations and warranties and take such other actions as are customary in such sales and are consistent with those being made by BioPharm.

### 5. Transfer Restrictions; Legend

- (a) <u>Transfer Restrictions</u>. MBPI hereby agrees that all transfers of the Company's capital stock made by it shall be made subject to this Agreement and any transferee will agree in writing to be bound by the terms and provisions of this Agreement as a condition precedent to any such transfer.
  - (b) Legend. Each certificate representing any shares of capital stock of the Company held by either party shall be endorsed with a legend in substantially the following form:

THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO CERTAIN VOTING REQUIREMENTS AND OTHER RESTRICTIONS SET FORTH IN A VOTING AGREEMENT BETWEEN THE HOLDER OF THIS CERTIFICATE AND CERTAIN OTHER PARTIES. TRANSFER OF THE SECURITIES IS SUBJECT TO THE RESTRICTIONS CONTAINED IN SUCH AGREEMENT.

(c) Removal of Transfer Restrictions. Following the underwritten initial public offering of the Company's capital stock or such other date that the Company's capital stock is first listed on a national securities exchange or quoted on the over-the-counter market, MBPI shall be entitled to transfer shares of capital stock of the Company in "brokers' transactions" within the meaning of Section 4(4) of the Securities Act of 1933 or in transactions directly with a market maker, as that term is defined in Section 3(a)(38) of the Securities Exchange Act of 1934 (a "Public Sale Transaction") free from any restriction hereunder, subject to the following conditions:

- (i) MBPI shall first deliver to BioPharm a written notice (the "First Offer Notice"), which First Offer Notice shall be irrevocable for a period of 7 days after receipt thereof, offering to sell to BioPharm at Fair Market Value (as defined below) all of such shares of capital stock of the Company that MBPI desires to sell.
- (ii) BioPharm shall have the right and option to notify MBPI, in a writing delivered within 7 days of receipt of the First Offer Notice, of its election to purchase all or any portion of the shares offered under the First Offer Notice at Fair Market Value and consummate such purchase within 7 days thereafter. Any shares so acquired from MBPI shall no longer be subject to this Agreement.
- (iii) If BioPharm declines to purchase all or any portion of the shares subject to the First Offer Notice, MBPI shall have the right to sell such shares in a Public Sale Transaction free from any restriction hereunder, including but not limited to the legend set forth in Section 5(b) above. Any shares not sold in accordance with the procedure set forth in this Section 5 shall remain subject to this Agreement.
- (iv) "Fair Market Value" of a share of capital stock of the Company as of a specified date for the purposes of this Section 5 shall mean the closing price of a share of such capital stock on the principal securities exchange on which such shares are traded on the day immediately preceding the date as of which Fair Market Value is being determined, or on the next preceding date on which such shares are traded if no shares were traded on such immediately preceding day, or if the shares are not traded on a securities exchange, Fair Market Value shall be deemed to be the average of the high bid and low asked prices of the shares in the over-the-counter market on the day immediately preceding the date as of which Fair Market Value is being determined or on the next preceding date on which such high bid and low asked prices were recorded.

6. Additional Shares. If, after the effective date hereof, either party or any of its affiliates acquires beneficial or record ownership of any additional shares of capital stock of the Company (any such shares, "Additional Shares"), including, without limitation, upon exercise of any option, warrant or right to acquire shares of capital stock of the Company or through any stock dividend or stock split, the provisions of this Agreement shall thereafter be applicable to such Additional Shares as if such Additional Shares had been held by such party as of the effective date hereof. The provisions of the immediately preceding sentence shall be effective with respect to Additional Shares without action by any person or entity immediately upon the acquisition by such party or its affiliates of beneficial ownership of such Additional Shares. Such Party shall cause any affiliate that acquires Additional Shares to enter into a written joinder to this Agreement in form and substance satisfactory to the other party.

7. Termination. It is the intention of the parties that this Agreement shall survive the initial public offering of the Company and continue in force at any time when the Company is a public

reporting company. This Agreement shall automatically terminate on the seventh (7th) anniversary of the effective date hereof. Upon the termination of this Agreement, except as otherwise set forth herein, the restrictions and obligations set forth herein shall terminate and be of no further effect, except that such termination shall not affect rights perfected or obligations incurred under this Agreement prior to such termination, and the parties shall each be entitled to receive certificate(s) representing such holder's shares without the legend required by Section 5 herein upon the surrender of the certificate(s) representing such shares to the Company.

#### 8. Miscellaneou

- (a) <u>Binding Effect</u>. This Agreement and all the provisions hereof shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by any of the parties hereto without the prior written consent of the other parties. The parties hereto agree to cause their affiliates to agree in writing to be bound by the terms of this Agreement prior to, or immediately upon, the acquisition of shares by such affiliates.
- (b) <u>Amendments</u>. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by each of the parties hereto. However, any party may waive any condition to the obligations of any other party hereunder.
- (c) Equitable Relief. The parties agree that it is impossible to determine the monetary damages which would accrue to any party by reason of the failure of any party to perform any of its obligations under this Agreement requiring the performance of an act other than the payment of money only. Each party shall be entitled to enforce its rights under this Agreement specifically and to exercise all other rights existing in its favor. The parties hereto agree and acknowledge that money damages may not be an adequate remedy for any breach of the provisions of this Agreement and that each party may in its sole discretion apply to any court of law or equity of competent jurisdiction for specific performance and/or injunctive relief (without posting a bond or other security) in order to enforce or prevent any violation of the provisions of this Agreement. In the event of a breach or threatened breach by a party of any of the provisions of this Agreement, the other parties hereto shall be entitled to an injunction restraining such party from any such breach, and each party hereto waives any claim or defense that there is an adequate remedy at law for such breach or threatened breach. The availability of such remedies shall not prohibit any party from pursuing any other remedies for such breach or threatened breach, including the recovery of damages from a breaching party.
- (d) Notices. All notices, requests, demands and other communications required or permitted hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand, facsimile or mail, certified or registered mail (return receipt requested) with postage prepaid:

(i) If to BioPharm, to:

BioPharm, LLC 3500 N. Martin Luther King, Jr. Blvd. Building one, 3rd Floor Lansing, MI 48906 Attn: Robert G. Kramer

(ii) If to MBPI, to:

Michigan Biologics Products, Inc. 3500 N. Martin Luther King, Jr. Blvd. Building one, 3rd Floor Lansing, MI 48906 Attn: Robert C. Myers

or to such other address as any party may have furnished to the others in writing in accordance herewith.

### (e) Arbitration.

Any controversy or claim arising out of or relating to this Agreement will be settled by arbitration in accordance with the following provisions:

- (i) <u>Disputes Covered</u>. The agreement of the parties to arbitrate covers all disputes of every kind relating to or arising out of this Agreement, <u>except</u> disputes determined not to be arbitratable by the arbitrator. Disputes include actions for breach of contract with respect to this Agreement or the related agreement. In addition, the arbitrator selected according to procedures set forth below will determine the arbitrability of any matter brought to them, including their authority to impose equitable remedies that may be requested in good faith by a party, and their decision will be final and binding on the parties.
  - (ii) Venue. The venue for the arbitration will be in Washington, D.C.
  - (iii) <u>Law</u>. The governing law for the arbitration will be the law of the State of Delaware without reference to its conflicts of laws provisions.
  - (iv) Selection. There will be a single arbitrator appointed by the American Arbitration Association.
  - (v) Administration. The arbitration will be administered by the American Arbitration Association.
- (vi) <u>Rules</u>. The rules of arbitration will be the Commercial Arbitration Rules of the American Arbitration Association, as modified by any other instructions that the parties may agree upon at the time. If there is any conflict between the Commercial Arbitration Rules and the provisions of this section, the provisions of this section will prevail.
- (vii) <u>Substantive Law</u>. The arbitrator will be bound by and shall strictly enforce the terms of this Agreement and may not limit, expand or otherwise modify its terms. The arbitrator will make a good faith effort to apply substantive applicable law, but an arbitration decision shall not be subject to review because of errors of law.

- (viii) <u>Decision</u>. The arbitrator's decision will provide a reasoned basis for the resolution of each dispute and for any award. The arbitrator will not have power to award damages in connection with any dispute in excess of actual compensatory damages.
- (ix) Fees; Expenses. Unless the arbitrator's decision otherwise directs each party will bear its own fees and expenses with respect to the arbitration and any proceeding related thereto and the parties will share equally the fees and expenses of the American Arbitration Association and the arbitrator.
- (x) Remedies; Award. The arbitrator will have power and authority to award any remedy or judgment that could be awarded by a court of law in the District of Columbia, subject to the limitations set forth in this Agreement. The award rendered by arbitrator will be final and binding upon the parties, and judgment upon the award may be entered in any court of competent jurisdiction in the United States.
- (f) <u>Applicable Law</u>. This Agreement and the legal relations among the parties hereto arising from this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without reference to or application of any conflicts of law principles.
- (g) <u>Counterparts</u>; <u>Facsimile Execution</u>. This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed original but all of which shall constitute one and the same instrument. Facsimile execution and delivery of this Agreement is legal, valid and binding for all purposes.
- (h) Entire Agreement. This Agreement constitutes the entire agreement and understanding of the parties hereto in respect of the subject matter contained herein. There are no restrictions, promises, warranties, covenants or undertakings, other than those expressly set forth or referred to herein. This Agreement supersedes all prior agreements and understandings among the parties with respect to such subject matter
- (i) <u>Severability of Provisions</u>. The provisions of this Agreement be enforced to the fullest extent permissible under the law and public policies applied in each jurisdiction in which enforcement is sought. Accordingly, if any provision of this Agreement would be held to be invalid, prohibited or unenforceable for any reason, such provision, as to such jurisdiction, shall be ineffective, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision. Notwithstanding the foregoing, if such provision could be more narrowly drawn so as to be invalid, prohibited or unenforceable, it shall be so narrowly drawn, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision.

[signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and made and entered into effective as of the date first set forth above.

# BIOPHARM, LLC

By: /s/ Robert G. Kramer

Name: Robert G. Kramer Title: General Manager

# MICHIGAN BIOLOGICS PRODUCTS, INC.

By: /s/ [Illegible]
Name:

Title:

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### VOTING AGREEMENT

VOTING AGREEMENT, effective as of June 30, 2004 (this "Agreement"), by and between BIOPHARM, LLC, a Delaware limited liability company ("BioPharm") and Biologika, L.L.C., a Maryland limited liability company ("Biologika").

### BACKGROUND

BioPharm is the beneficial and record owner of 1,412,896 shares (the "BioPharm Shares") of the voting class A common stock ("Class A Stock") of Emergent BioSolutions Inc., a Delaware corporation (the "Company") and Biologika is the beneficial and record owner of 477,941 shares of Class A Stock. The parties desire to enter into this voting agreement in order to codify their mutual understanding regarding the voting of the Class A Stock (and any other voting capital stock of the Company that may hereafter be held by either party) and Biologika's right to participate in certain sales of securities by BioPharm.

### AGREEMENT

NOW THEREFORE, in consideration of the mutual agreements contained herein and other good and adequate consideration, the parties hereby agree as follows:

- 1. Representations and Warranties. Each of BioPharm and Biologika hereby represent and warrant to the other that:
  - (a) it has the requisite power and authority to enter into and perform this Agreement;
  - (b) its execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action;
  - (c) this Agreement has been duly executed by an authorized officer of such party; and
- (d) the performance of this Agreement by it will not require it to obtain the consent, waiver or approval of any person and will not violate, result in a breach of, or constitute a default under any statute, regulation, agreement, judgment, consent, or decree by which it is bound.
- 2. Quorum. Biologika shall, at any time it owns any capital stock of the Company and such capital stock has rights to vote at any annual, special or other general meeting of the Company's stockholders, and at any adjournment or adjournments thereof, cause all such capital stock to be present in person or by proxy at such meeting for purposes of determining whether a quorum is present at any such meeting.
- 3. Voting. Biologika shall, at any time it owns any capital stock of the Company and such capital stock has rights to vote at any annual, special or other general meeting or pursuant to a written resolution of the Company's stockholders, vote such shares for and against and abstain from voting with respect to any proposal in the same manner and to the same extent as BioPharm. Biologika hereby irrevocably grants BioPharm a proxy, coupled with an interest, with full power of substitution, to vote all shares of the Company's capital stock owned by Biologika in the manner described in the preceding sentence.

4. <u>Co-Sale Right</u>. In the event that BioPharm receives a <u>bona fide</u> arms' length offer from an offeror to purchase a majority of the capital stock of the Company held by BioPharm for a specified price payable in cash or otherwise and on specified terms and conditions, BioPharm shall promptly forward a written notice to Biologika indicating the amount of shares to be sold, the purchase price for the shares and any other material terms of the offer. BioPharm shall not transfer any shares to the offer unless the terms of the offer are extended to Biologika with respect to Biologika's proportionate percentage of the aggregate number of shares to which the offer relates; provided, however that in the event that Biologika does not accept the terms of the offer within ten (10) days of receipt of notice by BioPharm, then such co-sale right shall terminate. The proportionate percentage is equal to a fraction the numerator of which is the number of shares then held by BioPharm or Biologika, as the case may be, and the denominator of which, is the number of shares, in the aggregate, then held by BioPharm and Biologika shall be required to execute and deliver such documents and make such representations and warranties and take such other actions as are customary in such sales and are consistent with those being made by BioPharm.

### 5. Transfer Restrictions; Legend.

- (a) <u>Transfer Restrictions</u>. Biologika hereby agrees that all transfers of the Company's capital stock made by it shall be made subject to this Agreement and any transferee will agree in writing to be bound by the terms and provisions of this Agreement as a condition precedent to any such transfer.
  - (b) Legend. Each certificate representing any shares of capital stock of the Company held by either party shall be endorsed with a legend in substantially the following form:

THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO CERTAIN VOTING REQUIREMENTS AND OTHER RESTRICTIONS SET FORTH IN A VOTING AGREEMENT BETWEEN THE HOLDER OF THIS CERTIFICATE AND CERTAIN OTHER PARTIES. TRANSFER OF THE SECURITIES IS SUBJECT TO THE RESTRICTIONS CONTAINED IN SUCH AGREEMENT.

- (c) <u>Removal of Transfer Restrictions</u>. Following the underwritten initial public offering of the Company's capital stock or such other date that the Company's capital stock is first listed on a national securities exchange or quoted on the over-the-counter market, Biologika shall be entitled to transfer shares of capital stock of the Company in "brokers' transactions" within the meaning of Section 4(4) of the Securities Act of 1933 or in transactions directly with a market maker, as that term is defined in Section 3(a)(38) of the Securities Exchange Act of 1934 (a "Public Sale Transaction") free from any restriction hereunder, subject to the following conditions:
  - (i) Biologika shall first deliver to BioPharm a written notice (the "First Offer Notice"), which First Offer Notice shall be irrevocable for a period of 7 days after receipt thereof, offering to sell to BioPharm at Fair Market Value (as defined below) all of such shares of capital stock of the Company that Biologika desires to sell.

- (ii) BioPharm shall have the right and option to notify Biologika, in a writing delivered within 7 days of receipt of the First Offer Notice, of its election to purchase all or any portion of the shares offered under the First Offer Notice at Fair Market Value and consummate such purchase within 7 days thereafter. Any shares so acquired from Biologika shall no longer be subject to this Agreement.
- (iii) If BioPharm declines to purchase all or any portion of the shares subject to the First Offer Notice, Biologika shall have the right to sell such shares in a Public Sale Transaction free from any restriction hereunder, including but not limited to the legend set forth in Section 5(b) above. Any shares not sold in accordance with the procedure set forth in this Section 5 shall remain subject to this Agreement.
- (iv) "Fair Market Value" of a share of capital stock of the Company as of a specified date for the purposes of this Section 5 shall mean the closing price of a share of such capital stock on the principal securities exchange on which such shares are traded on the day immediately preceding the date as of which Fair Market Value is being determined, or on the next preceding date on which such shares are traded if no shares were traded on such immediately preceding day, or if the shares are not traded on a securities exchange, Fair Market Value shall be deemed to be the average of the high bid and low asked prices of the shares in the over-the-counter market on the day immediately preceding the date as of which Fair Market Value is being determined or on the next preceding date on which such high bid and low asked prices were recorded.
- 6. Additional Shares. If, after the effective date hereof, either party or any of its affiliates acquires beneficial or record ownership of any additional shares of capital stock of the Company (any such shares, "Additional Shares"), including, without limitation, upon exercise of any option, warrant or right to acquire shares of capital stock of the Company or through any stock dividend or stock split, the provisions of this Agreement shall thereafter be applicable to such Additional Shares as if such Additional Shares had been held by such party as of the effective date hereof. The provisions of the immediately preceding sentence shall be effective with respect to Additional Shares without action by any person or entity immediately upon the acquisition by such party or its affiliates of beneficial ownership of such Additional Shares. Such Party shall cause any affiliate that acquires Additional Shares to enter into a written joinder to this Agreement in form and substance satisfactory to the other party.
- 7. <u>Termination</u>. It is the intention of the parties that this Agreement shall survive the initial public offering of the Company and continue in force at any time when the Company is a public reporting company. This Agreement shall automatically terminate on the seventh (7th) anniversary of the effective date hereof. Upon the termination of this Agreement, except as otherwise set forth herein, the restrictions and obligations set forth herein shall terminate and be of no further effect, except that such termination shall not affect rights perfected or obligations incurred under this Agreement prior to such termination, and the parties shall each be entitled to receive certificate(s) representing such holder's shares without the legend required by Section 5 herein upon the surrender of the certificate(s) representing such shares to the Company.

#### 8. Miscellaneous.

- (a) <u>Binding Effect</u>. This Agreement and all the provisions hereof shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by any of the parties hereto without the prior written consent of the other parties. The parties hereto agree to cause their affiliates to agree in writing to be bound by the terms of this Agreement prior to, or immediately upon, the acquisition of shares by such affiliates.
- (b) <u>Amendments</u>. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by each of the parties hereto. However, any party may waive any condition to the obligations of any other party hereunder.
- (c) Equitable Relief. The parties agree that it is impossible to determine the monetary damages which would accrue to any party by reason of the failure of any party to perform any of its obligations under this Agreement requiring the performance of an act other than the payment of money only. Each party shall be entitled to enforce its rights under this Agreement specifically and to exercise all other rights existing in its favor. The parties hereto agree and acknowledge that money damages may not be an adequate remedy for any breach of the provisions of this Agreement and that each party may in its sole discretion apply to any court of law or equity of competent jurisdiction for specific performance and/or injunctive relief (without posting a bond or other security) in order to enforce or prevent any violation of the provisions of this Agreement. In the event of a breach or threatened breach by a party of any of the provisions of this Agreement, the other parties hereto shall be entitled to an injunction restraining such party from any such breach, and each party hereto waives any claim or defense that there is an adequate remedy at law for such breach or threatened breach. The availability of such remedies shall not prohibit any party from pursuing any other remedies for such breach or threatened breach, including the recovery of damages from a breaching party.
- (d) Notices. All notices, requests, demands and other communications required or permitted hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand, facsimile or mail, certified or registered mail (return receipt requested) with postage prepaid:
  - (i) If to BioPharm, to:

BioPharm, LLC 3500 N. Martin Luther King, Jr. Blvd. Building One, 3<sup>rd</sup> Floor Lansing, MI 48906 Attn: Robert G. Kramer, Sr.

(ii) If to Biologika, to:

Mauro I. Gibellini 300 Professional Drive Gaithersburg, Maryland 20879 or to such other address as any party may have furnished to the others in writing in accordance herewith.

### (e) Arbitration.

Any controversy or claim arising out of or relating to this Agreement will be settled by arbitration in accordance with the following provisions:

- (i) <u>Disputes Covered</u>. The agreement of the parties to arbitrate covers all disputes of every kind relating to or arising out of this Agreement, <u>except</u> disputes determined not to be arbitratable by the arbitrator. Disputes include actions for breach of contract with respect to this Agreement or the related agreement. In addition, the arbitrator selected according to procedures set forth below will determine the arbitrability of any matter brought to them, including their authority to impose equitable remedies that may be requested in good faith by a party, and their decision will be final and binding on the parties.
  - (ii) Venue. The venue for the arbitration will be in Washington, D.C.
  - (iii) Law. The governing law for the arbitration will be the law of the State of Delaware without reference to its conflicts of laws provisions.
  - (iv) Selection. There will be a single arbitrator appointed by the American Arbitration Association.
  - (v) Administration. The arbitration will be administered by the American Arbitration Association.
- (vi) <u>Rules</u>. The rules of arbitration will be the Commercial Arbitration Rules of the American Arbitration Association, as modified by any other instructions that the parties may agree upon at the time. If there is any conflict between the Commercial Arbitration Rules and the provisions of this section, the provisions of this section will prevail.
- (vii) Substantive Law. The arbitrator will be bound by and shall strictly enforce the terms of this Agreement and may not limit, expand or otherwise modify its terms. The arbitrator will make a good faith effort to apply substantive applicable law, but an arbitration decision shall not be subject to review because of errors of law.
- (viii) <u>Decision</u>. The arbitrator's decision will provide a reasoned basis for the resolution of each dispute and for any award. The arbitrator will not have power to award damages in connection with any dispute in excess of actual compensatory damages.
- (ix) <u>Fees; Expenses</u>. Unless the arbitrator's decision otherwise directs each party will bear its own fees and expenses with respect to the arbitration and any proceeding related thereto and the parties will share equally the fees and expenses of the American Arbitration Association and the arbitrator.
- (x) Remedies; Award. The arbitrator will have power and authority to award any remedy or judgment that could be awarded by a court of law in the District of Columbia, subject to the limitations set forth in this Agreement. The award rendered by arbitrator will be

final and binding upon the parties, and judgment upon the award may be entered in any court of competent jurisdiction in the United States.

- (f) <u>Applicable Law</u>. This Agreement and the legal relations among the parties hereto arising from this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without reference to or application of any conflicts of law principles.
- (g) Counterparts; Facsimile Execution. This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed original but all of which shall constitute one and the same instrument. Facsimile execution and delivery of this Agreement is legal, valid and binding for all purposes.
- (h) Entire Agreement. This Agreement constitutes the entire agreement and understanding of the parties hereto in respect of the subject matter contained herein. There are no restrictions, promises, warranties, covenants or undertakings, other than those expressly set forth or referred to herein. This Agreement supersedes all prior agreements and understandings among the parties with respect to such subject matter.
- (i) <u>Severability of Provisions</u>. The provisions of this Agreement be enforced to the fullest extent permissible under the law and public policies applied in each jurisdiction in which enforcement is sought. Accordingly, if any provision of this Agreement would be held to be invalid, prohibited or unenforceable for any reason, such provision, as to such jurisdiction, shall be ineffective, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision. Notwithstanding the foregoing, if such provision could be more narrowly drawn so as to be invalid, prohibited or unenforceable, it shall be so narrowly drawn, without invalidating the remaining provisions of this Agreement or affecting the validity or enforceability of such provision.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and made and entered into effective as of the date first set forth above.

### BIOPHARM, L.L.C.

By: /s/ Robert G. Kramer

Name: Robert G. Kramer

Title:

### BIOLOGIKA, L.L.C.

By: /s/ Mauro Gibellini

Name: Mauro Gibellini Title: General Manager

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### VOTING AGREEMENT

VOTING AGREEMENT, effective as of June 30, 2004 (this "Agreement"), by and among the stockholders of Emergent BioSolutions Inc. (the "Company") named on Schedule 1 attached hereto (each a "Stockholder" and collectively, the "Stockholders").

#### BACKGROUND

The Stockholders, collectively, are the beneficial and record owners of 6,487,950 shares (the "Shares") of the voting class A common stock ("Class A Stock") of the Company and they hold the Shares in the amounts specified opposite their respective names on Schedule 1. The Stockholders desire to enter into this voting agreement in order to codify their mutual understanding regarding the voting of the Class A Stock and any other voting capital stock of the Company that may hereafter be held by a Stockholder.

### AGREEMENT

NOW THEREFORE, in consideration of the mutual agreements contained herein and other good and adequate consideration, the Stockholders hereby agree as follows:

- 1. Representations and Warranties. Each Stockholder hereby represents and warrants to the other Stockholders that:
  - (a) it has the requisite power and authority to enter into and perform this Agreement;
  - (b) its execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action;
  - (c) this Agreement has been duly executed by an authorized officer of such party; and
- (d) the performance of this Agreement by it will not require it to obtain the consent, waiver or approval of any person and will not violate, result in a breach of, or constitute a default under any statute, regulation, agreement, judgment, consent, or decree by which it is bound.
- 2. Quorum. Each Stockholder shall, at any time it owns any capital stock of the Company and such capital stock has rights to vote at any annual, special or other general meeting of the Company's stockholders, and at any adjournment or adjournments thereof, cause all such capital stock to be present in person or by proxy at such meeting for purposes of determining whether a quorum is present at any such meeting.
- 3. <u>Voting</u>. Each Stockholder shall, at any time it owns any shares of capital stock of the Company and such capital stock has rights to vote at any annual, special or other general meeting or pursuant to a written resolution of the Company's stockholders, vote such shares for and against and abstain from voting with respect to any proposal as directed by a majority in interest

of the Stockholders as measured by the percentage of ownership of the Company shown from time to time on <u>Schedule 1</u>. Each Stockholder hereby appoints the General Manager of Intervac, LLC, with full power of substitution, to vote all shares of the Company's capital stock owned by each Stockholder in the manner described in the preceding sentence.

### 4. Transfer Restrictions; Legend.

- (a) <u>Transfer Restrictions</u>. Except as set forth in Section 4(b), each Stockholder hereby agrees that all transfers of the Company's capital stock made by it shall be made subject to this Agreement and any transfere will agree in writing to be bound by the terms and provisions of this Agreement as a condition precedent to any such transfer.
- (b) Exception. This Section 4 shall not apply to any transfer by a Stockholder of the Company's capital stock made pursuant to: (i) an effective registration statement filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "1933 Act"); or (ii) Rule 144 promulgated under the 1933 Act.
  - (c) Legend. Each certificate representing any shares of capital stock of the Company held by a Stockholder shall be endorsed with a legend in substantially the following form:

THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO CERTAIN VOTING REQUIREMENTS AND OTHER RESTRICTIONS SET FORTH IN A VOTING AGREEMENT BETWEEN THE HOLDER OF THIS CERTIFICATE AND CERTAIN OTHER PARTIES. TRANSFER OF THE SECURITIES IS SUBJECT TO THE RESTRICTIONS CONTAINED IN SUCH AGREEMENT.

- 5. Additional Shares. If, after the effective date hereof, a Stockholder or any of its affiliates acquires beneficial or record ownership of any additional shares of capital stock of the Company (any such shares, "Additional Shares"), including, without limitation, upon exercise of any option, warrant or right to acquire shares of capital stock of the Company or through any stock dividend or stock split, the provisions of this Agreement shall thereafter be applicable to such Additional Shares as if such Additional Shares had been held by such party as of the effective date hereof and Schedule 1 shall be modified accordingly. The provisions of the immediately preceding sentence shall be effective with respect to Additional Shares without action by any person or entity immediately upon the acquisition by such Stockholder or its affiliates of beneficial ownership of such Additional Shares. Such Stockholder shall cause any affiliate that acquires Additional Shares to enter into a written joinder to this Agreement in form and substance satisfactory to the other party. This Section 5 shall terminate as to a Stockholder on the first anniversary following the date on which such Stockholder and its affiliates no longer hold any shares of capital stock of the Company for a continuous twelve month period.
- 6. <u>Termination</u>. It is the intention of the Stockholders that this Agreement shall survive any effective registration statement filed with the Securities and Exchange Commission under the 1933 Act and shall continue for so long as the Company is a reporting company under the Securities Exchange Act of 1934, as amended. This Agreement shall automatically terminate on the tenth (10<sup>th</sup>) anniversary of the effective date hereof. Upon the termination of this Agreement,

except as otherwise set forth herein, the restrictions and obligations set forth herein shall terminate and be of no further effect, except that such termination shall not affect rights perfected or obligations incurred under this Agreement prior to such termination, and the Stockholders shall each be entitled to receive certificate(s) representing such Stockholder's shares without the legend required by Section 4 herein upon the surrender of the certificate(s) representing such shares to the Company.

### 7. Miscellaneous.

- (a) <u>Binding Effect</u>. This Agreement and all the provisions hereof shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by any of the parties hereto without the prior written consent of the other parties. The parties hereto agree to cause their affiliates to agree in writing to be bound by the terms of this Agreement prior to, or immediately upon, the acquisition of shares by such affiliates.
- (b) <u>Amendments</u>. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by each of the parties hereto. However, any party may waive any condition to the obligations of any other party hereunder.
- (c) Equitable Relief. The parties agree that it is impossible to determine the monetary damages which would accrue to any party by reason of the failure of any party to perform any of its obligations under this Agreement requiring the performance of an act other than the payment of money only. Each party shall be entitled to enforce its rights under this Agreement specifically and to exercise all other rights existing in its favor. The parties hereto agree and acknowledge that money damages may not be an adequate remedy for any breach of the provisions of this Agreement and that each party may in its sole discretion apply to any court of law or equity of competent jurisdiction for specific performance and/or injunctive relief (without posting a bond or other security) in order to enforce or prevent any violation of the provisions of this Agreement. In the event of a breach or threatened breach by a party of any of the provisions of this Agreement, the other parties hereto shall be entitled to an injunction restraining such party from any such breach, and each party hereto waives any claim or defense that there is an adequate remedy at law for such breach or threatened breach. The availability of such remedies shall not prohibit any party from pursuing any other remedies for such breach or threatened breach, including the recovery of damages from a breaching party.
- (d) Notices. All notices, requests, demands and other communications required or permitted hereunder shall be in writing and shall be deemed to have been duly given if delivered by hand, facsimile or mail, certified or registered mail (return receipt requested) with postage prepaid to the addresses of the Stockholders as specified on the signature pages hereto or to such other address as any party may have furnished to the others in writing in accordance herewith.

(e) Arbitration.

Any controversy or claim arising out of or relating to this Agreement will be settled by arbitration in accordance with the following provisions:

- (i) <u>Disputes Covered</u>. The agreement of the parties to arbitrate covers all disputes of every kind relating to or arising out of this Agreement, <u>except</u> disputes determined not to be arbitratable by the arbitrator. Disputes include actions for breach of contract with respect to this Agreement or the related agreement. In addition, the arbitrator selected according to procedures set forth below will determine the arbitrability of any matter brought to them, including their authority to impose equitable remedies that may be requested in good faith by a party, and their decision will be final and binding on the parties.
  - (ii) Venue. The venue for the arbitration will be in Washington, D.C.
  - (iii) Law. The governing law for the arbitration will be the law of the State of Delaware without reference to its conflicts of laws provisions.
  - (iv) Selection. There will be a single arbitrator appointed by the American Arbitration Association.
  - (v) Administration. The arbitration will be administered by the American Arbitration Association.
- (vi) <u>Rules</u>. The rules of arbitration will be the Commercial Arbitration Rules of the American Arbitration Association, as modified by any other instructions that the parties may agree upon at the time. If there is any conflict between the Commercial Arbitration Rules and the provisions of this section, the provisions of this section will prevail.
- (vii) Substantive Law. The arbitrator will be bound by and shall strictly enforce the terms of this Agreement and may not limit, expand or otherwise modify its terms. The arbitrator will make a good faith effort to apply substantive applicable law, but an arbitration decision shall not be subject to review because of errors of law.
- (viii) <u>Decision</u>. The arbitrator's decision will provide a reasoned basis for the resolution of each dispute and for any award. The arbitrator will not have power to award damages in connection with any dispute in excess of actual compensatory damages.
- (ix) Fees; Expenses. Unless the arbitrator's decision otherwise directs each party will bear its own fees and expenses with respect to the arbitration and any proceeding related thereto and the parties will share equally the fees and expenses of the American Arbitration Association and the arbitrator.
- (x) Remedies; Award. The arbitrator will have power and authority to award any remedy or judgment that could be awarded by a court of law in the District of Columbia, subject to the limitations set forth in this Agreement. The award rendered by arbitrator will be final and binding upon the parties, and judgment upon the award may be entered in any court of competent jurisdiction in the United States.

- (f) <u>Applicable Law</u>. This Agreement and the legal relations among the parties hereto arising from this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without reference to or application of any conflicts of law principles.
- (g) Counterparts; Facsimile Execution. This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed original but all of which shall constitute one and the same instrument. Facsimile execution and delivery of this Agreement is legal, valid and binding for all purposes.
- (h) Entire Agreement. This Agreement constitutes the entire agreement and understanding of the parties hereto in respect of the subject matter contained herein. There are no restrictions, promises, warranties, covenants or undertakings, other than those expressly set forth or referred to herein. This Agreement supersedes all prior agreements and understandings among the parties with respect to such subject matter.

{Remainder of this page intentionally left blank}

\* \* \* \*

IN WITNESS WHEREOF, the undersigned Stockholder has executed this Voting Agreement effective as of the date first above written.

# INTERVAC, LLC

By: /s/ Fuad El-Hibri
Name: Fuad El-Hibri
Title: General Manager

# Address for Notices:

Intervac, LLC 1684 East Gude Drive Suite 301 Rockville, MD 20850 Attn: Fuad El-Hibri

IN WITNESS WHEREOF, the undersigned Stockholder has executed this Voting Agreement effective as of the date first above written.

# BIOPHARM, LLC

By: /s/ Robert G. Kramer
Name: Robert G. Kramer
Title: General Manager

# Address for Notices:

BioPharm, LLC 3500 N. Martin Luther King, Jr. Blvd. Building One, 3rd Floor Lansing, MI 48906 Attn: Robert G. Kramer

IN WITNESS WHEREOF, the undersigned Stockholder has executed this Voting Agreement effective as of the date first above written.

# MICHIGAN BIOLOGICS PRODUCTS, INC.

By: /s/ Robert C. Myers
Name: Robert C. Myers
Title: President

## Address for Notices:

Michigan Biologics Products, Inc. 3500 N. Martin Luther King, Jr. Blvd. Building One, 3rd Floor Lansing, MI 48906 Attn: Robert C. Myers

IN WITNESS WHEREOF, the undersigned Stockholder has executed this Voting Agreement effective as of the date first above written.

# BIOVAC, LLC

By: /s/ Fuad El-Hibri
Name: Fuad El-Hibri
Title: General Manager

# Address for Notices:

BioVac, LLC 1684 East Gude Drive Suite 301 Rockville, MD 20850 Attn: Fuad El-Hibri

IN WITNESS WHEREOF, the undersigned Stockholder has executed this Voting Agreement effective as of the date first above written.

# BIOLOGIKA, LLC

By: /s/ Mauro Gibellini
Name: Mauro Gibellini
Title: General Manager

## Address for Notices:

Biologika, LLC 3500 N. Martin Luther King, Jr. Blvd. Building One, 3rd Floor Lansing, MI 48906 Attn: Mauro Gibellini

IN WITNESS WHEREOF, the undersigned Stockholder has executed this Voting Agreement effective as of the date first above written.

# INTERVAC MANAGEMENT, LLC

By: /s/ Fuad El-Hibri
Name: Fuad El-Hibri
Title: General Manager

## Address for Notices:

Intervac Management, LLC 1684 East Gude Drive Suite 301 Rockville, MD 20850 Attn: Fuad El-Hibri

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IN WITNESS WHEREOF, the undersigned Stockholder has executed this Voting Agreement effective as of the date first above written.

# ARPI, LLC

By: /s/ Janice Mugriditchian
Name: Janice Mugriditchian
Title: General Manager

# Address for Notices:

ARPI, LLC 12001 Glen Road Potomac, MD 20854 Attn: Janice Mugriditchian

# SCHEDULE 1

# STOCKHOLDERS

## AS OF JUNE 30, 2004

Class A Shares	Number of Shares	Percent of Total Shares
1. Intervac, LLC	2,890,000	44.54%
2. BioPharm, LLC	1,412,896	21.78%
3. Michigan Biologics Products, Inc.	672,500	10.36%
4. BioVac, LLC	555,822	8.57%
5. Biologika, LLC	477,941	7.37%
6. Intervac Management, LLC	250,000	3.85%
7. ARPI, LLC	228,791	3.53%
Total =	6,487,950	100%

### EMERGENT BIOSOLUTIONS INC.

### EMPLOYEE STOCK OPTION PLAN

### (as amended and restated effective January 26, 2005)

BioPort Corporation, a Michigan corporation, previously adopted the BioPort Corporation Employee Stock Option Plan, as amended from time to time. Effective June 30, 2004, the Company has assumed the BioPort Corporation Employee Stock Option Plan, as amended and restated herein, and assumed all Options previously granted under that plan that have not been exercised on or before June 30, 2004. Options assumed by the Company are converted to Options to acquire Emergent Common Stock, and the Optionees are entitled to receive, upon Option exercise, one share of Common Stock for every share of BioPort class B common stock they would have otherwise been entitled to receive upon exercise of the Option before assumption.

When the Options were initially granted, they were intended to qualify as Incentive Stock Options. Certain Options would have expired on June 30, 2004, but are being extended in connection with this assumption. Those Options being extended will be considered Nonqualified Stock Options after June 30, 2004. Other Options are being assumed but not extended. Options which are being assumed but not extended will continue to be considered Incentive Stock Options. The assumption by the Company of this Plan and the options previously granted under the BioPort Corporation Employee Stock Option Plan are not intended to confer any additional benefits to Optionees holding those Options. The Company intends that the Options being assumed and not extended will continue to qualify as Incentive Stock Options after their assumption by the Company and the Company will interpret this Plan in a manner consistent with that intention.

### 1. Purpose

This Emergent BioSolutions Inc. Employee Stock Option Plan, sponsored by EMERGENT BIOSOLUTIONS INC., a Delaware corporation, is intended to provide incentive to persons who are Employees, and to promote the success of the Company's business, by providing those Employees with opportunities to purchase shares of the Company's Class B nonvoting common stock under (a) Incentive Stock Options, and (b) Nonqualified Stock Options.

### 2. Definitions

As used in this Plan, the following words and phrases shall have the meanings indicated:

- (a) "Board" shall mean the Company's board of directors
- (b) "Code" shall mean the Internal Revenue Code of 1986, as amended.
- (c) "Committee" shall mean the Company's Compensation Committee, or, in the absence of a Compensation Committee, the Board.

- (d) "Common Stock" shall mean the Class B nonvoting common stock of the Company.
- (e) "Company" shall mean Emergent BioSolutions Inc., a Delaware corporation, its successors and assigns.
- (f) "Employee" means an individual in the regular employment of the Employer and classified by the Employer as a common law employee and who is on the payroll of the Employer, excluding an independent contractor and any individual not reported through the payroll system of the Employer as a common law employee, even if that individual is subsequently recharacterized as a common law employee by a court of competent jurisdiction, appropriate administrative agency, the Employer, or any other person or entity.
  - (g) "Employer" shall mean the Company and any "parent corporation" or "subsidiary corporation" of the Company as defined in Sections 424(e) and 424(f) of the Code, respectively.
- (h) "Fair Market Value" per share as of a particular date shall mean (i) the closing sales price per share of Common Stock on the principal national securities exchange, if any, on which the shares of Common Stock shall then be listed for the last preceding date on which there was a sale of such Common Stock on such exchange, or (ii) if the shares of Common Stock are not then listed on a national securities exchange, the last sales price per share of Common Stock entered on a national inter-dealer quotation system, or (iii) if no closing or last sales price per share of Common Stock is entered on a national inter-dealer quotation system, the average of the closing bid and asked prices for the shares of Common Stock in the over-the-counter market for the last preceding date on which there was a quotation for such Common Stock in such market, or (iv) if no price can be determined under the preceding alternatives, then the price per share as most recently determined by the Board based on all the relevant facts and circumstances, including, but not limited to, any discount for any minority interest, lack of marketability, and illiquidity of the shares. The Board shall make such determinations of value in accordance with (iv) at least once annually; provided that, if such determination is not made by the Board in any given year, then the most recent determination of value shall continue in effect. Notwithstanding any provision of the Plan to the contrary, no determination made with respect to the Fair Market Value of Common Stock subject to an Option shall be inconsistent with Section 422 of the Code and the regulations the requireder.
  - (i) "Grant Date" means the date on which the Committee adopts a resolution expressly granting an Option.
  - (j) "Incentive Stock Option" means any Option to purchase Common Stock which is intended to qualify as an incentive stock option within the meaning of Section 422 of the Code.
  - (k) "Nonqualified Stock Option" means any Option to purchase Common Stock which is not intended to qualify as an Incentive Stock Option
  - (I) "Option" shall mean any option granted under this Plan, and any option originally granted by BioPort Corporation, and assumed by the Company.

- (m) "Option Agreement" means the written agreement evidencing the grant of an Option in such form as the Committee may from time to time prescribe.
- (n) "Option Exercise Price" shall have the meaning assigned to such term in Section 7(b).
- (o) "Optionee" shall mean any person to whom an Option is granted under this Plan.
- (p) "Plan" shall mean this Emergent BioSolutions Inc. Employee Stock Option Plan, as set forth in this plan document and as may be amended from time to time.
- (q) "Plan Action" shall have the meaning assigned to such term in Section 9(a).
- (r) "Ten Percent Shareholder" shall mean an Optionee who, at the time an Option is granted, owns directly or indirectly (within the meaning of Section 424(d) of the Code), stock possessing more than ten percent of the total combined voting power of all classes of stock of the Employer.
- (s) "Termination of Employment" shall mean termination of employment with the Employer as determined by the Committee. The Committee may in its discretion determine whether any leave of absence constitutes a Termination of Employment for purposes of this Plan and the impact, if any, of any such leave of absence on Options made under this Plan.

#### 3. General Administration

- (a) This Plan shall be administered by the Committee.
- (b) The Board may at any time and from time to time provide the Committee with instructions regarding the specific terms and conditions attributable to the Options to be granted to identified Optionees. In addition, the Board may provide general recommendations or guidelines to the Committee regarding the terms and conditions of Options to be granted with respect to particular unfilled job slots or Options to be granted among general categories of Employees. The Committee shall comply with any such instructions and shall consider in good faith any such recommendations or guidelines in developing its own decisions as to the issuance of Options in situations where the Board has not delivered specific instructions. Subject to the above-referenced authority of the Board, the Committee shall have the authority (i) to exercise all of the powers granted to it under this Plan, (ii) to construe, interpret and implement this Plan and any Option Agreements executed pursuant to Section 7 below, (iii) to prescribe, amend and rescind rules and regulations relating to this Plan, including rules governing the Committee's own operations, (iv) to make all determinations necessary or advisable in administering this Plan, (v) to correct any defect, supply any omission and reconcile any inconsistency in this Plan; (vi) to select the Employees to be granted Options under the Plan; (vii) to fix the number of shares granted under each Option; (viii) to determine the exercise price of Options granted; and (ix) to set the terms and conditions of each Option.
- (c) Actions of the Committee shall be taken by the affirmative vote of a majority of the Committee members. Any action may be taken by an instrument signed by a majority of the Committee members, including counterpart signatures, and action so taken shall be fully as

effective as if such action had been taken by a vote at a Committee meeting.

- (d) The determination of the Committee on all matters relating to this Plan or any Option Agreement shall be final, binding and conclusive on all persons.
- (e) No Committee member shall be liable for any action or determination made in good faith with respect to this Plan, including any Option.
- (f) Notwithstanding any provision of the Plan to the contrary, after December 31, 2004, the Board and the Committee may only grant those Options that either comply with the applicable requirements of Section 409A of the Code, or do not result in the deferral of compensation within the meaning of Section 409A of the Code.

### 4. Granting of Options and Term of Plan

Options may be granted from time to time within a period of five (5) years from the date of the Company's assumption of this Plan, which is June 30, 2004, unless the Plan is terminated sooner.

### 5. Eligibility

Subject to the authority of the Board described in Section 3(b), the Committee may grant Options in such amounts and to such Employees as the Committee determines in its sole discretion.

#### 6. Common Stock

- (a) The stock subject to the Options shall be Common Stock.
- (b) Subject to adjustment as described in Sections 6(c) and 6(f), the total number of shares of Common Stock which may be issued under options shall not exceed 1,250,000. Common Stock issued pursuant to this Plan may be authorized but unissued Common Stock or authorized and issued Common Stock held in the Company treasury or acquired by the Company for the purposes of this Plan. The Committee may direct that any certificate evidencing Common Stock pursuant to this Plan shall bear a legend setting forth such restrictions on transferability as may apply to such shares
- (c) If there is any change in the number of outstanding shares of Common Stock by reason of a stock dividend or distribution, stock split, reverse stock split, recapitalization, reclassification of shares, combination or exchange of shares, or by reason of any merger, consolidation, spinoff or other corporate reorganization in which the Company is the surviving corporation, the number of shares of Common Stock available for issuance both in the aggregate and with respect to each outstanding Option, and the purchase price per share under each outstanding Option, shall be equitably adjusted by the Committee, whose determination shall be final, binding and conclusive. In the event of any merger, consolidation or combination of the Company with or into another corporation (other than a merger, consolidation or combination in which the Company is the surviving corporation and which does not result in any reclassification or other change in the number of outstanding shares of Common Stock), each Optionee shall

have the right thereafter and during the term of each such Option to receive upon exercise (subject to the provisions of the Option Agreement) of such Option, for each share of Common Stock as to which the Option shall be exercised, the kind and amount of shares of the surviving or new corporation, cash, securities, evidence of indebtedness, other property or any combination thereof which would have been received upon such merger, consolidation or combination by the holder of one share of Common Stock immediately prior to such merger, consolidation or combination.

(d) Subject to adjustment from time to time to the extent consistent with this Section 6(d) and Section 424 of the Code, the maximum number of shares that may be issued under Incentive Stock Options is 1,250,000. Options granted under this Plan may be substituted or assumed in connection with mergers, reorganizations, separations, or other transactions to which Section 424(a) of the Code applies, provided such substitutions and assumptions are permitted by Section 424 of the Code and the regulations promulgated thereunder. The preceding sentence applies to Incentive Stock Options and Nonqualified Stock Options.

### (e) Company's Purchase Option.

- (1) Upon the occurrence of a Change In Control, the Company shall have the option to purchase and redeem from any Optionee, or executor or administrator or other duly appointed representative of such Optionee, all the Options owned by said Optionee or held for the benefit of said Optionee, for a purchase price equal to the difference between the Option Exercise Price and the Fair Market Value. In the event that the Company exercises its right to repurchase Optionee's Options, any unvested Options shall be deemed fully vested on the day preceding the date the Company exercises its repurchase option.
- (2) For purposes of this Section 6(e), a "Change In Control" shall be deemed to have occurred when any "person," including a "group," as such terms are defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended, and the rules promulgated thereunder (collectively, the "Exchange Act"), becomes the "beneficial owner" (as defined in Rule 13(d)-3 under the Exchange Act), directly or indirectly, whether by purchase or acquisition or agreement to act in concert or otherwise, of more than 50% of the outstanding voting common stock of the Company.
- (3) The aforesaid option contained in this Section 6(e) shall be exercised by the Compensation Committee by written notice to such Optionee, executor or administrator or other duly appointed representative of Optionee, at any time during the six month period following the date of the Change in Control or such longer period of time as is reasonable.
- (f) If any outstanding Option for any reason expires or is terminated without having been exercised in full, the Common Stock allocable to the unexercised portion of such Option shall (unless this Plan shall have been terminated) become available for subsequent grants of Options to other Employees. Shares of Common Stock purchased from Optionees in accordance with Section 6(e) or the shareholders agreement in Section 7(h) shall also become available for subsequent grants of Options to other Employees, but shall not increase the maximum number of

shares that may be issued under Incentive Stock Options.

### 7. Terms and Conditions of Options

Each Option granted shall be evidenced by an Option Agreement in such form as the Committee may from time to time prescribe. By accepting an Option, the Optione agrees that the Option shall be subject to the provisions of the terms of this Plan and the applicable Option Agreement. Options shall comply with and be subject to the following terms and conditions:

- (a) **Type of Options**. The Committee may grant Incentive Stock Options, Nonqualified Stock Options, or any combination of the two. Subject to Section 7(c), at the time of the grant of each Option, the Committee shall designate the Option in the Option Agreement as either an Incentive Stock Option or a Nonqualified Stock Option. An Option designated an Incentive Stock Option may, prior to its exercise, be changed to a Nonqualified Stock Option if the Optionee consents to the change; however, any change to extend the exercise period of an Incentive Stock Option pursuant to Section 7(e)(3) does not require the consent of the Optionee.
- (b) **Option Exercise Price**. Each Option shall state the option exercise price ("Option Exercise Price"), which for Options that are Incentive Stock Options shall be not less the 100% of the Fair Market Value of the shares of Common Stock on the Grant Date of the Option; provided, however, that in the case of an Incentive Stock Option granted to a Ten Percent Shareholder, the Option Exercise Price shall not be less than 110% of such Fair Market Value on the Grant Date of the Option. The Option Exercise Price for Nonqualified Stock Options shall not be less than 50% of the Fair Market Value of the shares of Common Stock on the Grant Date of the Option, unless otherwise approved by the Board.
- (c) Value of Common Stock. Options may be granted to any Optionee for Common Stock. To the extent that the aggregate Fair Market Value of the shares of Common Stock with respect to which Options designated as Incentive Stock Options are exercisable for the first time by an Optionee during any calendar year (under all plans of the Company) exceeds \$100,000, such excess Options, to the extent of the shares covered thereby in excess of the foregoing limitation, shall be treated as Nonqualified Stock Options. For this purpose, Options shall be taken into account in the order in which they were granted, and the Fair Market Value of the shares shall be determined as of the Grant Date of the relevant Option.
- (d) Medium and Time of Payment. An Option may be exercised, as to any or all full shares of Common Stock as to which the Option has become exercisable, by giving written notice of such exercise to the Company or its designee accompanied by payment of the Option Exercise Price. The notice shall identify the Option being exercised and specify the number of shares as to which such Option is being exercised. The notice of exercise, once given, shall be irrevocable. Prior to a Public Offering of Stock, the Option Exercise Price shall be paid in full, at the time of exercise, in United States dollars in cash or by check. After a Public Offering of Stock, the Option Exercise Price shall be paid in full, at the time of exercise, either: (i) in United States dollars in cash or by check; (ii) with the Committee's approval, surrendering Common Stock or delivering a properly executed form of attestation of ownership of Common Stock as the Committee may require (including withholding shares otherwise deliverable upon exercise of the Option) which have on the date of surrender or attestation a Fair Market Value in the

aggregate equal to such Option Exercise Price and that have been held by the Optionee for at least six months prior to the surrender or attestation; (iii) with the Committee's approval, by directing the Company to deduct from the shares issuable upon the exercise of an Option a number of whole shares having a Fair Market Value, as determined by the Committee, equal to the Option Exercise Price (an exercise in accordance with (iii) shall necessarily involve the surrender and cancellation of the Option with respect to the shares deducted); or (iv) with the Committee's approval, by any combination of (i) – (iii) above. A "Public Offering of Stock" shall be deemed to have occurred upon the effective date of a registration statement to sell common stock of the Company, of any class, on a national securities exchange or over the counter market.

### (e) Vesting, Term of Option and Exercise.

- (1) Each Option Agreement shall provide the applicable vesting and exercise schedule for the Option as determined in the discretion of the Committee. Each Option Agreement may contain a vesting or exercise schedule based on time or performance related goals.
- (2) Options shall be exercise beriod specified by the Committee in the Option Agreement; provided, however, that the exercise period shall be no more than five (5) years from the Grant Date thereof. The exercise period shall be subject to earlier termination as provided in Section 7(f) below.
- (3) Notwithstanding Section 7(e)(2) and any Option Agreement that provides to the contrary, any Option that has an exercise period that would otherwise expire on June 30, 2004, and has not been exercised on or before June 30, 2004, shall have its exercise period automatically extended to June 30, 2007 without any further action by the Company or the Optionee. The extension of the exercise period of any Option pursuant to this Section 7(e)(3) shall cause the Option to be considered a Nonqualified Stock Option after June 30, 2004.

#### (f) Termination of Employment; Death.

- (1) Upon an Optionee's Termination of Employment other than by death, or long-term disability (as defined in the Company's long-term disability plan) or termination without cause as determined by the Committee, any portion of an Option not theretofore exercised shall terminate simultaneously upon the Optionee's Termination of Employment, except to the extent otherwise provided in Section 7(f)(3).
- (2) Upon an Optionee's Termination of Employment by death or long-term disability or termination without cause, exercise must occur prior to 5:00 p.m. (Eastern Time) on the 90th day after the Termination of Employment (even if such date occurs after the date the Option would otherwise have expired but for this provision). Any exercise of an Option following an Optionee's death or long-term disability shall be made only by the Optionee's executor or administrator or other duly appointed representative, as the case may be, reasonably acceptable to the Committee, unless the Optionee's will specifically disposes of such Option, in which case such exercise shall be made only by

the recipient of such specific disposition. If an Optionee's legal representative or the recipient of a specific disposition under the Optionee's will is entitled to exercise any Option pursuant to the preceding sentence, such representative or recipient shall be bound by the provisions of this Plan and the applicable Option Agreement to which the Optionee's options are subject, and such representative or recipient must execute the then applicable shareholders agreement as a condition to the exercise of any such Option. Any portion of an Option not exercised in accordance with this Section 7(f)(2) shall terminate simultaneously upon the expiration of the applicable exercise period after Termination of Employment except to the extent otherwise provided in Section 7(f)(3).

- (3) The Committee may, in the applicable Option Agreement, waive or modify the application of any of the foregoing provisions of this Section 7, even though such waiver or modification may cause the Options granted under such Option Agreement to fail to qualify as Incentive Stock Options.
- (g) Nontransferability of Options. Options shall not be transferable other than by will or by the laws of descent and distribution, and Options may be exercised, during the lifetime of the Optionee, only by the Optionee or the Optionee's legal representative.
- (h) **Rights as a Shareholder and Execution of Shareholders Agreement**. An Optionee or a transferee of an Option shall have no rights as a shareholder with respect to any Common Stock covered by his Option until the date of the issuance of a stock certificate to him for such shares. No adjustments shall be made for dividends (ordinary or extraordinary, whether in cash, securities or other property) or distributions or other rights for which the record date is prior to the date such stock certificate is issued, except as provided in Section 6(c) above. Prior to the transfer to the Optionee of a certificate representing shares of Common Stock acquired pursuant to the exercise of an Option, the Company shall require the Optionee to become a party to the then current version of a shareholders agreement including a limitation on the transferability of shares of Common Stock and a right on the part of the Company to repurchase shares of Common Stock from its shareholders for Fair Market Value. A copy of such shareholders agreement shall be prepared and distributed to Optionee prior to the first date any Option granted hereunder first becomes exercisable. The form of shareholders agreement in effect as of the effective date of this Plan is attached hereto as Attachment A.
- (i) **Other Provisions**. The Option Agreements authorized under this Plan may contain such other provisions, including, without limitation: (i) the imposition of restrictions upon the exercise of an Option; and (ii) compliance with applicable federal and state laws, including securities laws, that the Committee shall deem advisable.

#### 8. Taxes

No shares shall be delivered under the Plan to any Optionee or other person until such Optionee or other person has made arrangements acceptable to the Committee for the satisfaction of any foreign, federal, state, or local income and employment tax withholding obligations, including, without limitation, obligations incident to the receipt of shares or the disqualifying disposition of shares received on exercise of an Incentive Stock Option. Upon exercise of an Option, the Company or its designee shall have the right to deduct from the shares issuable upon

the exercise of the Option, or to accept from Optionee (with the approval by the Company or its designee) the tender of, a number of whole shares having a Fair Market Value equal to all or any part of the federal, state, local and foreign taxes, if any, required by law to be withheld by the Company with respect to such Option or the shares acquired upon the exercise thereof. Alternatively or in addition, the Company or its designee, in its sole discretion, shall have the right to require Optionee, through payroll withholding, cash payment or otherwise, including by means of a cashless exercise, to make adequate provision for any such tax withholding obligations of the Company arising in connection with the Option, or the shares acquired upon the exercise thereof.

#### 0 Destrictions

The following rules shall apply in the event that the Company becomes publicly-traded or the rules are deemed by the Company to be appropriate to assure an exemption from any registration requirements.

- (a) If the Committee shall at any time determine that any Consent (as hereinafter defined) is necessary or desirable as a condition of, or in connection with, the granting of any Option, the issuance or purchase of Common Stock or other rights thereunder, or the taking of any other action thereunder (each such action being hereinafter referred to as a "Plan Action"), then such Plan Action shall not be taken, in whole or in part, unless and until such Consent shall have been effected or obtained to the Committee's full satisfaction.
- (b) The term "Consent" as used herein with respect to any Plan Action means (i) any and all listings, registrations or qualifications in respect thereof upon any inter-dealer quotation system of a registered national securities association or any national securities exchange or under any federal, state or local law, rule or regulation, (ii) any and all written agreements and representations by the Optionee with respect to the disposition of Common Stock, or with respect to any other matter, which the Committee shall deem necessary or desirable to comply with the terms of any such listing, registration or qualification, or to obtain an exemption from the requirement that any such listing, qualification or registration, be made, and (iii) any and all consents, clearances and approvals in respect of a Plan Action by any governmental or other regulatory bodies.
- (c) In furtherance of the foregoing, at the time of any exercise of an Option, the Committee may, if it shall determine it necessary or desirable for any reason, require the Optionee as a condition to the exercise thereof, to deliver to the Committee a written representation of the Optionee's present intention to purchase the Common Stock for investment and not for distribution. If such representation is required to be delivered, an appropriate legend may be placed upon each certificate delivered to the Optionee upon his exercise of part or all of an Option and a stop transfer order may be placed with the transfer agent. Each such Option shall also be subject to the requirement that, if at any time the Committee determines, in its discretion, that either (i) the listing, registration or qualification of Common Stock subject to an Option upon any securities exchange, inter-dealer quotation system or under any state, federal or foreign law, or (ii) the consent or approval of any governmental regulatory body is necessary or desirable as a condition of, or in connection with, the issue or purchase of Common Stock thereunder, the Option may not be exercised in whole or in part unless such listing, registration,

qualification, consent or approval shall have been effected or obtained free of any conditions not acceptable to the Committee. The Committee shall not have the power to require or oblige the Company to register any Common Stock subject to an Option and any requirement imposed by the Committee relating to the registration of Common Stock shall not bind the Company to cause the registration of such Common Stock.

### 10. Savings Clause

Notwithstanding any other provision hereof, this Plan is intended to qualify as a plan pursuant to which Incentive Stock Options may be granted under Section 422 of the Code. If this Plan or any provision of this Plan shall be held to be invalid or to fail to meet the requirements of Section 422 of the Code or the regulations promulgated thereunder, such invalidity or failure shall not affect the remaining parts of this Plan, but rather it shall be construed and enforced as if this Plan or the affected provision thereof, as the case may be, complied in all respects with the requirements of Section 422 of the Code.

### 11. Nature of Payments

- (a) All Options granted shall be in consideration of services performed for the Company by the Optionee.
- (b) All Options granted shall constitute a special incentive payment to the Optionee and shall not be taken into account in computing the amount of salary or compensation of the Optionee for the purpose of determining any benefits under any pension, retirement, profit-sharing, bonus, life insurance or other benefit plan of the Company or under any agreement between the Company and the Optionee, unless such plan or agreement specifically otherwise provides.
- (c) The Plan shall not confer upon any Optionee any right with respect to continuation of employment with the Company, nor shall it interfere in any way with his or her right or the Company's right to terminate his or her employment at any time, with or without cause.

### 12. Non-Uniform Determinations

The determinations of the Committee and the Board under this Plan need not be uniform and may be made selectively among persons who receive, or are eligible to receive, Options (whether or not such persons are similarly situated).

### 13. Other Payments or Options

Nothing contained in this Plan shall be deemed in any way to limit or restrict the Company from making any option to purchase Common Stock or payment to any person under any other plan, arrangement or understanding, whether now existing or hereafter in effect.

### 14. Section Readings

The section headings contained herein are for the purpose of convenience only and are not intended to define or limit the contents of said sections.

### 15. Amendment and Termination

- (a) The Board may from time to time suspend, discontinue, revise or amend this Plan in any respect whatsoever, provided that: (i) the Board shall consider the impact of Section 409A of the Code on any Plan revision or amendment; and (ii) any amendment that would increase the number of shares which may be issued under this Plan shall be subject to the approval of the holders of a majority of outstanding voting common stock at a meeting of shareholders at which a quorum is present or by written consent of a majority of outstanding voting common stock. In addition, no such amendment shall materially impair any rights or materially increase any obligations of an Optionee under an outstanding Option without the consent of the Optionee (or, upon the Optionee's death or adjudication of mental incapacity, the person having the right to exercise the Option).
- (b) The Committee may cancel any outstanding Option and grant a new Option in substitution therefore, provided that the Committee shall consider the impact of Section 409A of the Code on any such cancellation and substitution. The Committee also may amend any outstanding Option Agreement, including any amendment which would: (i) accelerate the time or times at which the Option becomes unrestricted or may be exercised; (ii) waive or amend any goals, restrictions or conditions set forth in the Option Agreement; or (iii) waive or amend the operation of Section 7(f) above with respect to the termination of the Option upon Termination of Employment; provided the Committee shall consider the impact of Section 409A of the Code on any such amendment. However, any such cancellation or amendment that materially impairs the rights or materially increases the obligations of an Optionee under an outstanding Option shall be made only with the consent of the Optionee (or, upon the Optionee's death, the person having the right to exercise the Option).

### 16. Governing Law

The Plan and all Agreements shall be construed in accordance with and governed by the laws of the State of Delaware without regard to its conflict of laws principles. As approved by the Board of Directors of Emergent BioSolutions Inc. this 26th day of January 2005.

# EMERGENT BIOSOLUTIONS INC. DIRECTOR STOCK OPTION AGREEMENT

A Stock Option award (hereinafter, "Stock Option" or "Option") is hereby granted by Emergent BioSolutions Inc., a Delaware corporation ("Company"), to the Director named below ("Optionee"), for and with respect to the Class B nonvoting common stock of the Company ("Common Stock"), subject to the terms and conditions contained in this Agreement ("Option Agreement").

#### 1. Grant of Options

Subject to the provisions set forth herein, and in consideration of the agreements of Optionee herein provided, the Company hereby grants to Optionee a Stock Option to purchase from the Company the number of shares of Common Stock, at the purchase price per share ("Option Exercise Price") and on the schedule, all as set forth below. Such Stock Option is sometimes referred to herein as the "Award." At the time of exercise of the Stock Option, payment of the purchase price must be made in cash or such other form of consideration permitted in this Option Agreement.

The Option is not intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended ("Code").

Name of Optionee

Number of Shares Subject to Stock Option:

Option Exercise Price Per Share:

Date of Grant:

Expiration Date:

### 2. General Administration

The Company's board of directors ("Board") has the authority to construe, interpret and implement this Option Agreement. The determination of the Board on all matters relating to this Option Agreement shall be final, binding and conclusive on all persons. No Board member shall be liable for any action or determination made in good faith with respect to this Option Agreement. This Option Agreement is not intended to provide deferred compensation within the meaning of Code section 409A and shall be interpreted in a manner to avoid the application of that section. Any provision in this Option Agreement that would necessarily result in the application of Code section 409A shall be null and void.

## 3. Vesting Schedule and Conditions to Exercisability of Options:

Vesting Schedule	Date First Exercisable	Expiration	Date	
33 1/3%		[	]	
33 1/3%	[ ]	]	1	
33 1/3%	[ ]	[	]	

Any Option not exercised by 5:00 p.m. Eastern Standard Time on [ ] shall expire at such time. The exercise of all or any portion of the Award is conditioned upon the acceptance by Optionee of the terms hereof as evidenced by his execution of this Option Agreement in the space provided therefore at the end hereof and the return of an executed copy to the Secretary of the Company.

The Option may be exercised, as to any or all full shares of Common Stock as to which the Option has become exercisable, by giving written notice of such exercise to the Company or its designee accompanied by payment of the Option Exercise Price, (a) by delivering such notice at the principal executive offices of the Company no later than the expiration date, or (b) by mailing such notice, postage prepaid, addressed to the Secretary of the Company at the Company's principal executive offices at least three business days prior to the expiration date. The notice shall identify the Option being exercised and specify the number of shares as to which such Option is being exercised. The notice of exercise, once given, shall be irrevocable.

Prior to a Public Offering of Stock, the Option Exercise Price shall be paid in full, at the time of exercise, in United States dollars in cash or by check. After a Public Offering of Stock, the Option Exercise Price shall be paid in full, at the time of exercise, either: (i) in United States dollars in cash or by check; (ii) with the Board's approval, surrendering Common Stock or delivering a properly executed form of attestation of ownership of Common Stock as the Board may require (including withholding shares otherwise deliverable upon exercise of the Option) which have on the date of surrender or attestation a Fair Market Value in the aggregate equal to such Option Exercise Price and that have been held by the Optionee for at least six months prior to the surrender or attestation; (iii) with the Board's approval, by directing the Company to deduct from the shares issuable upon the exercise of an Option a number of whole shares having a Fair Market Value, as determined by the Board, equal to the Option Exercise Price (an exercise in accordance with (iii) shall necessarily involve the surrender and cancellation of the Option with respect to the shares deducted); or (iv) with the Board's approval, by any combination of (i) (iii) above. A "Public Offering of Stock" shall be deemed to have occurred upon the effective date of a registration statement to sell common stock of the Company, of any class, on a national securities exchange or over the counter market.

For purposes of this Option Agreement, "Fair Market Value" per share as of a particular date shall mean (i) the closing sales price per share of Common Stock on the principal national securities exchange, if any, on which the shares of Common Stock shall then be listed for the last preceding date on which there was a sale of such Common Stock on such exchange, or (ii) if the shares of Common Stock are not then listed on a national securities exchange, the last sales price

per share of Common Stock entered on a national inter-dealer quotation system for the last preceding date on which there was a sale of such Common Stock on such national inter-dealer quotation system, or (iii) if no closing or last sales price per share of Common Stock is entered on a national inter-dealer quotation system, the average of the closing bid and asked prices for the shares of Common Stock in the over-the-counter market for the last preceding date on which there was a quotation for such Common Stock in such market.

#### 4. Cessation of Board Membership

- (a) Upon the Optionee's cessation of Board membership, as determined by the Board, other than by death, or long-term disability (as defined in the Company's long-term disability plan) or termination without cause as determined by the Board, any portion of an Option not theretofore exercised shall terminate simultaneously upon the Optionee's cessation of Board membership, except to the extent otherwise provided in Section 4(c).
- (b) Upon the Optionee's cessation of Board membership, as determined by the Board, by death or long-term disability or termination without cause, exercise must occur prior to 5:00 p.m. (Eastern Time) on the 90th day after the cessation of Board membership (even if such date occurs after the date the Option would otherwise have expired but for this provision). Any exercise of an Option following the Optionee's death or long-term disability shall be made only by the Optionee's executor or administrator or other duly appointed representative, as the case may be, reasonably acceptable to the Board, unless the Optionee's will specifically disposes of such Option, in which case such exercise shall be made only by the recipient of such specific disposition. If the Optionee's legal representative or the recipient of a specific disposition under the Optionee's will is entitled to exercise any Option pursuant to the preceding sentence, such representative or recipient shall be bound by the provisions of this Option Agreement to which the Optionee's Options are subject, and such representative or recipient must execute the then applicable stockholders' agreement as a condition to the exercise of any such Option. Any portion of an Option not exercised in accordance with this Section 4(b) shall terminate simultaneously upon the expiration of the applicable exercise period after cessation of Board membership, except to the extent otherwise provided in Section 4(c).
  - (c) The Board may waive or modify the application of any of the foregoing provisions of this Section 4.

### 5. Adjustment to Shares Subject to the Option and Company's Purchase Option

(a) If there is any change in the number of outstanding shares of Common Stock by reason of a stock dividend or distribution, stock split, reverse stock split, recapitalization, reclassification of shares, combination or exchange of shares, or by reason of any merger, consolidation, spin-off or other corporate reorganization in which the Company is the surviving corporation, the number of shares of Common Stock available for issuance both in the aggregate and with respect to each outstanding Option, and the purchase price per share under each outstanding Option, shall be equitably adjusted by the Board, whose determination shall be final, binding and conclusive. In the event of any merger, consolidation or combination of the Company with or into another corporation (other than a merger, consolidation or combination in which the Company is the surviving corporation and which does not result in any reclassification or other change in the number of outstanding shares of Common Stock), the Optionee shall have the right thereafter and during the term of each such Option to receive upon exercise (subject to the

provisions of the Option Agreement) of such Option, for each share of Common Stock as to which the Option shall be exercised, the kind and amount of shares of the surviving or new corporation, cash, securities, evidence of indebtedness, other property or any combination thereof which would have been received upon such merger, consolidation or combination by the holder of one share of Common Stock immediately prior to such merger, consolidation or combination; provided that any substitution or assumption of an Option in connection with a corporate transaction to which Treasury Regulation Section 1.424-1 would apply if the Option was an Incentive Stock Option under Code Section 422 shall comply with the requirements of Treasury Regulation Section 1.424.1.

- (b) Company's Purchase Option
- (1) Upon the occurrence of a Change In Control, the Company shall have the option to purchase and redeem from the Optionee, or executor or administrator or other duly appointed representative of such Optionee, all the Options owned by said Optionee or held for the benefit of said Optionee pursuant to this Option Agreement, for a purchase price equal to the difference between the Option Exercise Price and the Fair Market Value (as defined in Section 3). In the event that the Company exercises its right to repurchase Optionee's Options pursuant to this Section 5(b), any unvested Options shall be deemed fully vested on the day preceding the date the Company exercises its repurchase option.
- (2) For purposes of this Section 5(b), a "Change In Control" shall be deemed to have occurred when any "person," including a "group," as such terms are defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended, and the rules promulgated thereunder (collectively, the "Exchange Act"), becomes the "beneficial owner" (as defined in Rule 13(d)-3 under the Exchange Act), directly or indirectly, whether by purchase or acquisition or agreement to act in concert or otherwise, of more than 50% of the outstanding voting common stock of the Company.
- (3) The aforesaid option contained in this Section 5(b) shall be exercised by the Board by written notice to such Optionee, executor or administrator or other duly appointed representative of Optionee, at any time during the six month period following the date of the Change in Control or such longer period of time as is reasonable.
- (4) The closing of any purchase pursuant to this Section 5(b) (the "Closing") shall be held at the place designated by the Company within 30 days after the date of delivery of the Board's written notice of its intent to exercise such purchase option.
- (5) The aggregate purchase price payable pursuant to this Section 5(b) shall be paid either as a lump sum at Closing, or as follows, at the discretion of the Company. At the Closing, the Company shall make a cash down payment of 35% of the purchase price and shall execute and deliver to the Optionee, or executor or administrator or other duly appointed representative of such Optionee, a negotiable promissory note, representing the balance of the purchase price. Such note shall be payable in 4 equal semi-annual installments of principal, the first of which shall be due and payable 6 months from the date of Closing and each of which shall be accompanied by a payment of all interest accrued to the date thereof at the Mid Term Applicable Federal Rate, pursuant to Section 1274 of the Code, established for the month of the Closing,

compounded monthly. Such note may be prepaid in whole or in part, together with all interest accrued to the date of such prepayment, at any time at the option of the Company, without penalty or premium.

#### 6. Status as a Stockholder

Neither Optionee nor any other person entitled to exercise the Stock Option under the terms hereof shall be, or have any of the rights or privileges of, a stockholder of the Company in respect of any Common Stock issuable on exercise of the Stock Option, until the date of the issuance of a stock certificate for such Common Stock. No adjustments shall be made for dividends (ordinary or extraordinary, whether in cash, securities or other property) or distributions or other rights for which the record date is prior to the date such stock certificate is issued, except as provided in Section 5(a) above. Prior to the transfer to the Optionee of a certificate representing shares of Common Stock acquired pursuant to the exercise of an Option, the Company shall require the Optionee to become a party to the then current version of a stockholders' agreement including a limitation on the transferability of shares of Common Stock and a right on the part of the Company to repurchase shares of Common Stock from its stockholders as provided under the terms of the stockholders' agreement. A copy of such stockholders' agreement shall be prepared and distributed to Optionee prior to the first date any Option granted hereunder first becomes exercisable. The form of stockholders' agreement in effect as of the Date of Grant is attached hereto as Attachment A.

### 7. Delivery of Option Agreement

If the Award shall be exercised in whole, this Option Agreement shall be surrendered to the Company for cancellation. If the Award shall be exercised in part, or a change in the number or designation of the Common Stock shall be made, this Option Agreement shall be delivered by Optionee to the Company for the purpose of making appropriate notation thereon, or of otherwise reflecting, in such manner as the Company shall determine, the partial exercise or the change in the number or designation of the Common Stock. An Award may not be exercised for a fraction of a share of Common Stock.

#### 8. Nontransferability of Options

Options shall not be transferable other than by will or by the laws of descent and distribution, and Options may be exercised, during the lifetime of the Optionee, only by the Optionee or the Optionee's legal representative.

#### 9. Miscellaneous

The grant of the Award hereunder shall not be deemed to give the Optionee the right to be retained as a director of the Company or in any other capacity or to affect the right of the Company to discharge the Optionee in his capacity as a director or otherwise at any time, with or without cause.

#### 10. Taxes

(a) The Company makes no representations by way of this Option

Agreement, or otherwise, with respect to the actual tax consequences of the grant or exercise of this Award or the subsequent disposition of the Common Stock acquired under this Award.

(b) No shares shall be delivered to the Optionee or other person until such Optionee or other person has made arrangements acceptable to the Board for the satisfaction of any foreign, federal, state, or local income and employment tax withholding obligations, including, without limitation, obligations incident to the receipt of shares. Upon exercise of an Option, the Company or its designee shall have the right to deduct from the shares issuable upon the exercise of the Option, or to accept from Optionee (with the approval by the Company or its designee) the tender of, a number of whole shares having a Fair Market Value (as defined in Section 3) equal to all or any part of the federal, state, local and foreign taxes, if any, required by law to be withheld by the Company with respect to such Option or the shares acquired upon the exercise thereof. Alternatively, or in addition, the Company or its designee, in its sole discretion, shall have the right to require Optionee, through payroll withholding, cash payment or otherwise, including by means of a cashless exercise, to make adequate provision for any such tax withholding obligations of the Company arising in connection with the Option, or the shares acquired upon the exercise thereof.

#### 11. Governing Law

The Award and this Option Agreement shall be construed, administered and governed in all respects under and by the laws of the State of Delaware without giving effect to principles of conflict of laws.

#### 12. Amendment and Termination

The Board may cancel any outstanding Option and grant a new Option in substitution therefore, provided that the Board shall consider the impact of the Code section 409A on any such cancellation and substitution. The Board also may amend or revise the Option Agreement, including any amendment which would: (i) accelerate the time or times at which the Option becomes unrestricted or may be exercised; (ii) waive or amend any goals, restrictions or conditions set forth in the Option Agreement; or (iii) waive or amend the operation of Section 4 above with respect to the termination of the Option upon cessation of Board membership; provided the Board shall consider the impact of Code section 409A on any such amendment or revision. However, any such cancellation or amendment that materially impairs the rights or materially increases the obligations of the Optionee shall be made only with the consent of the Optionee (or, upon the Optionee's death, the person having the right to exercise the Option).

Emergent BioSolutions Inc., a Delaware Corporation

By:	
	Name:
	Title:
The undersigned hereby accepts the foregoing Award and the terms and conditions hereof.	
	Name:
	Date:
	7

#### **INDEMNITY AGREEMENT**

This Indemnity Agreement is made this	_day of	, 2005, by and between Emergent BioSolutions Inc. a Delaware corporation (the '	'Company"), and	, (the
"Indemnitee")				

#### WITNESSETH:

WHEREAS, the Company and the Indemnitee desire to enter into this Agreement, which is intended to replace any indemnification agreement that may exist between the Indemnitee and the Company.

NOW, THEREFORE, the Company and the Indemnitee for good and valuable consideration, the receipt of which is hereby acknowledged, hereby agree as follows:

- 1. <u>Definitions</u>. Capitalized terms used herein shall have the meaning as set forth below:
- (a) "Claim" shall mean any threatened, pending or completed claim, action, demand, suit or proceeding, whether civil, criminal, administrative or investigative, and whether formal or informal.
- (b) "<u>Damages</u>" shall mean any losses, liabilities, damages of any nature (including consequential, special and incidental), claims, demands, judgments, amounts paid in settlements, fines, penalties, expenses and costs, and ERISA excise taxes. Without limiting the generality of the foregoing, Damages shall include any and all Defense Costs.
- (c) "<u>Defense Costs</u>" shall mean any costs, charges, bonds, fees, expenses, including reasonable attorneys' fees and fees of experts, consultants, witnesses and court costs, incurred in the investigation, defense or prosecution of any Claim.
  - (d) "Final Adjudication" shall mean final judicial decision in a court of competent jurisdiction from which there is no further right to appeal.
- (e) "Person" shall mean any individual, partnership, limited partnership, corporation, company association, business trust, employee benefit or retirement plan or trust, limited liability company, unincorporated association, joint venture, enterprise of any nature (whether incorporated or unincorporated) that is capable of suing or being sued or that is recognized or recognizable in a court of law or equity as a "person", or any government entity, authority or agency.
- (f) "Third Party" shall mean any trustee, receiver, creditor, contractor, vendor, insurance carrier, service provider to the Company or any other person doing business or otherwise associated with the Company in any capacity.
  - (g) "Undertaking" shall have the meaning as set forth in Section 3.

- 2. <u>Right to Indemnification.</u> The Company shall defend, indemnify and hold harmless the Indemnitee from and against any and all Damages asserted against or suffered or incurred by the Indemnitee in connection with any Claim brought by any Person, including any Third Party, in respect of, relating to, or by reason of the fact that the Indemnitee is or was a director, officer, manager, employee, agent or representative of the Company or is or was serving at the request of the Company as a director, officer, manager, employee or agent of another Person, whether the basis of such Claim is alleged action or inaction in an official capacity as a director, officer, manager, employee, agent or representative, to the fullest extent permitted by applicable law, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Company to provide broader indemnification rights than permitted prior thereto), and such indemnification shall continue after the Indemnitee has ceased to be a director, officer, manager, employee, agent or representative and shall inure to the benefit of the Indemnitee's heirs, executors, trustees and administrators; <u>provided, however</u>, that, except as provided in Section 4 hereof with respect to proceedings to enforce rights to indemnification and advancement of Defense Costs, the Company shall indemnify the Indemnitee in connection with any Claim (or part thereof) initiated by the Indemnitee only if such Claim (or part thereof) was authorized by the board of directors of the Company.
- 3. Right to Advancement of Defense Costs. In addition to the right to indemnification conferred in Section 2 hereof, the Indemnitee shall have the right to be paid by the Company, in advance of Final Adjudication, all Defense Costs as incurred by the Indemnitee in connection with any Claim for which a right to indemnification is applicable under this Agreement. Defense Costs shall be paid by the Company not later than twenty (20) days after receipt by the Company of a statement of expenses from the Indemnitee requesting such payment, which request shall be supported by a statement of costs; provided, however, that, if the Delaware General Corporation Law requires, an advancement of Defense Costs incurred by the Indemnitee in the Indemnitee's capacity as a director or officer (and not in any other capacity in which service was or is rendered by the Indemnitee, including, without limitation, as an employee, manager, agent or for service to an employee benefit plan) shall be made only upon delivery to the Company of an undertaking (hereinafter an "Undertaking"), by or on behalf of the Indemnitee, to repay all amounts so advanced if it shall ultimately be determined by Final Adjudication that the Indemnitee is not entitled to be indemnified for such Defense Costs under this Agreement or otherwise.

#### 4. Right of Indemnitee to Bring Suit.

- (a) If a claim by the Indemnitee to the Company for indemnification under Section 2 of this Agreement is not paid in full by the Company within thirty (30) days after a written claim has been received by the Company, or if a claim by the Indemnitee to the Company for an advancement of Defense Costs under Section 3 of this Agreement is not paid in full within twenty (20) days as specified in Section 3, the Indemnitee may at any time thereafter bring suit against the Company to recover the unpaid amount of the claims.
  - (b) If the Indemnitee is successful in whole or in part in any suit brought under Section 4(a), or in a suit brought by the Company to recover an advancement of Defense

Costs pursuant to the terms of an Undertaking, the Indemnitee shall be entitled to be paid also all costs and expenses (including without limitation all reasonable attorneys' fees, court costs, witness fees) of prosecuting or defending such suit.

- (c) In any suit brought by the Indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the Indemnitee to enforce a right under Section 3 to an advancement of Defense Costs) it shall be a defense that it has been determined by Final Adjudication that the Indemnitee has not met any applicable standard for indemnification set forth in the Delaware General Corporation Law.
- (d) In any suit against the Indemnitee by the Company to recover an advancement of Defense Costs pursuant to the terms of an Undertaking, the Company shall be entitled to recover such Defense Costs only upon a Final Adjudication that the Indemnitee has not met any applicable standard for indemnification set forth in the Delaware General Corporation Law.
- (e) Neither the failure of the Company (including its directors who are not parties to such action, a committee of such directors, independent legal counsel, or its stockholders) to have made a determination prior to the commencement of such suit that indemnification of the Indemnitee is proper in the circumstances because the Indemnitee has met the applicable standard of conduct set forth in the Delaware General Corporation Law, nor an actual determination by the Company (including its directors who are not parties to such action, a committee of such directors, independent legal counsel, or its stockholders) that the Indemnitee has not met such applicable standard of conduct, shall create a presumption that the Indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the Indemnitee, be a defense to such suit. In any suit brought by the Indemnitee to enforce a right to indemnification or to an advancement of Defense Costs pursuant to the terms of an Undertaking, the burden of proving that the Indemnitee is not entitled to be indemnified, or to such advancement of Defense Costs, under this Agreement or otherwise, shall be on the Company by clear and convincing evidence.
- 5. <u>Settlement.</u> The Company shall have no obligation to indemnify the Indemnitee under this Agreement for any amounts paid in full settlement and/or compromise of any Claim that was effected without Company's prior written consent. The Company shall not enter into any full settlement and/or compromise of any Claim in any manner that would impose any Damages on the Indemnitee without the Indemnitee's written consent. Neither the Company nor the Indemnitee shall unreasonably withhold, condition or delay their consent to any proposed settlement or compromise. The exercise of any right of consent or withholding of consent under this Section 5 shall not affect, excuse, modify or relieve the Company of any of its obligations under this Agreement.

### 6. Maintenance of Insurance.

(a) The Company hereby represents and warrants that policies of directors' and officers' liability insurance ("D&O Insurance") have been purchased by the Company and that such policies are in full force and effect. The Indemnitee acknowledges that he has been informed of, and provided access to, the D&O Policies.

- (b) The Company hereby covenants and agrees that, so long as the Indemnitee shall continue to serve as a director or officer of the Company and thereafter so long as the Indemnitee shall be subject to any possible claim or threatened, pending or completed action, suit or proceeding, whether civil, criminal or investigative, by reason of the fact that the Indemnitee was a director or officer of the Company, the Company, subject to Section 2(d), shall maintain in full force and effect D&O Insurance.
- (c) In all policies of D&O Insurance, the Indemnitee shall be named as an insured in such a manner as to provide the Indemnitee the same rights and benefits, subject to the same limitations, as are accorded to the Company's directors or officers most favorably insured by such policy.
- (d) The Company shall have no obligation to maintain D&O Insurance if the Company determines in good faith that such insurance is not reasonably available, the premium costs for such insurance is disproportionate to the amount of coverage provided, or the coverage provided by such insurance is limited by exclusions so as to provide an insufficient benefit.
- 7. <u>Rights Not Exclusive.</u> The rights provided hereunder shall not be deemed exclusive of any other rights to which the Indemnitee may be entitled under any statute, provision of Company's certificate of incorporation, bylaw, agreement, vote of stockholders or of disinterested directors or otherwise, both as to action in his official capacity and as to action in any other capacity, and shall continue after the Indemnitee ceases to serve the Company as a director, officer, employee as the case may be.
- 8. <u>Severability.</u> In the event that any provision of this Agreement is determined by a court to require the Company to do or to fail to do an act that is in violation of applicable law, such provision shall be limited or modified in its application to the minimum extent necessary to avoid a violation of law, and, as so limited or modified, such provision and the balance of this Agreement shall be enforceable in accordance with their terms.
- 9. Choice of Law. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Delaware, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.
- 10. Consent to jurisdiction. The Company and the Indemnitee each hereby irrevocably consent to the jurisdiction of the courts of the State of Delaware for all purposes in connection with any action or proceeding which arises out of or relates to this Agreement and agree that any action instituted under this Agreement shall be brought only in the state courts of the State of Delaware.
- 11. <u>Successor and Assigns.</u> This Agreement shall be (i) binding upon all successors and assigns of the Company (including any transferee of all or substantially all of its assets and any successor by merger or otherwise by operation of law) and (ii) binding on and inure to the benefit of the heirs, personal representatives and estate of the Indemnitee.

- 12. <u>Amendment or Waiver.</u> No amendment, modification, termination or cancellation of this Agreement shall be effective unless made in a writing signed by each of the parties hereto, and no waiver of any provision hereunder shall be effective unless in writing.
- 13. Counterparts. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile signatures and such signatures shall be deemed to bind each party hereto as if they were original signatures.

IN WITNESS WHEREOF, the Company and the Indemnitee have executed this Agreement as of the day and year first above written.

Emei	rgent BioSolutions Inc.			
By:				
	Name: Title:			
Inde	mnitee			
[Nan	ne]			
	5			

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

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# Section B — Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0001		[**]		\$ [**]	\$ 71,248,954.50
	Doses of Vaccine FFP as identified in Section C, during the period of January 1, 2004 through December 31, 2004. PURCHASE REQUEST NUMBER: W90GXK33010005				
				MAX NET AMT	\$ 71,248,954.50
FOR	ACRN AA Funded Amount				
FOB:	Origin				
ITEM NO 0002	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE \$ [**]	MAX AMOUNT \$ 95,950,567.80
OPTION		[**]		\$ [**]	\$ 95,950,507.80
OFFICIN					
	Doses of Vaccine FFP as identified in Section C, during the period of January 1, 2005 through December 31, 2005. PURCHASE REQUEST NUMBER: W90GXK33010005				
				MAX NET AMT	\$ 95,950,567.80
	Funded Amount				\$ 0.00
FOB:	Origin				

ITEM NO 0003 OPTION	SUPPLIES/SERVICES	MAX QUANTITY [**]	UNIT	UNIT PRICE \$ [**]	\$ MAX AMOUNT 78,340,433.60
	Doses of Vaccine FFP as identified in Section C, during the period of January 1, 2006 through September 30, 2006. PURCHASE REQUEST NUMBER: W90GXK33010005				
				MAX NET AMT	\$ 78,340,433.60
	Funded Amount				\$ 0.00

FOB: Origin

### CLIN DELIVERY/TASK ORDER MINIMUM/MAXIMUM QUANTITY AND CLIN ORDER VALUE

The minimum quantity and order value for the given Delivery/Task Order issued for this CLIN shall not be less than the minimum quantity and order value stated in the following table. The maximum quantity and order value for the given Delivery/Task Order issued for this CLIN shall not exceed the maximum quantity and order value stated in the following table.

CLIN	MINIMUM QUANTITY	MINIMUM AMOUNT	MAXIMUM QUANTITY	MAXIMUM AMOUNT
0001	1,297,380	[**]	[**]	71,248,954
0002	1,533,090	[**]	[**]	\$95,950,568
0003	1,034,930	[**]	[**]	\$78,340,434

Section C — Descriptions and Specifications

### STATEMENT OF WORK

Section C. Statement of Work/Specifications

C.1 Summary. The contractor shall provide the necessary qualified personnel, facilities, material, equipment, and services to produce, test, bottle, and place into storage FDA licensed Anthrax Vaccine Adsorbed (AVA) in accordance with the contractor's standard operating procedures and BioPort's Food and Drug Administration Biologics License and all federal government regulatory, and statuary requirements applicable to the manufacture, formulation, filling and testing of AVA.

### C.1.2 Definitions.

a. Manufacturing Stage is defined as the completion of:

[\*\*

Upon receipt of test results and internal release by Quality Assurance/Quality Control, the material is advanced to the Formulation Stage.

- b. Formulation Stage means the [\*\*]. Upon receipt of test results and internal release by Quality Assurance/Quality Control, the subject lots are advanced to the Filling Stage.
- c. Filling Stage means the placement of bulk AVA in vials each containing sufficient volume to allow for 10 full doses. Samples are tested for safety, sterility, and potency. Upon receipt of test results and internal release by Quality Assurance/Quality Control, a release protocol is submitted to the FDA.
- d. Release Stage means the receipt from the FDA of a letter releasing a lot of AVA for sale and distribution.
- e. FOB Origin is defined as the Contractor's Facility 3500 N. Martin Luther King Jr., Boulevard, Lansing, Michigan 48906.
- f. The term "within" as related to paragraph (a) of FAR 52.217-9, is defined as "at least."
- C.1.3 The production process consists of the following four stages:
  - Manufacture
  - 2. Formulation
  - Filling
  - 4. FDA Release

C.1.4 Test and Evaluation During Production

- a. The contractor is responsible for establishing and maintaining quality assurance and quality control programs to ensure that product delivered under the contract, and that all testing requirements, meet both FDA regulatory requirements as well as the FDA license for AVA.
- b. All other testing, including testing of the Pentavalent Botulinum Vaccine, and is presently provided under contract DAMD17-99-D-0003. Upon completion of this contract, the testing requirements shall be incorporated into this contract. The costs for conducting the tests under DAMD17-99-C-0003 are not presently included in this contract.

#### C.1.5 Shipping

Shipping of the vaccine is presently accomplished under DAMD17-99-D-0003, but shall be incorporated into this contract upon completion. Presently, the cost to ship vaccine is not included in this contract.

### C.1.6 Early Delivery of Doses

The Contractor may deliver quantities of AVA doses in advance of the delivery schedule found at Attachment No. 1, Section J of this contract.

### C.2 Contractor Use of Government Owned Property.

The Contractor shall have exclusive use of the property owned by the Government at the Contractor's facility to manufacture AVA doses. A complete list of the Contractor Acquired Property is found in Attachment 2 in Section J of this contract. The fee for using this property shall be \$[\*\*] per dose of vaccine produced for private sales. For the first performance period of January 1, 2004 to December 31, 2004, the Contractor may be credited against the last invoice for doses delivered. For all other ensuing contract periods, the Contractor shall credit the usage fee on a monthly basis as the equipment is used in producing an inventory of doses for private sales.

### C.3 Dose Equivalent Invoicing.

The Contractor will invoice the Government using a dose equivalent of [\*\*] doses per lot for performance milestones 1, 2, &3. Upon reaching the fourth and final milestone, the contractor will adjust the final invoice either upward or downward, as appropriate to compensate for any difference in the actual number of doses delivered per lot.

#### C.4 FDA Action/Inaction.

The Contractor shall not be terminated for cause, in accordance with FAR 212-14 (m), if it is unable to deliver AVA doses in accordance with the delivery schedule set forth in Attachment 3 in Section J of the Contract due to action or inaction of the Food And Drug Administration, except to the extent that such action or inaction is a direct consequence of the Contractor's negligence.

#### C.3 Notification of Sales.

The Contractor agrees to provide notification as a courtesy to the JVAP Product Manager of any sale of AVA to any non-U.S. company or government within five business days of making the sale.

#### C.4 Reporting

The contractor shall provide a Monthly Contract Status Report. During the base contract period of January 1, 2004 to December 31, 2004, the report shall be submitted weekly at the conclusion of the business week. The weekly

report shall provide the same information as the monthly reports provide as of November 20, 2003, submitted under contract DAMD17-98-C-8052. Changes in the frequency of this data item may occur in the option periods.

### C.5 Government Space in Contractor's Facility

The contractor shall provide office space within the contractor's facility to accommodate a Defense Contract Management Agency representative and JVAP representative(s) who will be onsite on a full-time basis.

### C.6 Public Release of Information.

The contractor agrees to provide an advance copy of any release of information if there is a reference to the Anthrax Vaccine Program or if the information released may impact the Anthrax Vaccine Program. This provision is not intended to restrict dissemination of corporate information or the release of any information related to this Contract to third parties conducting normal due diligence on the Contractor in connection with capital raising activities or other types of corporate reorganizations where such release may be required. The advance notice will allow the DoD time to facilitate a response to any potential inquiries resulting from the information release and to be alert to the possibility of the inadvertent release of information, which could be taken out of context.

End of Section C.

Section E — Inspection and Acceptance

# INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Origin (Contractor's Facility)	Government	Origin (Contractor's Facility)	Government
0002	Origin (Contractor's Facility)	Government	Origin (Contractor's Facility)	Government
0003	Origin (Contractor's Facility)	Government	Origin (Contractor's Facility)	Government

# Section F — Deliveries or Performance

# DELIVERY INFORMATION

CLIN 0001	DELIVERY DATE  IAW Attachment No. 1 in Section J of the Contract	QUANTITY 1,297,380	SHIP TO ADDRESS To be determined	UIC TBD
0002	Will be provided at time of exercising option.	1,533,090	To be determined	TBD
0003	Will be provided at time of exercising option.	1,034,930	To be determined	TBD

# CLAUSES INCORPORATED BY REFERENCE

52.247-29 F.O.B. Origin JUN 1988

#### Section G — Contract Administration Data

#### ACCOUNTING AND APPROPRIATION DATA

AA: 9740300260145Y5YCM306100BP000252G12YMAVW90GXK43010005YMAV12044008

AMOUNT: To be obligated on individual delivery orders.

### PAYMENT/INVOICING

- 1. Payments shall be made, by the Finance and Accounting Office, upon acceptance by the Government as verified by a Government's Representative signature in Block 21 (b) of a DD Form 250 "Material Inspection and Receiving Report" and approval of the Administrative Contracting Officer (ACO). The Contractor shall submit 1 original and 3 copies of invoices to the ACO to process for payment. After acceptance and approval, the ACO will forward invoice with the DD 250 to the Defense Finance and Accounting Office. The DD 250 may also be used as an invoice.
- 2. Payments shall be accomplished in accordance with FAR 52.232-32 "Performance Based Payments" with the basis for performance payments identified in Attachment 1 "Basis for AVA Manufacturing Performance Payments."

#### POINTS OF CONTACT

Procuring Contracting Officer: Lynn M. Selfridge USASMDC ATTN: SMDC-CM-CB 64 Thomas Johnson Drive Frederick, MD 21702 (301) 619-2707

email: lynn.selfridge@det.amedd.army.mil

Administrative Contracting Officer: Sue Pihl DCMC Detroit-Grand Rapids Riverview Center Bldg. 678 Front Ave., NW Grand Rapids, MI 49504-5352 (616) 233-4625

Code: S2303A

Technical Representative: Dave Edman, Ph.D. CBMS 64 Thomas Johnson Drive Frederick, MD 21702 (301) 619-7391

End of Section G.

### Section H — Special Contract Requirements

### DELIVERY ORDER LIMITATIONS

#### Delivery Order Limitations for Placing Orders Above the Minimum Quantity

At the time of issuing a delivery order for anthrax vaccine doses for a quantity greater than the minimum quantity cited in Section B up to and including the maximum quantity cited in the Schedule, during either the base year or any of the options periods, the Government shall negotiate a quarterly delivery schedule for such doses. In all instances, except as provided below, manufacture of the doses shall commence within six months and be delivered within twelve months of delivery order issuance. In cases where a delivery order is issued for a quantity greater than the minimum within six months of the date of the previous delivery order, the contractor shall deliver the AVA according to a quarterly delivery schedule negotiated and agreed upon by both parties.

### Purchase of Government Owned, Contractor Acquired Property

The Contractor may purchase contractor-acquired property at any time during the contract period. Upon the payment by the Contractor to the Government for each item of contractor-acquired property by invoice credit, title to such contractor-acquired property shall automatically pass to the Contractor. Upon payment by the Contractor for all contractor-acquired property used to deliver AVA, as specifically identified in Attachment 2 to this contract, the Contractor shall no longer be required to pay any usage fee and such requirement shall cease to have nay further force or effect. If the Contractor purchases a portion of the contractor-acquired property, the contractor may request to negotiate a reduced usage fee for the use of that property.

#### Indemnification

The Contractor acknowledges that only the Secretary of the Army has authority under Public Law 85-804 to indemnify the Contractor for unusually hazardous risks in performing this contract. The Contractor further acknowledges that the Secretary of the Army may not provide indemnification. The Government shall pursue obtaining indemnification under Public Law 85-804 for the contract upon receipt of a FAR Part 50 fully compliant request from the contractor. It is expressly understood that receipt of the same indemnification provision as found in Contract DAMD17-98-C-8052 or such other insurance or protective measure as shall be mutually acceptable to the Government and the Contractor, shall be a condition precedent to the Contractor's obligations to deliver doses of AVA under this contract. In the event that the Secretary of the Army does not approve the request for indemnification, the Government agrees to fund the cost of reasonable protective measures and the Contractor fully understands that in the event of the need for the Government to fund these measures, the minimum requirement, for any period, may be reduced by an amount equivalent to its cost.

### Contractor Authority to Place Rated Orders

The Contractor is authorized to place rated orders for equipment and other items in the course of implementing its production capacity expansion project for AVA. The Government provides this authority as the delegate agency as required by 15 CFR part 700.18(2)(iv)(A). The Defense priority rating of the contract is DO-C9.

End of Section H.

#### Section I - Contract Clauses

### CLAUSES INCORPORATED BY REFERENCE

52.232-25	Prompt Payment	OCT 2003
52.242-13	Bankruptcy	JUL 1995
52.245-4	Government-Furnished Property (Short Form)	JUN 2003
252.204-7004	Required Central Contractor Registration	NOV 2001
252.245-7001	Reports Of Government Property	MAY 1994

#### CLAUSES INCORPORATED BY FULL TEXT

### 52.212-4 CONTRACT TERMS AND CONDITIONS— COMMERCIAL ITEMS (OCT 2003)

- (a) Inspection/Acceptance. The Contractor shall only tender for acceptance those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. The Government must exercise its post-acceptance rights (1) within a reasonable time after the defect was discovered or should have been discovered; and (2) before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.
- (b) Assignment. The Contractor or its assignee may assign its rights to receive payment due as a result of performance of this contract to a bank, trust company, or other financing institution, including any Federal lending agency in accordance with the Assignment of Claims Act (31 U.S.C. 3727). However, when a third party makes payment (e.g., use of the Governmentwide commercial purchase card), the Contractor may not assign its rights to receive payment under this contract.
- (c) Changes. Changes in the terms and conditions of this contract may be made only by written agreement of the parties.
- (d) Disputes. This contract is subject to the Contract Disputes Act of 1978, as amended (41 U.S.C. 601-613). Failure of the parties to this contract to reach agreement on any request for equitable adjustment, claim, appeal or action arising under or relating to this contract shall be a dispute to be resolved in accordance with the clause at FAR 52.233-1, Disputes, which is incorporated herein by reference. The Contractor shall proceed diligently with performance of this contract, pending final resolution of any dispute arising under the contract.
- (e) Definitions. The clause at FAR 52.202-1, Definitions, is incorporated herein by reference.
- (f) Excusable delays. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement or any excusable delay, setting for the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.
- (g) Invoice. (1) The Contractor shall submit an original invoice and three copies (or electronic invoice, if authorized) to the address designated in the contract to receive invoices. An invoice must include—

- (i) Name and address of the Contractor,
- (ii) Invoice date and number;
- (iii) Contract number, contract line item number and, if applicable, the order number;
- (iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;
- (v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;
- (vi) Terms of any discount for prompt payment offered;
- (vii) Name and address of official to whom payment is to be sent;
- (viii) Name, title, and phone number of person to notify in event of defective invoice; and
- (ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.
- (x) Electronic funds transfer (EFT) banking information.
- (A) The Contractor shall include EFT banking information on the invoice only if required elsewhere in this contract.
- (B) If EFT banking information is not required to be on the invoice, in order for the invoice to be a proper invoice, the Contractor shall have submitted correct EFT banking information in accordance with the applicable solicitation provision, contract clause (e.g., 52.232-33, Payment by Electronic Funds Transfer—Central Contractor Registration, or 52.232-34, Payment by Electronic Funds Transfer—Other Than Central Contractor Registration), or applicable agency procedures.
- (C) EFT banking information is not required if the Government waived the requirement to pay by EFT.
- (2) Invoices will be handled in accordance with the Prompt Payment Act (31 U.S.C. 3903) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR part 1315.
- (h) Patent indemnity. The Contractor shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.
- (i) Payment.—
- (1) Items accepted. Payment shall be made for items accepted by the Government that have been delivered to the delivery destinations set forth in this contract.
- (2) Prompt payment. The Government will make payment in accordance with the Prompt Payment Act (31 U.S.C. 3903) and prompt payment regulations at 5 CFR part 1315.
- (3) Electronic Funds Transfer (EFT). If the Government makes payment by EFT, see 52.212-5(b) for the appropriate EFT clause.
- (4) Discount. In connection with any discount offered for early payment, time shall be computed from the date of the invoice. For the purpose of computing the discount earned, payment shall be considered to have been made on

the date which appears on the payment check or the specified payment date if an electronic funds transfer payment is made.

- (5) Overpayments. If the Contractor becomes aware of a duplicate contract financing or invoice payment or that the Government has otherwise overpaid on a contract financing or invoice payment, the Contractor shall immediately notify the Contracting Officer and request instructions for disposition of the overpayment.
- (j) Risk of loss. Unless the contract specifically provides otherwise, risk of loss or damage to the supplies provided under this contract shall remain with the Contractor until, and shall pass to the Government upon:
- (1) Delivery of the supplies to a carrier, if transportation is f.o.b. origin; or
- (2) Delivery of the supplies to the Government at the destination specified in the contract, if transportation is f.o.b. destination.
- (k) Taxes. The contract price includes all applicable Federal, State, and local taxes and duties.
- (1) Termination for the Government's convenience. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.
- (m) Termination for cause. The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.
- (n) Title. Unless specified elsewhere in this contract, title to items furnished under this contract shall pass to the Government upon acceptance, regardless of when or where the Government takes physical possession.
- (o) Warranty. The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.
- (p) Limitation of liability. Except as otherwise provided by an express warranty, the Contractor will not be liable to the Government for consequential damages resulting from any defect or deficiencies in accepted items.
- (q) Other compliances. The Contractor shall comply with all applicable Federal, State and local laws, executive orders, rules and regulations applicable to its performance under this contract.
- (r) Compliance with laws unique to Government contracts. The Contractor agrees to comply with 31 U.S.C. 1352 relating to limitations on the use of appropriated funds to influence certain Federal contracts; 18 U.S.C. 431 relating to officials not to benefit; 40 U.S.C. 327, et seq., Contract Work Hours and Safety Standards Act; 41 U.S.C. 51-58, Anti-Kickback Act of 1986; 41 U.S.C. 265 and 10 U.S.C. 2409 relating to whistleblower protections; 49 U.S.C. 40118, Fly American; and 41 U.S.C. 423 relating to procurement integrity.

- (s) Order of precedence. Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order: (1) the schedule of supplies/services; (2) the Assignments, Disputes, Payments, Invoice, Other Compliances, and Compliance with Laws Unique to Government Contracts paragraphs of this clause; (3) the clause at 52.212-5; (4) addenda to this solicitation or contract, including any license agreements for computer software; (5) solicitation provisions if this is a solicitation; (6) other paragraphs of this clause; (7) the Standard Form 1449; (8) other documents, exhibits, and attachments; and (9) the specification.
- (t) Central Contractor Registration (CCR). (1) Unless exempted by an addendum to this contract, the Contractor is responsible during performance and through final payment of any contract for the accuracy and completeness of the data within the CCR database, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain registered in the CCR database after the initial registration, the Contractor is required to review and update on an annual basis from the date of initial registration or subsequent updates its information in the CCR database to ensure it is current, accurate and complete. Updating information in the CCR does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.
- (2)(i) If a Contractor has legally changed its business name, "doing business as" name, or division name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in FAR subpart 42.12, the Contractor shall provide the responsible Contracting Officer a minimum of one business day's written notification of its intention to (A) change the name in the CCR database; (B) comply with the requirements of subpart 42.12; and (C) agree in writing to the timeline and procedures specified by the responsible Contracting Officer. The Contractor must provide with the notification sufficient documentation to support the legally changed
- (ii) If the Contractor fails to comply with the requirements of paragraph (t)(2)(i) of this clause, or fails to perform the agreement at paragraph (t)(2)(i)(C) of this clause, and, in the absence of a properly executed novation or change-of-name agreement, the CCR information that shows the Contractor to be other than the Contractor indicated in the contract will be considered to be incorrect information within the meaning of the "Suspension of Payment" paragraph of the electronic funds transfer (EFT) clause of this contract.
- (3) The Contractor shall not change the name or address for EFT payments or manual payments, as appropriate, in the CCR record to reflect an assignee for the purpose of assignment of claims (see Subpart 32.8, Assignment of Claims). Assignees shall be separately registered in the CCR database. Information provided to the Contractor's CCR record that indicates payments, including those made by EFT, to an ultimate recipient other than that Contractor will be considered to be incorrect information within the meaning of the "Suspension of payment" paragraph of the EFT clause of this contract.
- (4) Offerors and Contractors may obtain information on registration and annual confirmation requirements via the internet at http://www.ccr.gov or by calling 1-888-227-2423 or 269-961-5757.
- 52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS-COMMERCIAL ITEMS (OCT 2003)
- (a) The Contractor shall comply with the following Federal **Acquisition Regulation** (FAR) clause, which is incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items: 52.233-3, Protest after Award (AUG 1996) (31 U.S.C. 3553).
- (b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: (Contracting Officer check as appropriate.)

X	(1) 52.203-6, Restrictions on Subcontractor Sales to the Government (JUL 1995), with Alternate I (OCT 1995) (41 U.S.C. 253g and 10 U.S.C. 2402).
	(2) 52.219-3, Notice of HUBZone Small Business Set-Aside (Jan 1999) (U.S.C. 657a).
(U.S.C.	(3) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Jan 1999) (if the offeror elects to waive the preference, it shall so indicate in its offer) 657a).
	(4) (i) 52.219-5, Very Small Business Set-Aside (JUNE 2003) (Pub. L. 103-403, section 304, Small Business Reauthorization and Amendments Act of 1994).
	(ii) Alternate I (MAR 1999) to 52.219-5.
	(iii) Alternate II to (JUNE 2003) 52.219-5.
	(5)(i) 52.219-6, Notice of Total Small Business Set-Aside (JUNE 2003) (15 U.S.C. 644).
	(ii) Alternate I (OCT 1995) of 52.219-6.
	(6)(i) 52.219-7, Notice of Partial Small Business Set-Aside (JUNE 2003) (15 U.S.C. 644).
	(ii) Alternate I (OCT 1995) of 52.219-7.
	(7) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637 (d)(2) and (3)).
	(8)(i) 52.219-9, Small Business Subcontracting Plan (JAN 2002) (15 U.S.C. 637(d)(4)).
	(ii) Alternate I (OCT 2001) of 52.219-9.
	(iii) Alternate II (OCT 2001) of 52.219-9.
	(9) 52.219-14, Limitations on Subcontracting (DEC 1996) (15 U.S.C. 637(a)(14)).
elects to	(10)(i) 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (JUNE 2003) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323) (if the offeror a waive the adjustment, it shall so indicate in its offer).
	(ii) Alternate I (JUNE 2003) of 52.219-23.
	(11) 52.219-25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting (OCT 1999) (Pub. L. 103-355, section 7102, and 10 U.S.G. 2323).
	(12) 52.219-26, Small Disadvantaged Business Participation Program—Incentive Subcontracting (OCT 2000) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323).
X	(13) 52.222-3, Convict Labor (JUNE 2003) (E.O. 11755).
X	(14) 52.222-19, Child Labor—Cooperation with Authorities and Remedies (SEP 2002) (E.O. 13126).
X	(15) 52.222-21, Prohibition of Segregated Facilities (FEB 1999).

X	(16) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).
X	(17) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212).
X	(18) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
X	(19) 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212).
	(20)(i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (AUG 2000) (42 U.S.C. 6962(c)(3)(A)(ii)).
	(ii) Alternate I (AUG 2000) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)).
	(21) 52.225-1, Buy American Act—Supplies (JUNE 2003) (41 U.S.C.10a-10d).
	(22)(i) 52.225-3, Buy American Act—North American Free Trade Agreement—Israeli Trade Act (JUNE 2003) (41 U.S.C. 10a-10d, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note).
	(ii) Alternate I (MAY 2002) of 52.225-3.
	(iii) Alternate II (MAY 2002) of 52.225-3.
	(23) 52.225-5, Trade Agreements (OCT 2003) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
X	(24) 52.225-13, Restrictions on Certain Foreign Purchases (OCT 2003) (E.O. 12722, 12724, 13059, 13067, 13121, and 13129).
	(25) 52.225-15, Sanctioned European Union Country End Products (FEB 2000) (E.O. 12849).
	(26) 52.225-16, Sanctioned European Union Country Services (FEB 2000) (E.O. 12849).
	(27) 52.232-29, Terms for Financing of Purchases of Commercial Items (FEB 2002) (41 U.S.C. 255(f), 10 U.S.C. 2307(f)).
	(28) 52.232-30, Installment Payments for Commercial Items (OCT 1995) (41 U.S.C. 255(f), 10 U.S.C. 2307(f)).
X	(29) 52.232-33, Payment by Electronic Funds Transfer—Central Contractor Registration (OCT 2003) (31 U.S.C. 3332).
	(30) 52.232-34, Payment by Electronic Funds Transfer—Other than Central Contractor Registration (MAY 1999) (31 U.S.C. 3332).
	(31) 52.232-36, Payment by Third Party (MAY 1999) (31 U.S.C. 3332).
	(32) 52239-1, Privacy or Security Safeguards (AUG 1996) (5 U.S.C. 552a).
	(33)(i) 52.247-64, Preference for Privately Owned U.SFlag Commercial Vessels (APR 2003) (46 U.S.C. Appx 1241 and 10 U.S.C. 2631).

(ii) Alternate I (APR 1984) of 52.247-64.
(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: [Contracting Officer check as appropriate.]
(1) 52.222-41, Service Contract Act of 1965, as Amended (MAY 1989) (41 U.S.C. 351, et seq.).
(2) 52.222-42, Statement of Equivalent Rates for Federal Hires (MAY 1989) (29 U.S.C. 206 and 41 U.S.C. 351, et seq.).
(3) 52.222-43, Fair Labor Standards Act and Service Contract Act—Price Adjustment (Multiple Year and Option Contracts) (MAY 1989) (29 U.S.C. 206 and 41 U.S.C. 351, et seq.).
(4) 52.222-44, Fair Labor Standards Act and Service Contract Act—Price Adjustment (February 2002) (29 U.S.C. 206 and 41 U.S.C. 351, et seq.).
(5) 52.222-47, SCA Minimum Wages and Fringe Benefits Applicable to Successor Contract Pursuant to Predecessor Contractor Collective Bargaining Agreements (CBA) (May 1989)

- (d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records—Negotiation.
- (1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.
- (2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.
- (3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.
- (e) (1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in paragraphs (i) through (vi) of this paragraph in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause—
- (i) 52.219-8, Utilization of Small Business Concerns (October 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$500,000 (\$1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (ii) 52.222-26, Equal Opportunity (April 2002) (E.O. 11246).

(41 U.S.C. 351, et seq.).

- (iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (December 2001) (38 U.S.C. 4212).
- (iv) 52.222-36, Affirmative Action for Workers with Disabilities (June 1998) (29 U.S.C. 793).
- (v) 52.222-41, Service Contract Act of 1965, as Amended (May 1989), flow down required for all subcontracts subject to the Service Contract Act of 1965 (41 U.S.C. 351, et seq.).
- (vi) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (April 2003) (46 U.S.C. Appx 1241 and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.
- (2) While not required, the contractor May include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

#### (End of clause)

#### 52.216-18 ORDERING. (OCT 1995)

- (a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from January 2, 2004 through December 31, 2004.
- (b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.
- (c) If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

#### (End of clause)

NOTE: THIS CLAUSE WILL BE UPDATED ANNUALLY ALONG WITH THE EXERCISE OF AN OPTION.

#### 52.216-19 ORDER LIMITATIONS. (OCT 1995)

- (a) Minimum order. When the Government requires supplies or services covered by this contract in an amount of less than 1,297,380 doses (insert dollar figure or quantity), the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.
- (b) Maximum order. The Contractor is not obligated to honor;
- (1) Any order for a single item in excess of 3,109,950 doses (insert dollar figure or quantity);
- (2) Any order for a combination of items in excess of 3,109,950 doses (insert dollar figure or quantity); or
- (3) A series of orders from the same ordering office within 30 days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.
- (c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal

Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.

(d) Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 10 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

(End of clause)

NOTE: TO BE UPDATED AT TIME OF EXERCISING OPTION.

### 52.216-22 INDEFINITE QUANTITY. (OCT 1995)

- (a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.
- (b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum". The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum".
- (c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.
- (d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after January 1, 2008.

(End of clause)

### 52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

- (a) The Government may extend the term of this contract by written notice to the Contractor within 109 days (insert the period of time within which the Contracting Officer may exercise the option); provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 120 days (60 days unless a different number of days is inserted) before the contract expires. The preliminary notice does not commit the Government to an extension.
- (b) If the Government exercises this option, the extended contract shall be considered to include this option clause.
- (c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 33 months.

(End of clause)

#### FAR 52.232-32 PERFORMANCE-BASED PAYMENTS (FEB 2002)

- (a) Amount of payments and limitations on payments. Subject to such other limitations and conditions as are specified in this contract and this clause, the amount of payments and limitations on payments shall be specified in the contract's description of the basis for payment.
- (b) Contractor request for performance-based payment. The Contractor may submit requests for payment of performance-based payments not more frequently than monthly, in a form and manner acceptable to the Contracting Officer. Unless otherwise authorized by the Contracting Officer, all performance-based payments in any period for which payment is being requested shall be included in a single request, appropriately itemized and totaled. The Contractor's request shall contain the information and certification detailed in paragraphs (1) and (m) of this clause.
- (c) Approval and payment of requests. (1) The Contractor shall not be entitled to payment of a request for performance-based payment prior to successful accomplishment of the event or performance criterion for which payment is requested. The Contracting Officer shall determine whether the event or performance criterion for which payment is requested has been successfully accomplished in accordance with the terms of the contract. The Contracting Officer may, at any time, require the Contractor to substantiate the successful performance of any event or performance criterion which has been or is represented as being payable.
- (2) A payment under this performance-based payment clause is a contract financing payment under the Prompt Payment clause of this contract and not subject to the interest penalty provisions of the Prompt Payment Act. The designated payment office will pay approved requests on the 30th day after receipt of the request for performance-based payment. However, the designated payment office is not required to provide payment if the Contracting Officer requires substantiation as provided in paragraph (c)(1) of this clause, or inquires into the status of an event or performance criterion, or into any of the conditions listed in paragraph (e) of this clause, or into the Contractor certification. The payment period will not begin until the Contracting Officer approves the request.
- (3) The approval by the Contracting Officer of a request for performance-based payment does not constitute an acceptance by the Government and does not excuse the Contractor from performance of obligations under this contract.
- (d) Liquidation of performance-based payments. (1) Performance-based finance amounts paid prior to payment for delivery of an item shall be liquidated by deducting a percentage or a designated dollar amount from the delivery payment. If the performance-based finance payments are on a delivery item basis, the liquidation amount for each such line item shall be the percent of that delivery item price that was previously paid under performance-based finance payments or the designated dollar amount. If the performance-based finance payments are on a whole contract basis, liquidation shall be by either predesignated liquidation amounts or a liquidation percentage.
- (2) If at any time the amount of payments under this contract exceeds any limitation in this contract, the Contractor shall repay to the Government the excess. Unless otherwise determined by the Contracting Officer, such excess shall be credited as a reduction in the unliquidated performance-based payment balance(s), after adjustment of invoice payments and balances for any retroactive price adjustments.
- (e) Reduction or suspension of performance-based payments. The Contracting Officer may reduce or suspend performance-based payments, liquidate performance-based payments by deduction from any payment under the contract, or take a combination of these actions after finding upon substantial evidence any of the following conditions:
- (1) The Contractor failed to comply with any material requirement of this contract (which includes paragraphs (h) and (i) of this clause).

- (2) Performance of this contract is endangered by the Contractor's (i) failure to make progress, or (ii) unsatisfactory financial condition.
- (3) The Contractor is delinquent in payment of any subcontractor or supplier under this contract in the ordinary course of business.
- (f) Title. (1) Title to the property described in this paragraph (f) shall vest in the Government. Vestiture shall be immediately upon the date of the first performance-based payment under this contract, for property acquired or produced before that date. Otherwise, vestiture shall occur when the property is or should have been allocable or properly chargeable to this contract
- (2) "Property," as used in this clause, includes all of the following described items acquired or produced by the Contractor that are or should be allocable or properly chargeable to this contract under sound and generally accepted accounting principles and practices:
- (i) Parts, materials, inventories, and work in process;
- (ii) Special tooling and special test equipment to which the Government is to acquire title under any other clause of this contract;
- (iii) Nondurable (i.e., noncapital) tools, jigs, dies, fixtures, molds, patterns, taps, gauges, test equipment and other similar manufacturing aids, title to which would not be obtained as special tooling under subparagraph (f)(2)(ii) of this clause; and
- (iv) Drawings and technical data, to the extent the Contractor or subcontractors are required to deliver them to the Government by other clauses of this contract.
- (3) Although title to property is in the Government under this clause, other applicable clauses of this contract (e.g., the termination or special tooling clauses) shall determine the handling and disposition of the property.
- (4) The Contractor may sell any scrap resulting from production under this contract, without requesting the Contracting Officer's approval, provided that any significant reduction in the value of the property to which the Government has title under this clause is reported in writing to the Contracting Officer.
- (5) In order to acquire for its own use or dispose of property to which title is vested in the Government under this clause, the Contractor must obtain the Contracting Officer's advance approval of the action and the terms. If approved, the basis for payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.
- (6) When the Contractor completes all of the obligations under this contract, including liquidation of all performance-based payments, title shall vest in the Contractor for all property (or the proceeds thereof\*) not—
- (i) Delivered to, and accepted by, the Government under this contract; or
- (ii) Incorporated in supplies delivered to, and accepted by, the Government under this contract and to which title is vested in the Government under this clause.
- (7) The terms of this contract concerning liability for Government-furnished property shall not apply to property to which the Government acquired title solely under this clause.
- (g) Risk of loss. Before delivery to and acceptance by the Government, the Contractor shall bear the risk of loss for

property, the title to which vests in the Government under this clause, except to the extent the Government expressly assumes the risk. If any property is damaged, lost, stolen, or destroyed, the basis of payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.

- (h) Records and controls. The Contractor shall maintain records and controls adequate for administration of this clause. The Contractor shall have no entitlement to performance-based payments during any time the Contractor's records or controls are determined by the Contracting Officer to be inadequate for administration of this clause.
- (i) Reports and Government access. The Contractor shall promptly furnish reports, certificates, financial statements, and other pertinent information requested by the Contracting Officer for the administration of this clause and to determine that an event or other criterion prompting a financing payment has been successfully accomplished. The Contractor shall give the Government reasonable opportunity to examine and verify the Contractor's records and to examine and verify the Contractor of this contract for administration of this clause.
- (j) Special terms regarding default. If this contract is terminated under the Default clause, (1) the Contractor shall, on demand, repay to the Government the amount of unliquidated performance-based payments, and (2) title shall vest in the Contractor, on full liquidation of all performance-based payments, for all property for which the Government elects not to require delivery under the Default clause of this contract. The Government shall be liable for no payment except as provided by the Default clause.
- (k) Reservation of rights. (1) No payment or vesting of title under this clause shall (i) excuse the Contractor from performance of obligations under this contract, or (ii) constitute a waiver of any of the rights or remedies of the parties under the contract
- (2) The Government's rights and remedies under this clause (i) shall not be exclusive, but rather shall be in addition to any other rights and remedies provided by law or this contract, and (ii) shall not be affected by delayed, partial, or omitted exercise of any right, remedy, power, or privilege, nor shall such exercise or any single exercise preclude or impair any further exercise under this clause or the exercise of any other right, power, or privilege of the Government.
- (1) Content of Contractor's request for performance-based payment. The Contractor's request for performance-based payment shall contain the following:
- (1) The name and address of the Contractor;
- (2) The date of the request for performance-based payment;
- (3) The contract number and/or other identifier of the contract or order under which the request is made;
- (4) Such information and documentation as is required by the contract's description of the basis for payment; and
- (5) A certification by a Contractor official authorized to bind the Contractor, as specified in paragraph (m) of this clause.
- (m) Content of Contractor's certification. As required in paragraph (1)(5) of this clause, the Contractor shall make the following certification in each request for performance-based payment:

I certify to the best of my knowledge and belief that-

(1) This request for performance-based payment is true and correct; this request (and attachments) has been prepared from the books and records of the Contractor, in accordance with the contract and the instructions of the

Contracting Officer;
(2) (Except as reported in writing on), all payments to subcontractors and suppliers under this contract have been paid, or will be paid, currently, when due in the ordinary course of business;
(3) There are no encumbrances (except as reported in writing on) against the property acquired or produced for, and allocated or properly chargeable to, the contract which would affect or impair the Government's title;
(4) There has been no materially adverse change in the financial condition of the Contractor since the submission by the Contractor to the Government of the most recent written information dated; and
(5) After the making of this requested performance-based payment, the amount of all payments for each deliverable item for which performance-based payments have been requested will not exceed any limitation in the contract, and the amount of all payments under the contract will not exceed any limitation in the contract.
(End of clause)
252.212-7001 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS APPLICABLE TO DEFENSE ACQUISITIONS OF COMMERCIAL ITEMS (OCT 2003)
(a) The Contractor agrees to comply with the following Federal Acquisition Regulation (FAR) clause which, if checked, is included in this contract by reference to implement a provision of law applicable to acquisitions of commercial items or components.
X 52.203-3 Gratuities (APR 1984) (10 U.S.C. 2207).
(b) The Contractor agrees to comply with any clause that is checked on the following list of Defense FAR Supplement clauses which, if checked, is included in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items or components.
252.205-7000 Provision of Information to Cooperative Agreement Holders (DEC 1991) (10 U.S.C. 2416).
252.219-7003 Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan (DoD Contracts) (APR 1996) (15 U.S.C. 637).
252.219-7004 Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan (Test Program) (JUN 1997) (15 U.S.C. 637 note).
X 252.225-7001 Buy American Act and Balance of Payment Program (APR 2003) (41 U.S.C. 10a-10d, E.O. 10582).
252.225-7012 Preference for Certain Domestic Commodities (FEB 2003) (10.U.S.C. 2533a).
252.225-7014 Preference for Domestic Specialty Metals (APR 2003) (10 U.S.C. 2533a).
252.225-7015 Preference for Domestic Hand or Measuring Tools (APR 2003) (10 U.S.C. 2533a).

252.225-7016 Restriction on Acquisition of Ball and Roller Bearings (APR 2003) ( Alternate I) (APR 2003) (10 U.S.C. 2534 and Section 8099 of Public Law 104-61 and similar sections in subsequent DoD appropriations acts).
252.225-7021 Trade Agreements (AUG 2003) (19 U.S.C. 2501-2518 and 19 U.S.C. 3301 note).
252.225-7027 Restriction on Contingent Fees for Foreign Military Sales (APR 2003) (22 U.S.C. 2779).
252.225-7028 Exclusionary Policies and Practices of Foreign Governments (APR 2003) (22 U.S.C. 2755).
252.225-7036 Buy American Act—North American Free Trade Agreement Implementation Act—Balance of Payment Program (APR 2003) ( Alternate I) (APR 2003) (41 U.S.C. 10a-10d and 19 U.S.C. 3301 note).
252.225-7038 Restriction on Acquisition of Air Circuit Breakers (APR. 2003) (10 U.S.C. 2534(a)(3)).
252,226-7001 Utilization of Indian Organizations, Indian-Owned Economic Enterprises, and Native Hawaiian Small Business Concerns (Oct 2003) (Section 8021 of Pub. L. 107-248).
252.227-7015 Technical Data—Commercial Items (NOV 1995) (10 U.S.C. 2320).
252.227-7037 Validation of Restrictive Markings on Technical Data (SEP 1999) (10 U.S.C. 2321).
X 252.232-7003 Electronic Submission of Payment Requests (MAR 2003) (10 U.S.C. 2227).
X 252.243-7002 Certification of Requests for Equitable Adjustment (MAR 1998) (10 U.S.C. 2410).
X 252.247-7023 Transportation of Supplies by Sea (MAY 2002) ( Alternate I) (MAR 2000) ( Alternate II) (MAR 2000) (Alternate III) (MAY 2002) (10 U.S.C. 2631).
X 252.247-7024 Notification of Transportation of Supplies by Sea (MAR 2000) (10 U.S.C. 2631).
(c) In addition to the clauses listed in paragraph (e) of the Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items clause of this contract (Federal Acquisition Regulation 52.212-5), the Contractor shall include the terms of the following clauses, if applicable, in subcontracts for commercial items or commercial components, awarded at any tier under this contract:
252.225-7014 Preference for Domestic Specialty Metals, Alternate I (APR 2003) (10 U.S.C. 2533a).
252.247-7023 Transportation of Supplies by Sea (MAY 2002) (10 U.S.C. 2631).
252.247-7024 Notification of Transportation of Supplies by Sea (MAR 2000) (10 U.S.C. 2631)
(End of clause)

# Section J — List of Documents, Exhibits and Other Attachments

## SECTION J

Section J, List of Attachments and Exhibits

Attachment Number	Description	No. of Pages
1	Performance Based Payments Breakout	1
2	Government Furnished Property	22
3	Delivery Schedule for the Minimum Quantity in for the Base Year (to be Revised with Exercising an Option)	1

# Attachment 1 Basis for AVA Manufacturing Performance Payments

Completion of Manufacturing Stage	50%
Completion of Formulation Stage	30%
Completion of Filling Stage	10%
Completion of Release Stage	10%

ent Owned Equipment Page 1

# DD-1662 for 2003

Contract Sys No	#		P T	Acquisition Class	Date	Description	Tax Acq Value
56	DAMD17-91-C-1139		R	Bu	9/1/93	Warehouse modular facility	264,674.00
47	DAMD17-91-C-1139		R	Bu	9/1/93	BL-3 Modular Facility	1,484,553.00
Class*		<u>Bu</u>					
Sub Total:							
							1,749,227.00
							·
52	DAMD17-91-C-1139		P	Co	9/1/93	Thermal Transfer Printer	7,128.00
31	DAMD17-91-C-1139		P	Co	9/1/93	Security room console, power panel, conduit and wi	20,000.00
30	DAMD17-91-C-1139		P	Co	9/1/93	door alarms, motion detectors, card readers, card ac	50,000.00
29	DAMD17-91-C-1139		P	Co	9/1/93	Intercom system to gates central control, remote an	60,000.00
32	DAMD17-91-C-1139		P	Co	9/1/93	Host computer, remote processors, conduit and wiri	80,000.00
28	DAMD17-91-C-1139		P	Co	9/1/93	Cameras, Video control, re corders, multiplexers, n	120,000.00
120	DAMD17-91-C-1139		P	Co	9/1/98	Printer — Hewlitt Packard	300.00
118	DAMD17-91-C-1139		P	Co	9/1/98	Printer — Epson	387.00
281	DAMD17-91-C-1139		P	Co	2/1/00	Compaq Proliant ML570 Server and Rack Mounts I	15,497.00
253	DAMD17-91-C-1139		P	Co	3/1/00	HP Laserjet Printer 4050N	1,360.00
222	DAMD17-91-C-1139		P	Co	3/1/00	Computer	1,499.97
216	DAMD17-91-C-1139		P	Co	3/1/00	Computer	1,699.97
190	DAMD17-91-C-1139		P	Co	3/1/00	Computer System	2,128.98
201	DAMD17-91-C-1139		P	Co	3/1/00	Z505R Laptop Computers	2,538.24
189	DAMD17-91-C-1139		P	Co	3/1/00	Mail server	3,624.61
224	DAMD17-91-C-1139		P	Co	3/1/00	Laptop Computers	3,711.24
261	DAMD17-91-C-1139		P	Co	4/1/00	Computer System	633.32
920	DAMD17-91-C-1139		P	Co	4/1/00	Computer System	633.32
921	DAMD17-91-C-1139		P	Co	4/1/00	Computer System	633.32
206	DAMD17-91-C-1139		P	Co	4/1/00	Laptop Computers	1,660.00
207	DAMD17-91-C-1139		P	Co	4/1/00	Laptop Computers F420	1,660.00
217	DAMD17-91-C-1139		P	Co	4/1/00	Laptop Computers F420	1,660.00
264	DAMD17-91-C-1139		P	Co	4/1/00	Bar Code Scanners	2,605.50
265	DAMD17-91-C-1139		P	Co	4/1/00	Bar Code Scanners	2,605.50
193	DAMD17-91-C-1139		P	Co	4/1/00	Compaq Proliant ML370	3,400.00

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
191	DAMD17-91-C-1139	P	Co	7/1/00	Viewsonic E771 .27MM	232.50
194	DAMD17-91-C-1139	P	Co	7/1/00	Viewsonic E771 .27MM	232.50
195	DAMD17-91-C-1139	P	Co	7/1/00	Viewsonic E771 .27MM	232.50
196	DAMD17-91-C-1139	P	Co	7/1/00	Viewsonic E771 .27MM	232.50
197	DAMD17-91-C-1139	P	Co	7/1/00	Viewsonic E771 .27MM	232.50
198	DAMD17-91-C-1139	P	Co	7/1/00	Viewsonic E771 .27MM	232.50
199	DAMD17-91-C-1139	P	Co	7/1/00	Viewsonic E771 .27MM	232.50
200	DAMD17-91-C-1139	P	Co	7/1/00	Viewsonic E771 .27MM	232.50
192	DAMD17-91-C-1139	P	Co	7/1/00	Compaq Proliant 7360 K6 500	606.13
202	DAMD17-91-C-1139	P	Co	7/1/00	Compaq Pesario 7360 K6 500	606.13
203	DAMD17-91-C-1139	P	Co	7/1/00	Compaq Pesario 7360 K6 500	606.13
204	DAMD17-91-C-1139	P	Co	7/1/00	Compaq Pesario 7360 K6 500	606.13
205	DAMD17-91-C-1139	P	Co	7/1/00	Compaq Pesario 7360 K6 500	606.13
223	DAMD17-91-C-1139	P	Co	7/1/00	17" P793 Monitor	606.13
210	DAMD17-91-C-1139	P	Co	7/1/00	Compaq Pesario 7360 K6 500	606.14
211	DAMD17-91-C-1139	P	Co	8/1/00	Monitors	221.43
212	DAMD17-91-C-1139	P	Co	8/1/00	Computers	651.43
170	DAMD17-91-C-1139	P	Co	8/1/00	Laptop Computers F420	1,660.00
209	DAMD17-91-C-1139	P	Co	8/1/00	Epson Projector	5,322.00
172	DAMD17-91-C-1139	P	Co	8/1/00	Compaq Proliant Server and Rack	5,908.74
173	DAMD17-91-C-1139	P	Co	9/1/00	Viewsonic 17" Color Monitor	227.25
175	DAMD17-91-C-1139	P	Co	9/1/00	Viewsonic 17" Color Monitor	227.25
188	DAMD17-91-C-1139	P	Co	9/1/00	Viewsonic 17" Color Monitor	227.25
219	DAMD17-91-C-1139	P	Co	9/1/00	Viewsonic 17" Color Monitor	227.25
174	DAMD17-91-C-1139	P	Co	9/1/00	Viewsonic 17" Color Monitor	227.26
214	DAMD17-91-C-1139	P	Co	9/1/00	Monitor	296.78
215	DAMD17-91-C-1139	P	Co	9/1/00	Printer	690.00
179	DAMD17-91-C-1139	P	Co	9/1/00	HP E-PC E-Vectra	787.06
176	DAMD17-91-C-1139	P	Co	9/1/00	HP E-PC E-Vectra	787.08
177	DAMD17-91-C-1139	P	Co	9/1/00	HP E-PC E-Vectra	787.08
178	DAMD17-91-C-1139	P	Co	9/1/00	HP E-PC E-Vectra	787.08
213	DAMD17-91-C-1139	P	Co	9/1/00	CPU P. I. F. N.T.W. I. C.	1,383.52
208	DAMD17-91-C-1139	P	Co	9/1/00	Compaq Deskpro En NT Workstation	1,878.91
263 180	DAMD17-91-C-1139	P P	Co Co	9/1/00	Compaq Proliant ML530 Server and Parts	10,842.00 1,019.35
	DAMD17-91-C-1139	P		10/1/00	HP Brio BA410 Computer	
220	DAMD17-91-C-1139	P	Co Co	10/1/00	Compaq Deskpro En Workstation Viewsonic 17" Color Monitor	1,440.00 228.87
183	DAMD17-91-C-1139	P		11/1/00		1,318.87
182 184	DAMD17-91-C-1139 DAMD17-91-C-1139	P	Co Co	11/1/00 11/1/00	Compaq Deskpro EN Pen III 733 mhz Compaq Deskpro EN Pen III 733 mhz and Viewsoni	1,318.87
184		P				
746	DAMD17-91-C-1139 DAMD17-91-C-1139	P	Co Co	11/1/00 11/1/00	Compaq Deskpro EN Pen III 733 mhz and Viewsonic Datafile Diskette for VAERS	1,318.87 1,344.00
181		P				
244	DAMD17-91-C-1139 DAMD17-91-C-1139	P	Co Co	12/1/00 12/1/00	Elron Software Server Security System Upgrade, Camera and wiring neces	3,669.46 128,502.20
273	DAMD17-91-C-1139 DAMD17-91-C-1139	P	Co	1/1/01	Viewsonic 17" Color Monitor	128,302.20
273 274	DAMD17-91-C-1139 DAMD17-91-C-1139	P	Co	1/1/01	Viewsonic 17" Color Monitor Viewsonic 17" Color Monitor	189.99
274	DAMD17-91-C-1139 DAMD17-91-C-1139	P	Co	1/1/01	Viewsonic 17" Color Monitor Viewsonic 17" Color Monitor	189.99
2/3	DAMD1/-91-C-1139	r	CO	1/1/01	VIEWSOINE 1 / COIOI IVIOINIOI	189.99

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
276	DAMD17-91-C-1139	P	Co	1/1/01	Viewsonic 17" Color Monitor	189.99
269	DAMD17-91-C-1139	P	Co	1/1/01	Compaq Deskpro EN	1,337.74
270	DAMD17-91-C-1139	P	Co	1/1/01	Compaq Deskpro EN	1,337.74
271	DAMD17-91-C-1139	P	Co	1/1/01	Compaq Deskpro EN	1,337.74
272	DAMD17-91-C-1139	P	Co	1/1/01	Compaq Deskpro EN	1,337.74
277	DAMD17-91-C-1139	P	Co	1/1/01	Compaq Deskpro Workstation Ap250	1,887.00
278	DAMD17-91-C-1139	P	Co	1/1/01	Compaq Deskpro Workstation Ap250	1,887.00
279	DAMD17-91-C-1139	P	Co	1/1/01	Compaq Deskpro Workstation Ap250	1,887.00
290	DAMD17-91-C-1139	P	Co	2/1/01	Monitor	290.00
289	DAMD17-91-C-1139	P	Co	2/1/01	Computer System Okidata 14E printer	371.04
291	DAMD17-91-C-1139	P	Co	2/1/01	Computer System	1,853.40
292	DAMD17-91-C-1139	P	Co	2/1/01	Compaq Proliant ML570 Server and Rack Mounts	20,376.50
302	DAMD17-91-C-1139	P	Co	3/1/01	Monitors for PAI Workroom	270.89
303	DAMD17-91-C-1139	P	Co	3/1/01	Viewsonic E70	270.89
304	DAMD17-91-C-1139	P	Co	3/1/01	Monitors for PAI Workroom	270.89
305	DAMD17-91-C-1139	P	Co	3/1/01	Monitors for PAI Workroom	270.89
306	DAMD17-91-C-1139	P	Co	3/1/01	Monitor	270.89
307	DAMD17-91-C-1139	P	Co	3/1/01	Monitors for PAI Workroom	270.89
308	DAMD17-91-C-1139	P	Co	3/1/01	Monitors for PAI Workroom	270.89
309	DAMD17-91-C-1139	P	Co	3/1/01	Monitors for PAI Workroom	270.89
283	DAMD17-91-C-1139	P	Co	3/1/01	Monitor	290.00
287	DAMD17-91-C-1139	P	Co	3/1/01	Monitor	290.00
288	DAMD17-91-C-1139	P	Co	3/1/01	Monitor	290.00
284	DAMD17-91-C-1139	P	Co	3/1/01	Computer System	1,220.00
285	DAMD17-91-C-1139	P	Co	3/1/01	Computer System	1,220.00
286	DAMD17-91-C-1139	P	Co	3/1/01	Computer Deskpro	1,220.00
294	DAMD17-91-C-1139	P	Co	3/1/01	Computers for PAI Workroom	1,263.89
295	DAMD17-91-C-1139	P	Co	3/1/01	Compaq PC	1,263.89
296	DAMD17-91-C-1139	P	Co	3/1/01	Computers for PAI Workroom	1,263.89
297	DAMD17-91-C-1139	P	Co	3/1/01	Compaq Deskpro EN	1,263.89
298	DAMD17-91-C-1139	P	Co	3/1/01	Computer	1,263.89
299	DAMD17-91-C-1139	P	Co	3/1/01	Computers for PAI Workroom	1,263.89
300	DAMD17-91-C-1139	P	Co	3/1/01	Computers for PAI Workroom	1,263.89
301	DAMD17-91-C-1139	P	Co	3/1/01	Computer	1,263.91
314	DAMD17-91-C-1139	P	Co	4/1/01	Monitor	186.00
315	DAMD17-91-C-1139	P	Co	4/1/01	Monitor	186.00
316	DAMD17-91-C-1139	P	Co	4/1/01	Monitor	186.00
317	DAMD17-91-C-1139	P	Co	4/1/01	Monitor	186.00
318	DAMD17-91-C-1139	P	Co	4/1/01	Monitor	186.00
325	DAMD17-91-C-1139	P	Co	4/1/01	Monitor	186.00
319	DAMD17-91-C-1139	P	Co	4/1/01	Computer Systems	1,017.50
320	DAMD17-91-C-1139	P	Co	4/1/01	Computer Systems	1,017.50
321	DAMD17-91-C-1139	P	Co	4/1/01	Computer Systems	1,017.50
322	DAMD17-91-C-1139	P	Co	4/1/01	Computer Systems	1,017.50
323	DAMD17-91-C-1139	P	Co	4/1/01	Computer Systems	1,017.50
324	DAMD17-91-C-1139	P	Co	4/1/01	Computer Systems	1,017.50

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
311	DAMD17-91-C-1139	P	Co	4/1/01	Server-Snap for PAI Workroom	2,405.00
312	DAMD17-91-C-1139	P	Co	4/1/01	Server-Snap for PAI Workroom	2,405.00
336	DAMD17-91-C-1139	P	Co	5/1/01	All in one Printer Fax Copier	784.00
334	DAMD17-91-C-1139	P	Co	6/1/01	UPS for Domain Controller	16,075.32
335	DAMD17-91-C-1139	P	Co	6/1/01	UPS for Domain Controller	16,075.32
376	DAMD17-91-C-1139	P	Co	7/1/01	IS Monitor	897.23
588	DAMD17-91-C-1139	P	Co	8/24/01	Developer Server	4,024.41
417	DAMD17-91-C-1139	P	Co	8/29/01	PowerEdge 700MHZ	10,310.28
684	DAMD17-91-C-1139	P	Co	11/1/01	Dell Optiplex GX 240 Small Mini Tower	1,430.83
685	DAMD17-91-C-1139	P	Co	11/1/01	Dell Optiplex GX 240 Small Mini Tower	1,430.83
686	DAMD17-91-C-1139	P	Co	11/1/01	Dell Optiplex GX 240 Small Mini Tower	1,430.83
421	DAMD17-91-C-1139	P	Co	11/1/01	Dell Optiplex GX 240 Small Mini Tower	1,430.83
407	DAMD17-91-C-1139	P	Co	11/2/01	Security System Multiplexer	2,313.18
405	DAMD17-91-C-1139	P	Co	11/26/01	Dell Optiplex GX 240 Small Mini Tower	1,213.91
409	DAMD17-91-C-1139	P	Co	11/28/01	Closed Circuit TV System	157,025.57
562	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 1700 Router	1,066.36
576	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3512 Network Switch	2,065.97
577	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3512 Network Switch	2,065.97
578	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3512 Network Switch	2,065.97
570	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3512 Network Switch	2,065.97
571	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3512 Network Switch	2,065.97
572	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3512 Network Switch	2,065.97
573	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3512 Network Switch	2,065.97
574	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3512 Network Switch	2,065.97
575	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3512 Network Switch	2,065.97
563	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3524 Network Switch	2,507.57
564	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3524 Network Switch	2,507.57
565	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3524 Network Switch	2,507.57
566	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3524 Network Switch	2,507.57
567	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3524 Network Switch	2,507.57
568	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3524 Network Switch	2,507.57
569	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3524 Network Switch	2,507.57
581	DAMD17-91-C-1139	P	Co	1/11/02	Pix Firewall 515 FO-Bun	2,552.97
551	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3548 Network Switch	4,216.48
552	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3548 Network Switch	4,216.48
553	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3548 Network Switch	4,216.48
554	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3548 Network Switch	4,216.48
555	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3548 Network Switch	4,216.48
556	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3548 Network Switch	4,216.48
557	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3548 Network Switch	4,216.48
558	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3548 Network Switch	4,216.48
559	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3548 Network Switch	4,216.48
560	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3548 Network Switch	4,216.48
561	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 3548 Network Switch	4,216.48
579	DAMD17-91-C-1139	P	Co	1/11/02	Cisco 6509 Switch	10,005.27
580	DAMD17-91-C-1139	P	Co	1/11/02	Pix Firewall 515UR	10,212.90

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
582	DAMD17-91-C-1139	P	Co	1/11/02	URT Policy Server 100Series	10,636.37
583	DAMD17-91-C-1139	P	Co	1/11/02	URT Policy Server 1100Series	10,636.37
550	DAMD17-91-C-1139	P	Co	1/11/02	Cisco Intrusion Detection System 4210	12,416.38
490	DAMD17-91-C-1139	P	Co	1/24/02	Flat Panel 340 Minitower Monitor 1702FD	274.54
498	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
499	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
500	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
501	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
502	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
503	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
504	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
505	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
506	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
507	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
508	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
509	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
510	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
511	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
512	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
513	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
514	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
515	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
516	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
517	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
518	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
519	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
520	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
521	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
522	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
523	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
524	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
525	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
526	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
527	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
528	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
529	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
530	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
531	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
532	DAMD17-91-C-1139	P P	Co	1/24/02	Dell P793 Monitor	274.54
533 534	DAMD17-91-C-1139	_	Co	1/24/02	Dell P793 Monitor	274.54
	DAMD17-91-C-1139	P	Co	1/24/02	Dell P703 Monitor	274.54
535 536	DAMD17-91-C-1139	P P	Co Co	1/24/02	Dell P793 Monitor Dell P793 Monitor	274.54
	DAMD17-91-C-1139	-		1/24/02		274.54
537	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
538	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
539	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
540	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
541	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
542	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
543	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
544	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
545	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
492	DAMD17-91-C-1139	P	Co	1/24/02	17" P793 Monitor	296.64
493	DAMD17-91-C-1139	P	Co	1/24/02	17" P793 Monitor	296.64
494	DAMD17-91-C-1139	P	Co	1/24/02	19" P992 Monitor	451.64
495	DAMD17-91-C-1139	P	Co	1/24/02	19" P992 Monitor	451.64
496	DAMD17-91-C-1139	P	Co	1/24/02	19" P992 Monitor	451.64
497	DAMD17-91-C-1139	P	Co	1/24/02	19" P992 Monitor	451.64
440	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
441	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
442	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
443	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
444	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
445	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
446	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
447	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
448	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
449	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
450	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
451	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
452	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
453	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
454	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
455	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
456	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
457	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
458	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
459	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
460	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
461	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
462	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
463	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
464	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
465	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
466	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
467	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
468	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
469	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
470	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
471	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
472	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
473	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
474	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
475	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
476	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
477	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
478	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
479	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
480	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
481	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
482	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
483	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
484	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
485	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
486	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
487	DAMD17-91-C-1139	P	Co	1/24/02	Dell Optiplex GX 240 Small Mini Tower	974.14
491	DAMD17-91-C-1139	P	Co	1/24/02	Precision 340 Minitower Workstation-Labwatch Sy	1,629.21
599	DAMD17-91-C-1139	P	Co	1/31/02	Exchange Bundle Media Kin	20.00
598	DAMD17-91-C-1139	P	Co	1/31/02	Server	4,837.49
639	DAMD17-91-C-1139	P	Co	2/28/02	Security System Workstation (CPU)	4,274.89
602	DAMD17-91-C-1139	P	Co	2/28/02	Security System Workstation (Monitor)	4,274.90
628	DAMD17-91-C-1139	P	Co	3/29/02	Plain-paper Impact printer	448.88
671	DAMD17-91-C-1139	P	Co	3/29/02	Maintenance Agreement	25,725.70
673	DAMD17-91-C-1139	P	Co	3/29/02	Computer Services	31,225.24
672	DAMD17-91-C-1139	P	Co	3/29/02	Computer Supplies	134,486.81
636	DAMD17-91-C-1139	P	Co	4/12/02	Dell Optiplex GX 240 Small Mini Tower	1,786.09
621	DAMD17-91-C-1139	P	Co	4/12/02	Profile 3 SE	1,934.00
772	DAMD17-91-C-1139	P	Co	7/1/02	17" P793 Monitor	482.29
773	DAMD17-91-C-1139	P	Co	7/1/02	17" P793 Monitor	482.29
774	DAMD17-91-C-1139	P	Co	7/1/02	17" P793 Monitor	482.29
775	DAMD17-91-C-1139	P	Co	7/1/02	17" P793 Monitor	482.29
776	DAMD17-91-C-1139	P	Co	7/1/02	17" P793 Monitor	482.29
777	DAMD17-91-C-1139	P	Co	7/1/02	17" P793 Monitor	482.29
778	DAMD17-91-C-1139	P	Co	7/1/02	17" P793 Monitor	482.29
779	DAMD17-91-C-1139	P	Co	7/1/02	17" P793 Monitor	482.29
780	DAMD17-91-C-1139	P	Co	7/1/02	17" P793 Monitor	482.30
781	DAMD17-91-C-1139	P	Co	7/1/02	17" P793 Monitor	482.30
762	DAMD17-91-C-1139	P	Co	7/1/02	Dell Optiplex GX 240 Small Mini Tower	1,181.91
763	DAMD17-91-C-1139	P	Co	7/1/02	Dell Optiplex GX 240 Small Mini Tower	1,181.91
764	DAMD17-91-C-1139	P	Co	7/1/02	Dell Optiplex GX 240 Small Mini Tower	1,181.91
765	DAMD17-91-C-1139	P	Co	7/1/02	Dell Optiplex GX 240 Small Mini Tower	1,181.91
766	DAMD17-91-C-1139	P	Co	7/1/02	Dell Optiplex GX 240 Small Mini Tower	1,181.91
767	DAMD17-91-C-1139	P	Co	7/1/02	Dell Optiplex GX 240 Small Mini Tower	1,181.91
768	DAMD17-91-C-1139	P	Co	7/1/02	Dell Optiplex GX 240 Small Mini Tower	1,181.91
769	DAMD17-91-C-1139	P	Co	7/1/02	Dell Optiplex GX 240 Small Mini Tower	1,181.91
770	DAMD17-91-C-1139	P	Co	7/1/02	Dell Optiplex GX 240 Small Mini Tower	1,181.91
771	DAMD17-91-C-1139	P	Co	7/1/02	Dell Optiplex GX 240 Small Mini Tower	1,181.91
805	DAMD17-91-C-1139	P	Co	9/1/02	Staging Server-Sandbox	4,091.61

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
806	DAMD17-91-C-1139	P	Co	9/1/02	Network Back Up	4,516.82
0.4.0	D.1360450464400	-		40/4/00	D. II DE00.14	250.04
812	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
813	DAMD17-91-C-1139	P P	Co	10/1/02	Dell P793 Monitor	350.26
814 815	DAMD17-91-C-1139 DAMD17-91-C-1139	P P	Co Co	10/1/02 10/1/02	Dell P793 Monitor Dell P793 Monitor	350.26 350.26
816	DAMD17-91-C-1139 DAMD17-91-C-1139	P P	Co	10/1/02	Dell P793 Monitor	350.26
817	DAMD17-91-C-1139 DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
818	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
819	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
820	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
821	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
822	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
823	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
824	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
825	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
826	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
827	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
828	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
829	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
830	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
831	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
832	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
833	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
834	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
835	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
836	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
837	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
838	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
839	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
840	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
841	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
842	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
843	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
844	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
845	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
846	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
847	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
848	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
849	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
850	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
851	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
852	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
853	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
854	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
855	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
85	6 DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
85	7 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.94
85	8 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.94
85	9 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.94
86	0 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.94
86	1 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
86		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
86	3 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
86		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
86	5 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
86	6 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
86		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
86		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
86		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
87		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
87	1 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
87	2 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
87.	3 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
87-	4 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
87.	5 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
87	6 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
87	7 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
87	8 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
87	9 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
88	0 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
88		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
88	2 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
88	3 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
88		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
88.		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
88	6 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
88	7 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
88	8 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
88	9 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
89	0 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
89	1 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
89:	2 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
89.	3 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
89		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
89		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
89		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
89		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
89		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
89		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
90		P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
90	1 DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
922	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
923	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
924	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
925	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
926	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
927	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
928	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
929	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
930	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
931	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
932	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
933	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
934	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
935	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
936	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
937	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
938	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
939	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
940	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
941	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
942	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
943	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
944	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
945	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
946	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
947	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
948	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
949	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
950	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
951	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
952	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
953	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
954	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
990	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
991	DAMD17-91-C-1139	P	Co	5/1/03	Dell M782 Monitor	350.00
958	DAMD17-91-C-1139	P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
959	DAMD17-91-C-1139	P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
960	DAMD17-91-C-1139	P P	Co Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
961	DAMD17-91-C-1139	P P		5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
962	DAMD17-91-C-1139		Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
963 964	DAMD17-91-C-1139 DAMD17-91-C-1139	P P	Co Co	5/1/03 5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08 1,230.08
965	DAMD17-91-C-1139 DAMD17-91-C-1139	P P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower Dell Optiplex GX 240 Small Mini Tower	1,230.08
966		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower  Dell Optiplex GX 240 Small Mini Tower	1,230.08
	DAMD17-91-C-1139	P P	Co		* *	1,230.08
967 968	DAMD17-91-C-1139	P P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
968	DAMD17-91-C-1139	Р	CO	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08

ontract ys No		#		P T	Acquisition Class	Date	Description	Tax Acq Value
	969	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	970	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	971	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	972	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	973	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	974	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	975	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	976	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	977	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	978	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	979	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	980	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	981	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	982	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	983	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	984	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	985	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	986	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	987	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	989	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	988	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
	955	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.09
	956	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.09
	957	DAMD17-91-C-1139		P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.09
Class=			Co				* *	127,357.24
SubTotal:								(40,000.00)
								(6,528.00)
								1,225.98
								1,408,629.95
	35	DAMD17-91-C-1139		P	Eq	9/1/93	Refrigerator	530.00
	40	DAMD17-91-C-1139		P	Eq	9/1/93	Chart recorder	1,071.43
	41	DAMD17-91-C-1139		P	Eq	9/1/93	Chart recorder	1,071.43
	42	DAMD17-91-C-1139		P	Eq	9/1/93	Chart recorder	1,071.43
	43	DAMD17-91-C-1139		P	Eq	9/1/93	Chart recorder	1,071.43
	44	DAMD17-91-C-1139		P	Eq	9/1/93	Chart recorder	1,071.43
	45	DAMD17-91-C-1139		P	Eq	9/1/93	Chart recorder	1.071.43
	46	DAMD17-91-C-1139		P	Eq	9/1/93	Chart recorder	1,071.43
	34	DAMD17-91-C-1139		P	Eq	9/1/93	Incubator	2,600.00

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
61	DAMD17-91-C-1139	P	Eq	9/1/93	Radios	3,375.00
37	DAMD17-91-C-1139	P	Eq	9/1/93	6' Biological Safety Cabinet	9,800.00
49	DAMD17-91-C-1139	P	Eq	9/1/93	Cages and racks	12,750.00
50	DAMD17-91-C-1139	P	Eq	9/1/93	Cages and racks	12,750.00
33	DAMD17-91-C-1139	P	Eq	9/1/93	Biocontainment Hood - 8' Biological Safety Cabine	18,500.00
57	DAMD17-91-C-1139	P	Eq	9/1/93	Wire security carts	19,681.00
53	DAMD17-91-C-1139	P	Eq	9/1/93	Labeler	27,415.00
39	DAMD17-91-C-1139	P	Eq	9/1/93	Cagewasher	41,600.00
38	DAMD17-91-C-1139	P	Eq	9/1/93	Small Autoclave	61,300.00
36	DAMD17-91-C-1139	P	Eq	9/1/93	Large Autoclave	124,400.00
48	DAMD17-91-C-1139	P	Eq	9/1/93	5 Animal Cubicles	130,000.00
58	DAMD17-91-C-1139	P	Eq	9/1/93	Vial Capper	132,977.00
60	DAMD17-91-C-1139	P	Eq	9/1/93	Tray Loader	132,977.00
62	DAMD17-91-C-1139	P	Eq	9/1/93	Diesel generator, fuel tank, conduit and wiring	175,000.00
51	DAMD17-91-C-1139	P	Eq	9/1/93	Cartoner	242,260.00
83	DAMD17-91-C-1139	P	Eq	9/1/97	WFI Heat Exchanger	3,715.00
80	DAMD17-91-C-1139	P	Eq	9/1/97	WFI Pump	4,405.00
81	DAMD17-91-C-1139	P	Eq	9/1/97	WFI Pump	4,405.00
93	DAMD17-91-C-1139	P	Eq	9/1/97	Air Handling Unit	7,012.00
89	DAMD17-91-C-1139	P	Eq	9/1/97	WFI Heat Exchanger	10,890.00
92	DAMD17-91-C-1139	P	Eq	9/1/97	Vertical Conveyor	14,000.00
84	DAMD17-91-C-1139	P	Eq	9/1/97	WFI Storage Tanks	17,933.00
94	DAMD17-91-C-1139	P	Eq	9/1/97	Air Handling (Condensing) Unit	17,950.00
87	DAMD17-91-C-1139	P	Eq	9/1/97	Clean in place piping	18,750.00
90	DAMD17-91-C-1139	P	Eq	9/1/97	SIP Station and Piping	20,000.00
88	DAMD17-91-C-1139	P	Eq	9/1/97	Clean Steam Distribution Piping	25,000.00
85	DAMD17-91-C-1139	P	Eq	9/1/97	WFI Cooling System	26,122.00
82	DAMD17-91-C-1139	P	Eq	9/1/97	Clean Steam Generator	78,628.00
91	DAMD17-91-C-1139	P	Eq	9/1/97	Clean Steam Generator	125,875.00
86	DAMD17-91-C-1139	P	Eq	9/1/97	Clean in Place Skid (Pump, Heat Exchanger, Electri	174,066.00
79	DAMD17-91-C-1139	P	Eq	9/1/97	eGMP Autoclave	186,900.00
130	DAMD17-91-C-1139	P	Eq	9/1/98	Water closet	150.00
391	DAMD17-91-C-1139	P	Eq	9/1/98	Lavatory (2)	300.00
115	DAMD17-91-C-1139	P	Eq	9/1/98	sinks (2)	300.00
127	DAMD17-91-C-1139	P	Eq	9/1/98	Hot water heater	450.00
390	DAMD17-91-C-1139	P	Eq	9/1/98	Mop Receptor	500.00
133	DAMD17-91-C-1139	P	Eq	9/1/98	heat water pump	700.00
116	DAMD17-91-C-1139	P	Eq	9/1/98	air separator	800.00
109	DAMD17-91-C-1139	P	Eq	9/1/98	Emergency Shower/Eyebath	900.00
135	DAMD17-91-C-1139	P	Eq	9/1/98	hot water reticulator	1,300.00
129	DAMD17-91-C-1139	P	Eq	9/1/98	Expansion tank	1,500.00
132	DAMD17-91-C-1139	P	Eq	9/1/98	by-pass chemical feeder	1,800.00
112	DAMD17-91-C-1139	P	Eq	9/1/98	Glove extenders for rigid and flex wall systems	1,800.00
134	DAMD17-91-C-1139	P	Eq	9/1/98	steam condensate pump	2,200.00
97	DAMD17-91-C-1139	P	Eq	9/1/98	2 Undercounter Refrigerators	2,848.00
128	DAMD17-91-C-1139	P	Eq	9/1/98	Heat Exchangers (3)	3,000.00

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
136	DAMD17-91-C-1139	P	Eq	9/1/98	Nitrogen regulator	3,000.00
137	DAMD17-91-C-1139	P	Eq	9/1/98	CO2 regulator	3,000.00
392	DAMD17-91-C-1139	P	Eq	9/1/98	Double Sink (Stainless)	3,000.00
106	DAMD17-91-C-1139	P	Eq	9/1/98	Folding Lockable Carts	3,580.00
103	DAMD17-91-C-1139	P	Eq	9/1/98	Horizontal Laminat Flow Hood	4,870.00
111	DAMD17-91-C-1139	P	Eq	9/1/98	Sterility Isolator — Air Handling System	5,573.00
102	DAMD17-91-C-1139	P	Eq	9/1/98	Biosafety Cabinet	6,709.00
131	DAMD17-91-C-1139	P	Eq	9/1/98	Jacket Water reservoir	8,000.00
101	DAMD17-91-C-1139	P	Eq	9/1/98	Reach-in refrigerators (2)	9,784.00
121	DAMD17-91-C-1139	P	Eq	9/1/98	New panel for EMS, Honeywell	10,133.00
126	DAMD17-91-C-1139	P	Eq	9/1/98	AHU 4	11,000.00
114	DAMD17-91-C-1139	P	Eq	9/1/98	Stainless steel benchwork, racks and tables	17,670.00
123	DAMD17-91-C-1139	P	Eq	9/1/98	Bag-in/Bag-out filters	18,395.00
113	DAMD17-91-C-1139	P	Eq	9/1/98	Laboratory Casework (Stainless Steel)	18,950.00
107	DAMD17-91-C-1139	P	Eq	9/1/98	AHU 5 Air Handling Unit	19,787.50
108	DAMD17-91-C-1139	P	Eq	9/1/98	AHU 7 Air Handling Unit	19,787.50
674	DAMD17-91-C-1139	P	Eq	9/1/98	Standard Guinea Pig Unit	20,100.00
95	DAMD17-91-C-1139	P	Eq	9/1/98	Standard Guinea Pig Unit	20,100.00
393	DAMD17-91-C-1139	P	Eq	9/1/98	Process Chiller	23,000.00
98	DAMD17-91-C-1139	P	Eq	9/1/98	Holding tank	26,468.00
125	DAMD17-91-C-1139	P	Eq	9/1/98	Carbon Filter, Building 16, Penthouse	26,700.00
122	DAMD17-91-C-1139	P	Eq	9/1/98	AHU-3	28,875.00
96	DAMD17-91-C-1139	P	Eq	9/1/98	SE Recruiting Water System	34,825.43
104	DAMD17-91-C-1139	P	Eq	9/1/98	5 tanks — retrofit old tanks	72,677.54
100	DAMD17-91-C-1139	P	Eq	9/1/98	Glassware washer/dryer	76,656.00
99	DAMD17-91-C-1139	P	Eq	9/1/98	GMP autoclave	136,225.00
110	DAMD17-91-C-1139	P	Eq	9/1/98	Barrior Isolation Units and VHP Generator	189,000.00
147	DAMD17-91-C-1139	P	Eq	9/1/99	Lockable Cages	530.00
911	DAMD17-91-C-1139	P	Eq	9/1/99	Lockable Cages	530.00
912	DAMD17-91-C-1139	P	Eq	9/1/99	Lockable Cages	530.00
913	DAMD17-91-C-1139	P	Eq	9/1/99	Lockable Cages	530.00
914	DAMD17-91-C-1139	P	Eq	9/1/99	Lockable Cages	530.00
915	DAMD17-91-C-1139	P	Eq	9/1/99	Lockable Cages	530.00
916	DAMD17-91-C-1139	P	Eq	9/1/99	Lockable Cages	530.00
917	DAMD17-91-C-1139	P	Eq	9/1/99	Lockable Cages	530.00
918	DAMD17-91-C-1139	P	Eq	9/1/99	Lockable Cages	530.00
919	DAMD17-91-C-1139	P	Eq	9/1/99	Lockable Cages	530.00
148	DAMD17-91-C-1139	P	Eq	9/1/99	Sterility Isolator Parts	6,702.55
145	DAMD17-91-C-1139	P	Eq	9/1/99	6 SS difuseable pans	8,820.00
145	DAMD17-91-C-1139	P	Eq	9/1/99	hood and bench laminar flow	9,224,35
144	DAMD17-91-C-1139	P	Eq	9/1/99	Redundant HVAC BL-3	31,919.00
262	DAMD17-91-C-1139	P	Eq	3/1/00	Eppendorf CH-500 Column Heater	2,225.36
259	DAMD17-91-C-1139	P	Eq Eq	3/1/00	Eppendorf Centrifuge 5417R w/rotor	5,357.00
260	DAMD17-91-C-1139	P	Eq Eq	3/1/00	Eppendorf Centrifuge 5417R w/rotor	5,357.00
254	DAMD17-91-C-1139 DAMD17-91-C-1139	P	Eq Eq	3/1/00	96 Well Plate Washer	7,229.16
266		P		3/1/00		*
200	DAMD17-91-C-1139	r	Eq	3/1/00	Imaging Densiometer	11,500.09

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
255	DAMD17-91-C-1139	P	Eq	4/1/00	BioChemistry Analyzer	11,865.00
256	DAMD17-91-C-1139	P	Eq	6/1/00	Control Box & Digital Display for Steinmixer	1,504.93
257	DAMD17-91-C-1139	P	Eq	6/1/00	Control Box & Digital Display for Steinmixer	1,504.94
258	DAMD17-91-C-1139	P	Eq	6/1/00	Control Box & Digital Display for Steinmixer	1,504.94
159	DAMD17-91-C-1139	P	Eq	7/1/00	SL Stainless Pressure Vessel	1,226.65
162	DAMD17-91-C-1139	P	Eq	7/1/00	SL Stainless Pressure Vessel	1,226.65
163	DAMD17-91-C-1139	P	Eq	7/1/00	SL Stainless Pressure Vessel	1,226.65
149	DAMD17-91-C-1139	P	Eq	7/1/00	Standard Guinea Pig Unit & Watering Unit	3,789.90
150	DAMD17-91-C-1139	P	Eq	7/1/00	Standard Guinea Pig Unit & Watering Unit	3,789.90
151	DAMD17-91-C-1139	P	Eq	7/1/00	Standard Guinea Pig Unit & Watering Unit	3,789.90
152	DAMD17-91-C-1139	P	Eq	7/1/00	Standard Guinea Pig Unit & Watering Unit	3,789.90
153	DAMD17-91-C-1139	P	Eq	7/1/00	Standard Guinea Pig Unit & Watering Unit	3,789.90
160	DAMD17-91-C-1139	P	Eq	8/1/00	Pen & Multichannel Recorder & Enclosure	1,940.00
161	DAMD17-91-C-1139	P	Eq	8/1/00	Pen & Multichannel Recorder & Enclosure	2,950.00
167	DAMD17-91-C-1139	P	Eq	8/1/00	150L Holding Tank	26,434.44
168	DAMD17-91-C-1139	P	Eq	8/1/00	150L Holding Tank	26,434.44
169	DAMD17-91-C-1139	P	Eq	8/1/00	SIP Lead Equipment	45,257.61
166	DAMD17-91-C-1139	P	Eq	8/1/00	Vial Washer GW24	64,434.00
164	DAMD17-91-C-1139	P	Eq	9/1/00	SAIP Filling & Packaging Project	59,759.13
350	DAMD17-91-C-1139	P	Eq	10/1/00	Temperature Carts for Redundancy Filling and Packs	7,738.84
351	DAMD17-91-C-1139	P	Eq	10/1/00	Temperature Carts for Redundancy Filling and Packs	7,738.84
352	DAMD17-91-C-1139	P	Eq	10/1/00	Temperature Carts for Redundancy Filling and Packs	7,738.84
353	DAMD17-91-C-1139	P	Eq	10/1/00	Temperature Carts for Redundancy Filling and Packs	7,738.84
354	DAMD17-91-C-1139	P	Eq	10/1/00	Temperature Carts for Redundancy Filling and Packs	7,738.84
247	DAMD17-91-C-1139	P	Eq	10/1/00	5 Cages for transportation to Contract Filler	15,084.06
248	DAMD17-91-C-1139	P	Eq	10/1/00	5 Cages for transportation to Contract Filler	15,084.06
249	DAMD17-91-C-1139	P	Eq	10/1/00	5 Cages for transportation to Contract Filler	15,084.06
250	DAMD17-91-C-1139	P	Eq	10/1/00	5 Cages for transportation to Contract Filler	15,084.06
251	DAMD17-91-C-1139	P	Eq	10/1/00	5 Cages for transportation to Contract Filler	15,084.06
245	DAMD17-91-C-1139	P	Eq	11/1/00	Heat Exchange Redesign	28,533.31
158	DAMD17-91-C-1139	P	Eq	12/1/00	Standard Guinea Pig Unit & Watering Unit	4,402.26
154	DAMD17-91-C-1139	P	Eq	12/1/00	Standard Guinea Pig Unit & Watering Unit	4,402.27
155	DAMD17-91-C-1139	P	Eq	12/1/00	Standard Guinea Pig Unit & Watering Unit	4,402.27
156	DAMD17-91-C-1139	P	Eq	12/1/00	Standard Guinea Pig Unit & Watering Unit	4,402.27
157	DAMD17-91-C-1139	P	Eq	12/1/00	Standard Guinea Pig Unit & Watering Unit	4,402.27
355	DAMD17-91-C-1139	P	Eq	1/1/01	Kjeldahl digestion apparatus, rotary base	1,810.00
356	DAMD17-91-C-1139	P	Eq	3/1/01	Rapid Still 1, Labonco	2,850.00
333	DAMD17-91-C-1139	P	Eq	4/1/01	Trash Pump	1,088.57
313	DAMD17-91-C-1139	P	Eq	4/1/01	Mini Neph Unit and Printer	3,357.50
329	DAMD17-91-C-1139	P	Eq	4/1/01	Fermentor Datalogger	5,870.85
328	DAMD17-91-C-1139	P	Eq	4/1/01	ExMark Mower	8,914.54
339	DAMD17-91-C-1139	P	Eq	5/1/01	Honeywell Chart Recorder	2,114.89
338	DAMD17-91-C-1139	P	Eq	5/1/01	Honeywell Chart Recorder	2,114.90
357	DAMD17-91-C-1139	P	Eq	5/1/01	Flange Fitness Gauge	4,129.00
332	DAMD17-91-C-1139	P	Eq	5/1/01	Centrifuge with Rotor and Microplus Carriers	7,908.25
342	DAMD17-91-C-1139	P	Eq	5/1/01	Machining of Formulation Tanks Project 211	32,138.82

Contract Sys No	#	P T	Acquisitio Class	n Date	Description	Tax Acq Value
331	DAMD17-91-C-1139	P	Eq	5/1/01	TOC Analyzer	33,621.26
337	DAMD17-91-C-1139	P	Eq	5/1/01	Building 1 Air Conditioning Unit	92,633.24
330	DAMD17-91-C-1139	P	Eq	6/1/01	Chryo Freezer	13,962.33
340	DAMD17-91-C-1139	P	Eq	6/1/01	Stability Chamber	17,906.00
341	DAMD17-91-C-1139	P	Eq	6/1/01	Stability Chamber	17,906.00
364	DAMD17-91-C-1139	P	Eq	7/1/01	Fuel Tank	2,236.81
365	DAMD17-91-C-1139	P	Eq	7/1/01	Stainless Steel Carts	7,248.00
367	DAMD17-91-C-1139	P	Eq	7/1/01	RO System Move to Bld 30	199,603.53
584	DAMD17-91-C-1139	P	Eq	8/15/01	Undercounter Refrigerator	747.00
585	DAMD17-91-C-1139	P	Eq	8/21/01	Automatic Polarimeter	19,465.00
587	DAMD17-91-C-1139	P	Eq	8/30/01	Sanitary Conical Tank	2,838.68
384	DAMD17-91-C-1139	P	Eq	9/1/01	Clean Steam Generators Outlet Piping Modification	12,260.00
589	DAMD17-91-C-1139	P	Eq	9/10/01	Compressor for Building 45	4,067.00
586	DAMD17-91-C-1139	P	Eq	9/25/01	Ice Flaker	2,180.00
638	DAMD17-91-C-1139	P	Eq	10/1/01	Repair to Forklift Mast System	1,245.49
403	DAMD17-91-C-1139	P	Eq	10/1/01	GPS System for contract filler truck	2,212.00
809	DAMD17-91-C-1139	P	Eq	10/1/01	Hollister Stier-Vial Rinser	5,300.00
394	DAMD17-91-C-1139	P	Eq	10/1/01	Security Related Equipment	22,809.97
810	DAMD17-91-C-1139	P	Eq	10/1/01	Hollister Stier-Filling Pumps	35,000.00
811	DAMD17-91-C-1139	P	Eq	10/1/01	Hollister Stier-Ultrasonic Bath	44,343.00
808	DAMD17-91-C-1139	P	Eq	10/1/01	Hollister Stier-Cold Room	136,740.00
396	DAMD17-91-C-1139	P	Eq	10/25/01	Refrigerator	2,986.90
397	DAMD17-91-C-1139	P	Eq	10/25/01	Haske Bath	3,017.71
395	DAMD17-91-C-1139	P	Eq	10/25/01	Incubator	3,987.00
406	DAMD17-91-C-1139	P	Eq	11/7/01	Condensate Tanks	11,780.00
414	DAMD17-91-C-1139	P	Eq	11/8/01	Tube Bender	5,275.08
404	DAMD17-91-C-1139	P	Eq	11/20/01	AVA Kill Tank System	5,763.03
412	DAMD17-91-C-1139	P	Eq	12/1/01	Pipe Rack Modifications	29,728.12
411	DAMD17-91-C-1139	P	Eq	12/1/01	Modifications to Trains 2, 3, 4	77,813.20
429	DAMD17-91-C-1139	P	Eq	12/3/01	Micro Kheldahl	1,349.92
430	DAMD17-91-C-1139	P	Eq	12/3/01	Micro Kjeldahl	1,349.92
431	DAMD17-91-C-1139	P	Eq	12/3/01	Micro Kjeldahl	2,091.18
426	DAMD17-91-C-1139	P	Eq	12/18/01	Micro Kjeldahl Distillation	2,035.97
427	DAMD17-91-C-1139	P	Eq	12/18/01	Micro Kjeldahl Distillation	2,035.97
428	DAMD17-91-C-1139	P	Eq	12/18/01	Micro Kjeldahl Distillation	2,035.97
416	DAMD17-91-C-1139	P	Eq	12/31/01	Nikon Eclipse E400	7,245.26
593	DAMD17-91-C-1139	P	Eq	1/1/02	Building #12 Fermentation Room Camera	8,642.00
547	DAMD17-91-C-1139	P	Eq	1/8/02	Undercounter Continental Refrigerator 7.4cft	1,727.26
434	DAMD17-91-C-1139	P	Eq	1/8/02	Bench Top Incubator Shaker	5,160.00
433	DAMD17-91-C-1139	P	Eq	1/8/02	Artel Pipette Calibration System	8,105.62
435	DAMD17-91-C-1139	P	Eq	1/8/02	Incubator Shaker	8,930.00
438	DAMD17-91-C-1139	P	Eq	1/21/02	UV1201 SCP Printer Kit	1,189.06
439	DAMD17-91-C-1139	P	Eq	1/21/02	UV1201 SCP Printer Kit	1,189.06
436	DAMD17-91-C-1139	P	Eq	1/21/02	UV1201 Spectrophotometer	5,371.56
437	DAMD17-91-C-1139	P	Eq	1/21/02	UV1201 Spectrophotometer	5,371.56
600	DAMD17-91-C-1139	P	Eq	1/31/02	Tunnel Camera and Motion Units	66,109.02

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
603	DAMD17-91-C-1139	P	Eq	1/31/02	Trailer for Contract Filler	85,145.82
601	DAMD17-91-C-1139	P	Eq	1/31/02	Fire Alarm System Upgrade	273,375.00
606	DAMD17-91-C-1139	P	Eq	2/28/02	Locknetics Prox Cipher Locks	8,000.00
595	DAMD17-91-C-1139	P	Eq	2/28/02	EMS System Upgrade (1of3 Stations)	9,623.32
640	DAMD17-91-C-1139	P	Eq	2/28/02	EMS System Upgrade (2of3 Stations)	9,623.34
641	DAMD17-91-C-1139	P	Eq	2/28/02	EMS System Upgrade (3of3 Stations)	9,623.34
902	DAMD17-91-C-1139	P	Eq	3/1/02	300 Liter Formulation Tank	65,883.23
903	DAMD17-91-C-1139	P	Eq	3/1/02	300 Liter Formulation Tank	65,883.23
904	DAMD17-91-C-1139	P	Eq	3/1/02	300 Liter Formulation Tank	65,883.23
905	DAMD17-91-C-1139	P	Eq	3/1/02	300 Liter Formulation Tank	65,883.23
615	DAMD17-91-C-1139	P	Eq	3/1/02	300 Liter Formulation Tank	65,883.24
614	DAMD17-91-C-1139	P	Eq	3/1/02	Water for Injection (WFI) Capacity Improvement P	115,000.00
622	DAMD17-91-C-1139	P	Eq	3/29/02	SMA Portable Compressed Air Sampler	1,126.95
627	DAMD17-91-C-1139	P	Eq	3/29/02	Benchtop pH/temp/MV Meter (model 390)	1,221.57
630	DAMD17-91-C-1139	P	Eq	3/29/02	Standard Guinea Pig Unit	3,787.50
631	DAMD17-91-C-1139	P	Eq	3/29/02	Standard Guinea Pig Unit	3,787.50
632	DAMD17-91-C-1139	P	Eq	3/29/02	Standard Guinea Pig Unit	3,787.50
633	DAMD17-91-C-1139	P	Eq	3/29/02	Standard Guinea Pig Unit	3,787.50
634	DAMD17-91-C-1139	P	Eq	3/29/02	Standard Guinea Pig Unit	3,787.50
635	DAMD17-91-C-1139	P	Eq	3/29/02	Standard Guinea Pig Unit	3,787.50
626	DAMD17-91-C-1139	P	Eq	3/29/02	Spot Insight Color "C" Mount Camera	3,877.43
624	DAMD17-91-C-1139	P	Eq	3/29/02	1240 Spectrophotometer	5,258.25
625	DAMD17-91-C-1139	P	Eq	3/29/02	Nikon E400 Microscope	6,541.78
623	DAMD17-91-C-1139	P	Eq	3/29/02	PR Wire/elx 405 VR Plate Washer & Reader	28,571.25
605	DAMD17-91-C-1139	P	Eq	3/29/02	D1 Water Skid	114,375.11
637	DAMD17-91-C-1139	P	Eq	3/29/02	PBX Telephone System	160,000.00
687	DAMD17-91-C-1139	P	Eq	3/29/02	Housing for Water for Injection Capacity PART B	1,110,980.00
719	DAMD17-91-C-1139	P	Eq	4/1/02	Security Gates in Tunnels	5,460.00
803	DAMD17-91-C-1139	P	Eq	4/1/02	Hollister Stier - Security System - Security Equipme	245,098.00
629	DAMD17-91-C-1139	P	Eq	4/12/02	Greenlee Bender	5,905.00
723	DAMD17-91-C-1139	P	Eq	5/1/02	Lockable Cage	555.00
737	DAMD17-91-C-1139	P	Eq	5/1/02	Lockable Cage	555.00
738	DAMD17-91-C-1139	P	Eq	5/1/02	Lockable Cage	555.00
739	DAMD17-91-C-1139	P	Eq	5/1/02	Lockable Cage	555.00
740	DAMD17-91-C-1139	P	Eq	5/1/02	Lockable Cage	555.00
741	DAMD17-91-C-1139	P	Eq	5/1/02	Lockable Cage	555.00
742	DAMD17-91-C-1139	P	Eq	5/1/02	Lockable Cage	555.00
743	DAMD17-91-C-1139	P	Eq	5/1/02	Lockable Cage	555.00
744	DAMD17-91-C-1139	P	Eq	5/1/02	Lockable Cage	555.00
745	DAMD17-91-C-1139	P	Eq	5/1/02	Lockable Cage	555.00
730	DAMD17-91-C-1139	P	Eq	5/1/02	X6000-Validation Reference Manual	750.00
729	DAMD17-91-C-1139	P	Eq	5/1/02	X6005-IQ/OQ Validation Protocols for Validator 2	1,500.00
728	DAMD17-91-C-1139	P	Eq	5/1/02	X2020-ICAL Kit	1,600.00
724	DAMD17-91-C-1139	P	Eq	5/1/02	X0855-IRTD 400 High Accuracy Probe	3,730.00
731	DAMD17-91-C-1139	P	Eq	5/1/02	Sublot Transfer Cart	4,905.00
732	DAMD17-91-C-1139	P	Eq	5/1/02	Sublot Transfer Cart	4,905.00

Contract Sys No		#	P T	Acquisition Class	n Date	Description	Tax Acq Value
	720	DAMD17-91-C-1139	P	Eq	5/1/02	Building #29 Camera	8,105.00
	725	DAMD17-91-C-1139	P	Eq	5/1/02	X200 Validator 2000 High Accuracy Validation Sy	13,360.00
	726	DAMD17-91-C-1139	P	Eq	5/1/02	X2000 Validator 2000-High Accuracy Validation S	13,360.00
	727	DAMD17-91-C-1139	P	Eq	5/1/02	X2000 Validator 2000-High Accuracy Validation S	13,360.00
	718	DAMD17-91-C-1139	P	Eq	5/1/02	Guardhouse	58,750.00
	756	DAMD17-91-C-1139	P	Eq	6/1/02	Honeywell Minitrend Data Recorder	7,250.20
	786	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	787	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	788	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	789	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	790	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	791	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	792	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	793	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	794	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	795	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	796	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	797	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	798	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.46
	799	DAMD17-91-C-1139	P	Eq	8/1/02	Standard Guinea Pig Unit	3,729.52
Class-			<u>Eq</u>	· ·		- C	
SubTotal			·				7,009,192.12
	55	DAMD17-91-C-1139	P	Fu	9/1/93	Shelving	9,600.00
	218	DAMD17-91-C-1139	P	Fu	4/1/00	Server Racks	3,814.04
	229	DAMD17-91-C-1139	P	Fu	5/1/00	Tables & Chairs for Meeting Rooms	2,787.06
	237	DAMD17-91-C-1139	P	Fu	8/1/00	Office furniture	546.00
	235	DAMD17-91-C-1139	P	Fu	8/1/00	Table and Chairs	636.00
	232	DAMD17-91-C-1139	P	Fu	8/1/00	Office furniture	1,678.28
	226	DAMD17-91-C-1139	P	Fu	8/1/00	Office furniture	1,949.00
	231	DAMD17-91-C-1139	P	Fu	8/1/00	Office furniture	1,949.00
	233	DAMD17-91-C-1139	P	Fu	8/1/00	Office furniture	1,933.00
	234	DAMD17-91-C-1139	P	Fu	8/1/00	Office furniture	2,077.00
	239	DAMD17-91-C-1139	P	Fu Fu	8/1/00		2,543.00
	239	DAMD17-91-C-1139 DAMD17-91-C-1139	P P	Fu Fu	8/1/00	Office furniture Office furniture	2,543.00 4,302.20
	236	DAMD17-91-C-1139 DAMD17-91-C-1139	P P	Fu Fu	8/1/00	Furniture  Furniture	4,302.20 7,341.31
	228	DAMD17-91-C-1139 DAMD17-91-C-1139	P P	Fu Fu	8/1/00	Furniture	21,390.75
	243	DAMD17-91-C-1139 DAMD17-91-C-1139	P	Fu Fu	10/1/00	Management Chair	21,390.75 541.87
	230	DAMD17-91-C-1139 DAMD17-91-C-1139	P P	Fu Fu	10/1/00	Office Furniture	2,120.00
	240	DAMD17-91-C-1139 DAMD17-91-C-1139	P	Fu Fu	10/1/00	Office Furniture	
			P P	Fu Fu	10/1/00		2,120.00
	238	DAMD17-91-C-1139	P P			(13) Task Chairs, Paint and Carpet Squares 10 Chairs	2,535.58
	241 242	DAMD17-91-C-1139 DAMD17-91-C-1139	P P	Fu Fu	12/1/00 12/1/00	Office Furniture	2,039.99
			P P				2,231.50
	715	DAMD17-91-C-1139		Fu	3/1/01	Heather Blue Chair	75.34 75.34
	716	DAMD17-91-C-1139	P	Fu	3/1/01	Heather Blue Chair	75.34

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
712	DAMD17-91-C-1139	P	Fu	3/1/01	Heather Blue Chair	150.68
713	DAMD17-91-C-1139	P	Fu	3/1/01	Heather Blue Chair	150.68
714	DAMD17-91-C-1139	P	Fu	3/1/01	Heather Blue Chair	150.68
280	DAMD17-91-C-1139	P	Fu	3/1/01	Heather Blue Chair	192.60
707	DAMD17-91-C-1139	P	Fu	3/1/01	Heather Blue Chair	192.68
708	DAMD17-91-C-1139	P	Fu	3/1/01	Heather Blue Chair	192.68
709	DAMD17-91-C-1139	P	Fu	3/1/01	Heather Blue Chair	192.68
710	DAMD17-91-C-1139	P	Fu	3/1/01	Heather Blue Chair	192.68
711	DAMD17-91-C-1139	P	Fu	3/1/01	Heather Blue Chair	192.68
282	DAMD17-91-C-1139	P	Fu	3/1/01	Furniture for AVA Trailer Project 178	9,487.82
310	DAMD17-91-C-1139	P	Fu	3/1/01	Cubicles for Workroom	13,141.98
326	DAMD17-91-C-1139	P	Fu	4/1/01	Building 29 Cubicles	25,383.55
348	DAMD17-91-C-1139	P	Fu	6/1/01	Marker Board	33.57
343	DAMD17-91-C-1139	P	Fu	6/1/01	Light Walnut Low Coffee Table	38.57
369	DAMD17-91-C-1139	P	Fu	6/1/01	Cherry Laminate Table	50.00
651	DAMD17-91-C-1139	P	Fu	6/1/01	Cherry Wood Guest Chair	54.28
344	DAMD17-91-C-1139	P	Fu	6/1/01	Cherry Wood Guest Chair	55.29
347	DAMD17-91-C-1139	P	Fu	6/1/01	Guest Chair	58.57
664	DAMD17-91-C-1139	P	Fu	6/1/01	Lateral File	100.00
665	DAMD17-91-C-1139	P	Fu	6/1/01	Lateral File	100.00
666	DAMD17-91-C-1139	P	Fu	6/1/01	Lateral File	100.00
667	DAMD17-91-C-1139	P	Fu	6/1/01	Lateral File	100.00
668	DAMD17-91-C-1139	P	Fu	6/1/01	Lateral File	100.00
346	DAMD17-91-C-1139	P	Fu	6/1/01	Big Man Chair	108.57
345	DAMD17-91-C-1139	P	Fu	6/1/01	Blue Superior Chair	158.57
349	DAMD17-91-C-1139	P	Fu	6/1/01	Desk National 30x60	258.58
368	DAMD17-91-C-1139	P	Fu	6/1/01	Conference Table	300.00
669	DAMD17-91-C-1139	P	Fu	6/1/01	Dark Walnut Desk	589.68
659	DAMD17-91-C-1139	P	Fu	7/1/01	Lateral File	162.83
660	DAMD17-91-C-1139	P	Fu	7/1/01	Lateral File	162.83
658	DAMD17-91-C-1139	P	Fu	7/1/01	Lateral File	162.84
677	DAMD17-91-C-1139	P	Fu	7/1/01	Heather Blue Chair	223.60
678	DAMD17-91-C-1139	P	Fu	7/1/01	Heather Blue Chair	223.60
374	DAMD17-91-C-1139	P	Fu	7/1/01	Heather Blue Chair	236.50
655	DAMD17-91-C-1139	P	Fu	7/1/01	Executive Chair	236.50
656	DAMD17-91-C-1139	P	Fu	7/1/01	Executive Chair	236.50
657	DAMD17-91-C-1139	P	Fu	7/1/01	Executive Chair	236.50
675	DAMD17-91-C-1139	P	Fu	7/1/01	Lateral File	271.25
676	DAMD17-91-C-1139	P	Fu	7/1/01	Lateral File	271.25
652	DAMD17-91-C-1139	P	Fu	7/1/01	36" Bookcase	278.00
654	DAMD17-91-C-1139	P	Fu	7/1/01	Office Furniture	424.48
653	DAMD17-91-C-1139	P	Fu	7/1/01	4 Drawer Lateral File	620.00
375	DAMD17-91-C-1139	P	Fu	7/1/01	IS Storage Shelves	790.04
683	DAMD17-91-C-1139	P	Fu	7/1/01	Work Surface & Cubicle Area	2,577.74
679	DAMD17-91-C-1139	P	Fu	7/1/01	Work Surface & Cubicle Area	2,577.75
680	DAMD17-91-C-1139	P	Fu	7/1/01	Work Surface & Cubicle Area	2,577.75

Contract Sys No	#	P T	Acquisition Class	Date	Description	Tax Acq Value
681	DAMD17-91-C-1139	P	Fu	7/1/01	Work Surface & Cubicle Area	2,577.75
682	DAMD17-91-C-1139	P	Fu	7/1/01	Work Surface & Cubicle Area	2,577.75
661	DAMD17-91-C-1139	P	Fu	7/1/01	Office Furniture	3,000.97
662	DAMD17-91-C-1139	P	Fu	7/1/01	Office Furniture	3,000.97
663	DAMD17-91-C-1139	P	Fu	7/1/01	Office Furniture	3,000.98
363	DAMD17-91-C-1139	P	Fu	7/1/01	Building 29 Cubicles	15,622.62
293	DAMD17-91-C-1139	P	Fu	7/1/01	Document Control Fire Suppression System #1	48,321.30
688	DAMD17-91-C-1139	P	Fu	8/1/01	Blue Side Chair	103.00
689	DAMD17-91-C-1139	P	Fu	8/1/01	Blue Side Chair	103.00
690	DAMD17-91-C-1139	P	Fu	8/1/01	Blue Side Chair	103.00
691	DAMD17-91-C-1139	P	Fu	8/1/01	Blue Side Chair	103.00
692	DAMD17-91-C-1139	P	Fu	8/1/01	Blue Side Chair	103.00
693	DAMD17-91-C-1139	P	Fu	8/1/01	Blue Side Chair	103.00
377	DAMD17-91-C-1139	P	Fu	8/1/01	Wild Cherry Laminate Table	868.95
383	DAMD17-91-C-1139	P	Fu	9/1/01	System Wall w/Locking Doors	2,450.34
642	DAMD17-91-C-1139	P	Fu	10/25/01	Shelving for Bldg 30 Coldroom	524.00
643	DAMD17-91-C-1139	P	Fu	10/25/01	Shelving for Bldg 30 Coldroom	524.00
644	DAMD17-91-C-1139	P	Fu	10/25/01	Shelving for Bldg 30 Coldroom	524.00
645	DAMD17-91-C-1139	P	Fu	10/25/01	Shelving for Bldg 30 Coldroom	524.00
646	DAMD17-91-C-1139	P	Fu	10/25/01	Shelving for Bldg 30 Coldroom	524.00
647	DAMD17-91-C-1139	P	Fu	10/25/01	Shelving for Bldg 30 Coldroom	524.00
648	DAMD17-91-C-1139	P	Fu	10/25/01	Shelving for Bldg 30 Coldroom	524.00
649	DAMD17-91-C-1139	P	Fu	10/25/01	Shelving for Bldg 30 Coldroom	524.00
650	DAMD17-91-C-1139	P	Fu	10/25/01	Shelving for Bldg 30 Coldroom	524.00
401	DAMD17-91-C-1139	P	Fu	10/25/01	Shelving for Bldg 30 Coldroom	524.00
424	DAMD17-91-C-1139	P	Fu	12/1/01	Stainless Steel Cabinets	5,034.28
425	DAMD17-91-C-1139	P	Fu	12/1/01	Lockers	6,450.50
413	DAMD17-91-C-1139	P	Fu	12/1/01	Scientific Tables	7,167.15
423	DAMD17-91-C-1139	P	Fu	12/1/01	Security Office Storage	11,674.08
594	DAMD17-91-C-1139	P	Fu	1/31/02	36" Bookcase	170.00
694	DAMD17-91-C-1139	P	Fu	1/31/02	36" Bookcase	170.00
695	DAMD17-91-C-1139	P	Fu	1/31/02	36" Bookcase	170.00
696	DAMD17-91-C-1139	P	Fu	1/31/02	36" Bookcase	170.00
697	DAMD17-91-C-1139	P	Fu	1/31/02	36" Bookcase	170.00
698	DAMD17-91-C-1139	P	Fu	1/31/02	36" Bookcase	170.00
699	DAMD17-91-C-1139	P	Fu	1/31/02	36" Bookcase	170.00
700	DAMD17-91-C-1139	P	Fu	1/31/02	36" Bookcase	170.00
701	DAMD17-91-C-1139	P	Fu	1/31/02	36" Bookcase	170.00
702	DAMD17-91-C-1139	P	Fu	1/31/02	36" Bookcase	170.00
703	DAMD17-91-C-1139	P	Fu	1/31/02	36" Bookcase	170.00
706	DAMD17-91-C-1139	P	Fu	1/31/02	60" Bookcase	418.60
704	DAMD17-91-C-1139	P	Fu	1/31/02	60" Bookcase	418.61
705	DAMD17-91-C-1139	P	Fu	1/31/02	60" Bookcase	418.61
736	DAMD17-91-C-1139	P	Fu	4/1/02	Stainless Steel Equipment Stand	328.40
722	DAMD17-91-C-1139	P P	Fu	4/1/02	Stainless Steel Utility Cart	370.30 270.30
733	DAMD17-91-C-1139	Р	Fu	4/1/02	Stainless Steel Utility Cart	370.30

Contract Sys No		#	P T	Acquisition Class	Date	Description	Tax Acq Value
, , , , ,	734	DAMD17-91-C-1139	P	Fu	4/1/02	Stainless Steel Insurance Table	444.00
	735	DAMD17-91-C-1139	P	Fu	4/1/02	Stainless Steel Insurance Table	444.00
	747	DAMD17-91-C-1139	P	Fu	6/1/02	FireKing Vertical Fire Cabinet	1,919.89
	748	DAMD17-91-C-1139	P	Fu	6/1/02	FireKing Vertical Fire Cabinet	1,919.93
	749	DAMD17-91-C-1139	P	Fu	6/1/02	FireKing Vertical Fire Cabinet	1,919.93
	750	DAMD17-91-C-1139	P	Fu	6/1/02	FireKing Vertical Fire Cabinet	1,919.93
	751	DAMD17-91-C-1139	P	Fu	6/1/02	FireKing Vertical Fire Cabinet	1,919.93
	752	DAMD17-91-C-1139	P	Fu	6/1/02	FireKing Vertical Fire Cabinet	1,919.93
	753	DAMD17-91-C-1139	P	Fu	6/1/02	FireKing Vertical Fire Cabinet	1,919.93
	754	DAMD17-91-C-1139	P	Fu	6/1/02	FireKing Vertical Fire Cabinet	1,919.93
	782	DAMD17-91-C-1139	P	Fu	7/1/02	Lateral Fireproof File Cabinet	2,024.00
	783	DAMD17-91-C-1139	P	Fu	7/1/02	Lateral Fireproof File Cabinet	2,024.00
Class-			<u>Fu</u>				
lubTotal							280,532.20
	67	DAMD17-91-C-1139	R	Im	9/1/93	Security Doors	24,800.00
	54	DAMD17-91-C-1139	R	Im	9/1/93	Coldroom Modular Facility	112,681.00
	124	DAMD17-91-C-1139	R	Im	9/1/98	Backup generator	227,200.00
	143	DAMD17-91-C-1139	R	Im	9/1/98	coldrooms (3A, 3B, 4)	230,000.00
	165	DAMD17-91-C-1139	R	Im	8/1/00	Lab Renovations	8,108.00
	246	DAMD17-91-C-1139	R	Im	10/1/00	Building 30 & Building 6 Roof	63,965.41
	327	DAMD17-91-C-1139	R	Im	4/1/01	Building 29 Renovations	5,176.55
	362	DAMD17-91-C-1139	R	Im	9/1/01	Fire Suppression IS	18.054.97
	410	DAMD17-91-C-1139	R	Im	11/1/01	Paving Project	48,885.00
	415	DAMD17-91-C-1139	R	Im	11/28/01	Perimeter Fence Building 15	1,749.00
	408	DAMD17-91-C-1139	R	Im	11/28/01	Sheridan Rd Mechanical Slide Gate	35,196.00
	420	DAMD17-91-C-1139	R	Im	12/1/01	Bullet Resistant Windows	30,845.00
	422	DAMD17-91-C-1139	R	Im	12/1/01	Repairs to Domestic Water and Gas	92,349.00
	590	DAMD17-91-C-1139	R	Im	1/1/02	Intercom System for Security Gates	17,600.00
	591	DAMD17-91-C-1139	R	Im	1/1/02	Perimeter Fence Detection System	100,200.00
	604	DAMD17-91-C-1139	R	Im	2/28/02	Coldroom 150 Temporary Loading Platform	83,881.22
	801	DAMD17-91-C-1139	R	Im	4/1/02	Hollister Stier - Security System - Fiber Cabling in :	2,730.00
	717	DAMD17-91-C-1139	R	Im	4/1/02	Hollister Stier-Security System - Reception Area Gh:	6,480.00
	802	DAMD17-91-C-1139	R	Im	4/1/02	Hollister Stier-Security System - Campus Modific	24,868.00
	721	DAMD17-91-C-1139	R	Im	5/1/02	Stainless Steel Razor Wire	20,978.00
	755	DAMD17-91-C-1139	R	Im	6/1/02	Campus Lighting	4,923.00
	757	DAMD17-91-C-1139	R	Im	6/1/02	Coldroom 150 Modifications	21,441.00
Class-			<u>Im</u>				
ubtotal							1,182,111.15
	66	DAMD17-91-C-1139	R	La	9/1/93	Tunnel Barricade	9,570.00
	64	DAMD17-91-C-1139	R	La	9/1/93	Light pole lights, poles, conduit and wiring	20,000.00
	65	DAMD17-91-C-1139	R	La	9/1/93	Pipe access covers	72,600.00
	63	DAMD17-91-C-1139	R	La	9/1/93	Security fence	101,000.00

Contract Sys No		#	P T	Acquisition Class	Date	Description	Tax Acq Value
	142	DAMD17-91-C-1139	R	La	9/1/98	Wooden fencing	8,413.00
	379	DAMD17-91-C-1139	R	La	7/1/01	Tunnel Renovation	20,480.98
	385	DAMD17-91-C-1139	R	La	9/1/01	Tunnel Barricade	14,361.35
Class-			La				
Subtotal							246,425.33
	117	DAMD17-91-C-1139	P	So	9/1/98	Date Acquisition System (Software and net packs)	36,765.00
	105	DAMD17-91-C-1139	P	So	9/1/98	MRP-Fourth Shift Software Package	99,421.00
	221	DAMD17-91-C-1139	P	So	3/1/00	Calhoun Computer System	1,699.96
	252	DAMD17-91-C-1139	P	So	7/1/00	Seal Force Tester & Interface Software	12,675.00
	225	DAMD17-91-C-1139	P	So	9/1/00	SAIP Compliance Software	212,153.00
	268	DAMD17-91-C-1139	P	So	10/1/00	ABRA Suite Payroll Software	50,786.42
	382	DAMD17-91-C-1139	P	So	9/1/01	Statistical Software	1,052.00
	399	DAMD17-91-C-1139	P	So	10/9/01	STAT View Software	5,560.00
	400	DAMD17-91-C-1139	P	So	10/12/01	Affirmative Action Plan (HR)	3,990.00
	419	DAMD17-91-C-1139	P	So	1/31/02	Norton, Anti Virus Desk Server	7,653.75
	607	DAMD17-91-C-1139	P	So	2/28/02	STAT View Software	6,500.00
	761	DAMD17-91-C-1139	P	So	7/1/02	Office XP Property Licenses (60)	25,018.20
	784	DAMD17-91-C-1139	P	So	8/1/02	Ghost Media Pack	2,884.00
	785	DAMD17-91-C-1139	P	So	8/1/02	Office XP Property Licenses	20,875.00
	906	DAMD17-91-C-1139	P	So	11/1/02	Network/Backup Archive System	99,232.59
Class-			So			•	
Subtotal							586,265.92
Contract #-							
SubTotal		DAMD17-91-C-1139					12,462,383.67
	1	DAMD17-97-E-0004	P	Eq	9/1/89	Balance, Bench Top Model	1,503.00
	2	DAMD17-97-E-0004	P	Eq	9/1/89	Bright Field Microscope	2,819.00
	3	DAMD17-97-E-0004	P	Eq	9/1/89	Automated Kjeldahl Apparatus	24,400.00
	5	DAMD17-97-E-0004	P	Eq	9/1/90	Holding Tank B, Train 2	67,883.66
	6	DAMD17-97-E-0004	P	Eq	9/1/90	10 Liter Fermenter, Train 2	67,883.67
	7	DAMD17-97-E-0004	P	Eq	9/1/90	100 Liter Fermenter, Train 2	67,883.67
	23	DAMD17-97-E-0004	P	Eq	9/1/91	pH Meter	1,895.00
	11	DAMD17-97-E-0004	P	Eq	9/1/91	Balance	2,625.50
	21	DAMD17-97-E-0004	P	Eq	9/1/91	Balance	2,625.50
	18	DAMD17-97-E-0004	P	Eq	9/1/91	CO2 Incubator	2,767.00
	12	DAMD17-97-E-0004	P	Eq	9/1/91	Refrigerated Low Speed Centrifuge	17,113.00
	13	DAMD17-97-E-0004	P	Eq	9/1/91	Autoclave	30,000.00
	14	DAMD17-97-E-0004	P	Eq	9/1/91	100 Liter Fermenter, Train 1	102,900.00
			P	Eq	9/1/91	10 Liter Fermenter, Train 3	102,900.00
	15	DAMD17-97-E-0004	P				
	15 16	DAMD17-97-E-0004 DAMD17-97-E-0004	P	Eq	9/1/91	100 Liter Fermenter, Train 4	102,900.00

Contract Sys No		#		P T	Acquisition Class	Date	Description	Tax Acq Value
-,	19	DAMD17-97-E-0004		P	Eq	9/1/91	Autoclave, Double-door	128,350.00
	24	DAMD17-97-E-0004		P	Eq	9/1/92	Holding Tank A, Train 3	102,900.00
	25	DAMD17-97-E-0004		P	Eq	9/1/92	Holding Tank A, Train 4	102,500.00
	72	DAMD17-97-E-0004		P	Eq	9/1/94	Hoist	575.00
	73	DAMD17-97-E-0004		P	Eq	9/1/94	Hoist	575.00
	68	DAMD17-97-E-0004		P	Eq	9/1/94	10 Liter Fermenter, Train 1	71,610.00
	69	DAMD17-97-E-0004		P	Eq	9/1/94	Holding Tank A, Train 2	71,610.00
	70	DAMD17-97-E-0004		P	Eq	9/1/94	100 Liter Fermenter, Train 3	71,610.00
	78	DAMD17-97-E-0004		P	Eq	9/1/95	Two-Chart Recorder for Freezer #2	1,349.00
Class-			<u>Eq</u>					
Subtotal								1,252,478.00
	77	DAMD17-97-E-0004		R	Im	9/1/94	Stairs	1,000.00
Class-			<u>Im</u>					
Subtotal								1,000.00
								<u> </u>
Contract #-		DAMD17-97-E-0004						
Subtotal								1,253,478.00
	386	DAMD17-98-C-8052		P	Eq	9/1/98	Holding Tank	62,500.00
	387	DAMD17-98-C-8052		P	Eq	9/1/98	Holding Tank	62,500.00
	388	DAMD17-98-C-8052		P	Eq	9/1/98	Holding Tank	62,500.00
	389	DAMD17-98-C-8052		P	Eq	9/1/98	Holding Tank	62,500.00
Class-			<u>Eq</u>					
Subtotal								250,000.00
Contract #-		DAMD17-98-C-8052						
Subtotal								250,000.00
								13,965,861.67

		Jan	Feb	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec	Total
Ja	an 04-Dec 05	0	0	0	108,120	108,120	108,120	108,120	108,120	108,120	108,120	108,120	108,120	973,080
Ja	an 05-Dec 05	235,880	235,880	235,820	127,760	127,760	127,760	127,760	127,760	127,760	127,760	127,760	127,730	1,857,390
Ja	an 06-Sep 06	115,000	115,000	115,000	115,000	115,000	115,000	115,000	115,000	114,930				1,034,930
														3 865 400

MENDM	ENT OF SOLICITAT	TION/MODIFICATION	ON OF CONTRACT	I. CONTRA	CT ID CODE	PAGE (	F PAGES		
AMENDMENT/M	DDIFICATION NO	3. EFFECTIVE DATE 20-Jan-2004	4. REQUISITION/PURCHASE REQ. W90GXK33010005	NO.	5. PROJECT NO	D. (If applicable)			
S ARMY SPACE & dDC-CM-CB / MS. 1-819-2895	COL MISSILE DEFENSE COMMAND O'CONNELL	E W9113M	7. ADMINISTERED BY (If other thee DCMA GRAND RAPIDS RIVERVIEW CENTER BUILDING 678 FRONT STREET, NW GRAND RAPIDS, MI 49504-5352	RIVERVIEW CENTER BUILDING 678 FRONT STREET, NW					
THOMAS JOHNS LEDERICK, MD 21									
NAME AND ADD	RESS OF CONTRACTOR (No., Street,	County, State and ZIP Code)			9A. AN	MENDMENT OF SOI	ETATION		
	IN LUTHER KING JR. BLVD					ATED (SEE ITEM 11)			
LANSING, MI	48906			X	W9113	MOD OF CONTRACT M-04-D-0002 ATED (SEE ITEM 1:			
CODE 1E	1086	FACILITY COD	E	X	08-Jan-		9		
	- 11	. THIS ITEM ONLY APPI	IES TO AMENDMENTS OF S	OLICITATIO	ONS				
Offers must ack (a) By completion or (c) By separa PLACE DESIG your desire to ch	nowledge receipt of this amendment prioring items 8 and 15, and returning the letter or telegram which includes a refined NATED FOR THE RECEIPT OF OFFE	copies of the amendment; (b) By ack trence to the solicitation and amendment in SPRIOR TO THE HOUR AND DATE S age may be made by telegram or letter, p	fied for receipt of Offers is extended, itation or as amended by one of the following m snowledging receipt of this amendment on each mathers. FAILURE OF YOUR ACKNOWLEI SPECIFIED MAY RESULT IN REJECTION OF COVIDED and the step of the	ethods: copy of the offer sul GMENT TO BE RI F YOUR OFFER. I	CEIVED AT TH	E amendment			
12. ACCOUNT	ING AND APPROPRIATION DATA (E	required)							
			TO MODIFICATION OF COM						
			ACT/ORDER NO. AS DESCRIE in) THE CHANGES SET FORTH IN ITEM 14			ORDER			
Х	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN TIEM 14, FURSUANT TO THE AUTHORITY OF FAR 45.10N(B).								
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO FURSUANT TO AUTHORITY OF:								
	D. OTHER (Specify type of mod	fication and authority)							
E. IMPOR	TANT: Contractor	is not, is required to si	ign this document and return	copies	to the issui	ng office.			
14. DESCRIPTI See Attached	ON OF AMENDMENT/MODIFICATION	N (Organized by UCF section headings, i	ncluding solicitation/contract subject matter wh	ere feasible.)					
		document referenced in Bern 9A or 10A,	as heretofore changed, remains unchanged and i						
15A. NAME A?	NDTITLE OF SIGNER (Type or print)		16A. NAME AND TITLE LYNN M. SELFRIDGE® TEL: 301-619-2707	CONTRACTING OF	FICER	se or print) ET.AMEDO.ARMY.N	IIL.		
	CTOR-OFFEROR	15C. DATE SIGNED	1 6B. UNITED STATES O BY /w/Lynn M. Selfridge		16C, DATE SIGNED 22-JAN-2004				
(signature of pe	rson authorized to sign)		(Signature of Contracting	orneer)					
EXCEPTION T APPROVED BY			30-105-04		Pres	NDARD FORM 30 ( cribed by GSA L (48 CFR) 53.243	REV. 10-83)		

## SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

# SECTION A — SOLICITATION/CONTRACT FORM

The Payment will be made by organization has changed from

DFAS-COLUMBUS CENTER
DFAS-CO/SOUTH ENTITLEMENT OPERATION
P.O. BOX 182264
COLUMBUS, OH 43218-2264
to
DFAS-COLUMBUS CENTER
NORTH ENTITLEMENT OPERATIONS
PO BOX 182266
COLUMBUS, OH 43218-2266

(End of Summary of Changes)

AMEND	MENT OF SOLICE	TATION/MODIFICATION	ON OF CONTRACT	1. CONTRACT	ID CODE	PAGE 1	OF PAGES			
2. AMENDMEN P00002	T/MODIFICATION NO	3. EFFECTIVE DATE 2-Sep-2004	4. REQUISITION/PURCHASE REQ. NO. W90GXK33010005		5. PROJECT NO. (If applicable)					
6. ISSUED BY	COD	E W9113M	7. ADMINISTERED BY (If other than lite	п б)	CODE	S2303A				
SMDC-CM-CB / 301-619-2707	CE & MISSILE DEFENSE COMMA: /MS. SELFRIDGE HINSON DRIVE ID 21702	ND	DCM GRAND RAPIDS RIVERVIEW CENTER BUILDING 678 FRONT STREET, NW GRAND RAPIDS, MI 49594-5352							
8. NAME AND	ADDRESS OF CONTRACTOR (No.,	Street, County, State and Zip Code)			9A. AMENDMI	ENT OF SOLICITA	TION NO.			
BIOPORT CORT 3500 N. MARTII LANSING, MI	N LUTHER KING, JR. BLVD				9B. DATED (SE	SE ITEM 11)				
				Х	10A. MODIFIC W9113M-04-D-	ATION OF CONTI	ACT/ORDER NO.			
				X	10B. DATED (S 06-Jan-2004	SEE ITEM 13)				
CODE 1HDB6		FACILITY CODE	TO AMENDMENTS OF SO	TCTTATEC						
		11. THIS ITEM ONLY APPLIES		ACHAIC	INS					
_		set forth in Item 14. The hour and date specified for	_		t extended.					
		ior to the hour and date specified in the solicitation								
or (c) By separate PLACE DESIGN amendment your	NATED FOR THE RECEIPT OF OFF	eference to the solicitation and amendment number ERS PRIOR TO THE HOUR AND DATE SPECI nitted, such change may be made by telegram or le	FIED MAY RESULT IN REJECTION OF Y	ENT TO BE RE	CEIVED AT TH Thy virtue of this					
12. ACCOUNTS	NG AND APPROPRIATION DATA	(If required)								
	13. 1	THIS ITEM ONLY APPLIES TO	MODIFICATION OF CONT	RACTS/OF	RDERS.					
	IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.									
		ISSUED PURSUANT TO: (Specify authority) Te				RDER				
	B. THE ABOVE NUMBERED IT EM 14, PURSUANT TO	CONTRACT/ORDER IS MODIFIED TO REFLE THE AUTHORITY OF FAR 43.103(B).	CT THE ADMINISTRATIVE CHANGES (	such as changes i	n paying office, a	ppropriation date, es	c.) SET FORTH IN			
	C. THIS SUPPLEMENTAL AC	GREEMENT IS ENTERED INTO PURSUANT T	AUTHORITY OF:							
x	D. OTHER (Specify type of mo FAR52.217-9	diffication and authority)								
E. IMPOR	L ΓΑΝΤ: Contractor [	is not, is required to sign t	his document and return	copies	to the issui	ng office.				
14. DESCRIPTION	ON OF AMENDMENT/MODIFICAT	TON (Organized by UCF section headings, includi	ng solicitation/contract subject matter where	easible.)						
Exercise Option										
E	and having all targets and the		4-f	II 6						
	ed herein, all terms and conditions of ID TITLE OF SIGNER (Type or print)	the document referenced in Item 9A or 10A, as her	tofore changed, remains unchanged and in fi 16A, NAME AND TITLE OF CONTR			0				
TOTAL DEPOSIT PARTY	or more trape of pain	,	LYNN SELFRIDGE, / CONTRACTIN TEL: 301-619-2707	G OFFICER		U T.AMEDD.ARMY	MIL.			
ISB CONTEST	TOR/OFFERING	TATE SWINED	1 6B. UNITED STATES OF AMERIC				ureahi			
ISB. CONTRAC	TOR/OFFEROR 150	. DATE SIGNED			16C. DATE S 2-Sep	HGNED ►2004				
(Signature of per	son authorized to sign)		BY /s' Lynn M. Selfridge (Signature of Contracting Officer)		2-049					

EXCEPTION TO SF 30 APPROVED BY ORM 11-84 30-105-04

STANDARD FORM 30 (REV. 10-83) Prescribed by GSA FAR (48 CFR) 53.243

### SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

# SECTION A — SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by \$95,950,567.80 from \$71,248,954.50 to \$167,199,522.30.

### SECTION B — SUPPLIES OR SERVICES AND PRICES

CLIN 0002

The option status has changed from Option to Option Exercised.

(End of Summary of Changes)

AMEND	MENT OF SOLI	1. CONTRAC	T ID CODE	PAGE OF PAGES					
2. AMENDMEN P00003	T/MODIFICATION NO		3. EFFECTIVE DATE 09/28/04	REQUISITION/PURCHASE REQ. NO. N/A	L	O. (If applicable)			
Alln: SMDC-CN	and Missile Defense Command	CODE	W9113M	7. ADMINISTERED BY (If other than liem 6) CODE \$2303A  DCMA Detroit-Grand Rapids 678 Front Asserts N. W. S. S. Sent Asserts N.					
64 Thomas John Fradrick, MD 21				Grand Rapids, MI 49504-5352					
8. NAME AND a BioPort Corporat	ADDRESS OF CONTRACTOR	(No., street, c	ounty, State and ZIP Code)		(X)	9A. AMENDM	ENT OF SOLICITATION NO.		
	her King Jr., Blvd.					9B. DATED (S	EE ITEM II)		
					х	10A. MODIFK W9113M-04-D	CATION OF CONTRACT/ORDER NO. 1-0002		
CODE	1H0B6		FACILITY CODE		-		SEE ITEM 11) 01/04/04		
		11. THIS	_	O AMENDMENTS OF SOLIC	TATION	S			
_	numbered solicitation is amende	d as set forth	in Item 14. The hour and date specified	for receipt of Offers is extended,	is ns	ot extended.			
	owledge receipt of this amendme g items 8 and 1 5, and returning _			on or as amended, by one of the following met vledging receipt of this amendment on each co		damitto-fr			
or (c) By separate DESIGNATED I your desire to ch	e letter or telegram which include FOR THE RECEIPT OF OFFER:	es a reference S PRIOR TO such change 1	to the solicitation and amendment numb THE HOUR AND DATE SPECIFIED I may be made by telegram or letter, provide	man factor of was an administration of the con- man result in religious of the con- ded each telegram or letter makes reference to	MENT TO BE R	ECEIVED AT THE se of this amenda	HE PLACE		
12. ACCOUNTE	NG AND APPROPRIATION DA	ATA (If requi	red)						
N/A									
				MODIFICATION OF CONTRA RDER NO. AS DESCRIBED					
CHECK ONE				HE CHANGES SET FORTH IN ITEM 14 AF			ORDER		
	B. THE ABOVE NUMBER appropriation date, etc.)	RED CONTE	ACT/ORDER IS MODIFIED TO REFL HINITEM 14, PURSUANT TO THE AU	ECT THE ADMINISTRATIVE CHANGES ( THORITY OF FAR 43.103(b).	such as changes	in paying office,			
	C. THIS SUPPLEMENTA	AL AGREEM	ENT IS ENTERED INTO PURSUANT	TO AUTHORITY OF:					
Х	D. OTHER (Specify type of PL 85-804, Implemente	of modification of byFAR 50.	n and sutherity) 403-2(b) and MoD dated Sep. 28, 2004						
E. IMPOR	ΓΑΝΤ: Contracto	or 🛛 is	not,  is required to sign	this document and return	copie:	s to the issu	ing office.		
14. DESCRIPTION	ON OF AMENDMENT/MODIFF	ICATION (O	rganized by UCF section headings, inclu-	ding solicitation/contract subject matter where	feasible.)				
See Attached.									
			ment referenced in Item 9A or 10A, as be	eretofore changed, remains unchanged and in f			-0		
12A. NAME AN	D TITLE OF SIGNER (Type or)	pndt)		LYNN M. SELFRIDGE	CHARLES OF THE	ones (1 ype or pm	mj		
15B, CONTRAC	TOR/OFFEROR	ISC, DATE	SIGNED	1 6B. UNITED STATES OF AMERIC	A	16C, DATE	SIGNED		
(Signature of per	son authorized to sign)			(s/ Lynn M. Selfridge (Signature of Contracting Officer)			09/28/04		
				1					

NSN 7540-01-152-8070 Previous edition unusable STANDARD FORM 30 (REV. 10-83) Prescribed by GSA FAR (48 CFR) 53.243

- A. This modification incorporates the full text FAR clause 50.250-1 entitled "Indemnification under Public Law 85-804" into contract number W9113M-04-D-0002 and is added to Section I.
- B. The Memorandum of Decision signed by the Acting Secretary of the Army on September 28, 2004, is incorporated into Section J of the contract as Attachment Number 4, 3 pages. The definition of unusually hazardous risk applicable to this contract is delineated in TAB A to the Memorandum of Decision.
- C. This modification is executed without cost to either party and is without effect to any other contract terms or conditions comprising contract W9113M-04-D-0002.

Modification P00003 to Contract W9113M-04-D-0002 Page 2 of 4

#### - Extraordinary Contractural Actions Provisions and Clauses.

#### 52.250-1 — Indemnification Under Public Law 85-804.

As prescribed in 50.403-3, insert the following clause in contacts whenever the approving official determines that the contractor shall be indemnified against unusually hazardous or nuclear risks (also-see 50.403-2(c)):

#### Indemnification Under Public Law 85-804 (Apr 1984)

- (a) "Contractor's principal officials," as used in this clause, means directors, officers, managers, superintendents, or other representatives supervising or directing
  - All or substantially all of the Contractor's business;
  - (2) All or substantially all of the Contractor's operations at any one plant or separate location in which this contract is being performed; or
  - A separate and complete major industrial operation in connection with the performance of this contract.
- (b) Under Public Law 85-804 (50 U.S.C. 1431-1435) and Executive Order 10789, as amended, and regardless of any other provisions of this contract the Government shall, subject to the limitations contained in the other paragraphs of this clause, indemnify the Contractor against —
  - Claims (including reasonable expenses of litigation or settlement) by third persons (including employees the Contractor) for death; personal injury; or loss of, damage to, or loss of use of property;
  - (2) Loss of, damage to, or loss of use of Contractor property, excluding loss of profit; and
  - (3) Loss of, damage to, or loss of use of Government property, excluding loss of profit.
- (c) This indemnification applies only to the extent that the claim, loss, or damage
  - (1) arises out of or results from a risk defined in this contract as unusually hazardous or nuclear and
  - is not compensated for by insurance or otherwise. (2)
    - Any such claim, loss, or damage, to the extent that it is within the deductible amounts of the Contractor's insurance, is not covered under this clause. If insurance coverage or other financial protection in effect on the date the approving official authorizes use of this clause is reduced, the Government's liability under this clause shall not increase as a result.
- (d) When the claim, loss, or damage is caused by willful misconduct or lack of good faith on the part of any of the Contractor's principal officials, the Contactor shall not be indemnified for
  - (1) Government claims against the Contractor (other than those arising through subrogation); or
  - Loss or damage affecting the Contractor's property.
- (e) With the Contracting Officer's prior written approval, the Contractor may, in any subcontract under this contract, indemnify the subcontractor against any risk defined in this contract as unusually hazardous or nuclear. This indemnification shall provide, between the Contractor and the subcontractor, the same rights and duties, and the same

Modification P00003 to Contract W9113M-04-B-0002

Page 3 of 4

provisions for notice, furnishing of evidence or proof, and Government settlement or defense of claims as this clause provides. The Contracting Officer may also approve indemnification of subcontractors at any lower tier, under the same terms and conditions. The Government shall indemnify the Contractor against liability to subcontractors incurred under subcontract provisions approved by the Contracting Officer.

(f) The rights and obligations of the parties under this clause shall survive this contract's termination, expiration, or completion. The Government shall make no payment under this clause unless the agency head determines that the amount is just and reasonable. The Government may pay the Contractor or subcontractors, or may directly pay parties to whom the Contract or subcontractors may be liable.

### (g) The Contractor shall —

- (1) Promptly notify the Contracting Officer of any claim or action against, or any loss by, the Contractor or any subcontractors that may be reasonably be expected to involve indemnification under this clause;
- (2) Immediately furnish to the Government copies of all pertinent papers the Contractor receives;
- (3) Furnish evidence or proof of any claim, loss, or damage covered by this clause in the manner and form the Government requires; and
- (4) Comply with the Government's directions and execute any authorizations required in connection with settlement or defense of claims or actions.
- (h) The Government may direct, control, or assist in settling or defending any claim or action that may involve indemnification under this clause.

(End of Clause)

Modification P00003 to Contract W9113M-04-B-0002 Page 4 of 4

AMENDM	ENT OF SOL	ICITA	TION/MODIFICATIO	N OF CONTRACT	1. CONTRA	J CODE	PAGE OF	PAGES 2		
2. AMENDMENT/MODIFIC: POOOO4	ATION NO		3. EFFECTIVE DATE 26-Oct-2004	4. REQUISITION/PURCHASE REQ. NO. W90GXK33010005		5. PROJECT NO	O. ([f applicable)			
6. ISSUED BY		CODE	W90GXK	7. ADMINISTERED BY (If other than Item	6)	CODE	S2303A			
CHEMICAL-BIOLOGICAL- 64 THOMAS JOHNSON DRI FREDERICK MD 21702		0		DCM GRAND RAPIDS RIVERVIEW CENTER BUILDING 678 FRONT STREET, NW GRAND RAPIDS MI 49564-5352						
8. NAME AND ADDRESS O	F CONTRACTOR (No., St	ireet, County,	State and ZIP Code)			9A. AMENDMI	ENT OF SOLICITATIO	N NO.		
3500 N MARTINLUTHER KI LANSING MI 48906	ING JR BLVD					9B. DATED (SI	E ITEM 11)			
					(X)	10A. MODIFIC W9113M-04-D	ATION OF CONTRAC 0002	T/ORDER NO.		
CODE 1HOB6			FACILITY CODE		(X)	10B. DATED (3 06-Jan-2004	EE ITEM 13)			
		11. THE	S ITEM ONLY APPLIES TO	AMENDMENTS OF SOLICE	TATIONS	,				
The above numbered solicitation is amended as set forth in Item 14. The bour and date specified for needing of Offies  Offices must acknowledge receipt of this amendment prior to the hour and date specified for needing of the set of the following methods:  (a) By completing items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment to each copy of the offer submitted;  or (c) By separate letter or slegams which includes a reference to the solicitation and amendment numbers. FAILIRE OF YOUR, ACKNOWLEDGMENT TO BE RECEIVED AT THE  PLACE DESIGNATED FOR THE RECEIVED OF SPEER PRIOR TO THE HOUR AND DATA PRESILT IN REJECTIVED OF SPEER. Hisystrine of this amendment your desire to change as offer already submitted, such change may be made by selegams or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and are received prior to the opening hour and date specified.										
12. ACCOUNTING AND APPROPRIATION DATA (If required)										
13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.										
A	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 19A.									
В.		ERED CONT T TO THE AU	RACT/ORDER IS MODIFIED TO REFLEX JTHORITY OF FAR 43.103(B).	T THE ADMINISTRATIVE CHANGES (suc	h as changes i	a paying office, a	ppropriation date, etc.) S	SET FORTH IN		
x c	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Muteal Agreement									
D	OTHER (Specify type	of modificati	on and authority)							
E. IMPORTANT: Contractor is not, is required to sign this document and return 2 copies to the issuing office.										
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)  Add new contract line items for Pentavalent Bot annual testing.										
Except as provided herein, all 15A, NAME AND TITLE OF		document ref	ferenced in Item 9A or 10A, as heretofore cha	nged, remains unchanged and in full force and		EB (Toma or min	0			
Robert Kramer, President & C				LYNN M. SELFRIDGE / CONTRACTIN						
15B. CONTRACTOR/OFFER		15C. DAT	E SIGNED	16B. UNITED STATES OF AMERICA						
(s/Robert Kramer (Signature of person authorize	d to sign)	11/12/04		BY /s/ Lvnn M. Selfridge (Signsture of Contracting Officer)	_	16C. DATE SIGNED 03-New-2004				

EXCEPTION TO SF 30 APPROVED BY ORM 11-84 30-105-04

STANDARD FORM 30 (REV. 10-83) Prescribed by GSA FAR (48 CFR) 53.243

# SECTION SF 30 BLOCK 14 CONTINUATION PAGE

# SUMMARY OF CHANGES

SECTION A — SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by \$52,324.00 from \$167,199,522.30 to \$167,251,846.30.

# SECTION B — SUPPLIES OR SERVICES AND PRICES

CLIN 0004 is added as follows:

(End of Summary of Changes)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0004		1		\$ 52,324.00	\$ 52,324.00
	Pentavalent Botulinum Testing FFP Conduct Pentavalent Botulinum Long-Term Interval Testing for lots PBP003 and PBP0004 using Protocol Numbers LTIT2003-001 and LTIT2003-002				
	NET AMT				\$ 52,324.00
FOB: Destination	Funded Amount				\$ 0.00
SECTION E — INS	PECTION AND ACCEPTANCE				
The following Accep	otance/Inspection Schedule was added for CLIN 0004:				
INSPECT AT N/A			INSPECT BY N/A	ACCEPT AT N/A	ACCEPT BY Government

AMENDMENT OF SOLICIT	ATION/MO	DDIFICATION O	F CONTRACT	1. CONTRACT ID	CODE	PAGE OF PAGES
2. AMENDMENT/MODIFICATION NO P00005		ECTIVE DATE 16 2004	4. REQUISITION/PURCHASE F W90GXK33010005	EQ. NO.	5. PROJECT N	SO. (If applicable)
6. ISSUED BY	CODE W90G	XK.	7. ADMINISTERED BY (If other	than Item 6)	CODE	S2303A
CHEMICAL-BIOLOGICAL-MEDICAL SYSTEMS PMO 64 THOMAS JOHNSON DRIVE FREDERICK MD 21702			DCM GRAND RAPIDS RIVERVIEW CENTER BUILDI 678 FRONT STREET, NW GRAND RAPIDS MI 49504-535			
8. NAME AND ADDRESS OF CONTRACTOR (No., Stre BIOPORT CORPORATION 3500 N MARTIN LUTHER KING JR BLVD	eet, County, State and I	ZIP Code)			9A. AMENDA	MENT OF SOLICITATION NO.
LANSING MI 48906					9B. DATED (S	SEE ITEM 11)
				х	10A. MODIFI W9113M-04-E	CATION OF CONTRACT/ORDER NO. 0-0002
				x	10B, DATED 06-Jan-2004	(SEE ITEM 13)
CODE 1HOB6		FACILITY CODE	AMENDMENTS OF S	OLICITATIO		
The above numbered solicitation is amended as set for	orth in Item 14. The h	our and date specified for receipt	of Offers is extende	sd,	is not extended.	
Offers must acknowledge receipt of this amendment price to (a) By completing items 8 and 15, and returning or (c) By separate letter or telegram which includes a reference PLACE DESIGNATED FOR THE RECEIPT OF OFFERS	copies of the amer	dment; (b) By acknowledging re- and amendment numbers. FAIL3	eipt of this amendment on each cop URE OF YOUR ACKNOWLEDGN	y of the offer submi MENT TO BE RECE	IVED AT THE	men)i
your desire to change an offer already submitted, such char amendment, and is received prior to the opening hour and o	age may be made by tel date specified.	legram or letter, provided each tel	egram or letter makes reference to t	he solicitation and th	iis	
12. ACCOUNTING AND APPROPRIATION DATA (If to	equired)					
			ODIFICATION OF CO			
			DER NO. AS DESCRI E CHANGES SET FORTH IN ITE			ORDER
			CT THE ADMINISTRATIVE CHA THORITY OF FAR 43.103(B).	LNGES (such as cho	nges in paying office,	
X C. THIS SUPPLEMENTA Mutual Agreement	L AGREEMENT IS E	NTERED INTO PURSUANT TO	AUTHORITY OF:			
D. OTHER (Specify type of	of modification and aut	hority)				
E. IMPORTANT: Contractor is n	ot, 🔀 is requi	red to sign this docum	ent and return1 c	opies to the is	ssuing office.	
14. DESCRIPTION OF AMENDMENT/MODIFICATION				feasible.)		
Revise quantity of CLIN 0004 in P00004 dated November. The Statement of Work Paragraph C.1.4.b. is revised to rea				ow		
FAR 52.216-19 and FAR 52.232-32 of the contract are not	_		one as universe on the minimum of			
Funding will be provided on individual delivery orders.						
All other terms and conditions of the contract remain uncha	_					
Except as provided herein, all terms and conditions of the d	focument referenced in	Hem 9A or 10A, as heretofore ch	<del></del>			
15A. NAME AND TITLE OF SIGNER (Type or print)			16A, NAME AND TITLE OF LYNN M. SELFRIDGE	CONTRACTING	OFFICER (Type or pri	nt)
Robert Kramer, President & CEO			TEL:	EMA	IL:	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	)	16B. UNITED STATES OF A	MERICA	16C. DATE	SIGNED
By be Robert Kramer (Signature of person authorized to sign)	11/12/04		BY /w Lynn M. Selfridge (Signature of Contracting Offi	cer)	Nov 16, 200	14

EXCEPTION TO SF 30 APPROVED BY ORM 11-84 30-105-04

STANDARD FORM 30 (REV. 10-83) Prescribed by GSA FAR (48 CFR) 53,243 
 NO
 SUPPLIES/SERVICES
 MAX QUANTITY
 UNIT
 UNIT PRICE
 MAX AMOUNT

 0004
 2
 \$ 52,324.00
 \$ 104,648.00

Pentavalent Botulinum Testing

FFP

Conduct Pentavalent Botulinum Long Term Interval Testing Testing for lots PBP003 and PBP0004 using Protocol Numbers LTIT2003-001 and LTIT2003-002.

Modification P00005 to Contract W9113M-04-D-0002 Page 2 of 5

#### Section C. Statement of Work/Specifications

C.1 Summary. The contractor shall provide the necessary qualified personnel, facilities, material, equipment, and services to produce, test, bottle, and place into storage FDA licensed Anthrax Vaccine Adsorbed (AVA) in accordance with the contractor's standard operating procedures and BioPort's Food and Drug Administration Biologics License and all federal government regulatory, and statutory requirements applicable to the manufacture, formulation, filling and testing of AVA.

# C.1.2 Definitions.

a. Manufacturing Stage is defined as the completion of:

[\*\*]

Upon receipt of test results and internal release by Quality Assurance/Quality Control, the material is advanced to the Formulation Stage.

- b. Formulation Stage means the [\*\*]. Upon receipt of test results and internal release by Quality Assurance/Quality Control, the subject lots are advanced to the Filling Stage.
- c. Filling Stage means the placement of bulk AVA in vials each containing sufficient volume to allow for 10 full doses. Samples are tested for safety, sterility, and potency. Upon receipt of test results and internal release by Quality Assurance/Quality Control, a release protocol is submitted to the FDA.
- d. Release Stage means the receipt from the FDA of a letter releasing a lot of AVA for sale and distribution
- e. FOB Origin is defined as the Contractor's Facility 3500 N. Martin Luther King Jr., Boulevard, Lansing, Michigan 48906.
- f. The term "within" as related to paragraph (a) of FAR 52.217-9, is defined as "at least."
- C.1.3 The production process consists of the following stages:
  - 1. Manufacture
  - 2. Formulation
  - 3. Filling
  - 4. FDA Release

# C.1.4 Test and Evaluation During Production

a. The contractor is responsible for establishing and maintaining quality assurance and quality control programs to ensure that product delivered under the contract, and that all testing requirements, meet both FDA regulatory requirements as well as the FDA license for AVA.

MODIFICATION P00005 TO CONTRACT W9113M-04-D-0002 PAGE 3 OF 5 b. All other testing, other than testing of the Pentavalent Botulinum Vaccine, and is presently provided under contract DAMD17-97-D-0003. Upon completion of this contract, the testing requirements shall be incorporated into this contract. The costs for conducting the tests under DAMD17-97-D-0003 are not presently included in this contract.

# C.1.5 Shipping

Shipping of the vaccine is presently accomplished under DAMD17-97-D-0003, but shall be incorporated into this contract upon completion. Presently, the cost to ship vaccine is not included in this contract.

#### C.1.6 Early Delivery of Doses

The Contractor may deliver quantities of AVA doses in advance of the delivery schedule found at Attachment No. 1, Section J of this contract.

# C.2 Contractor Use of Government Owned Property.

The Contractor shall have exclusive use of the property owned by the Government at the Contractor's facility to manufacture AVA doses. A complete list of the Contractor Acquired Property is found in Attachment 2 in Section J of this contract. The fee for using this property shall be \$[\*\*] per dose of vaccine produced for private sales. For the first performance period of January 3, 2004 to December 31, 2004, the Contractor may be credited against the last invoice for doses delivered. For all other ensuing contract periods, the Contractor shall credit the usage fee on a monthly basis as the equipment is used in producing an inventory of doses for private sales.

#### C.3 Dose Equivalent Invoicing.

The Contractor will invoice the Government using a dose equivalent of [\*\*] doses per lot for performance milestones 1, 2, & 3. Upon reaching the fourth and final milestone, the contractor will adjust the final invoice either upward or downward, as appropriate to compensate for any difference in the actual number of doses delivered per lot.

#### C.4 FDA Action/Inaction

The Contractor shall not be terminated for cause, in accordance with FAR 212-14 (m), if it is unable to deliver AVA doses in accordance with the delivery schedule set forth in Attachment 3 in Section J of the Contract due to action or inaction of the Food and Drug Administration, except to the extent that such action or inaction is a direct consequence of the Contractor's negligence.

# C.5 Notification of Sales.

The contractor agrees to provide notification as a courtesy to the JVAP Product Manager of any sale of AVA to any non-U.S. company or government within five business days of making the sale.

### C.6 Reporting

The contractor shall provide a Monthly Contract Status Report. During the base contract period of January 1, 2004 to December 31, 2004, the report shall be submitted weekly at the conclusion of the business week. The weekly report shall provide the same information as the monthly reports provide as of November 20, 2003, submitted under contract DAMD17-98-C-8052. Changes in the frequency of this data item may occur in the option periods.

C.7 Government Space in Contractor's Facility

MODIFICATION P00005 TO CONTRACT W9113M-04-D-0002 PAGE 4 OF 5 The contractor shall provide office space within the contractor's facility to accommodate a Defense Contract Management Agency representative and JVAP representative(s) who will be onsite on a full-time basis.

# C.8 Public Release of Information.

The contractor agrees to provide an advance copy of any release of information if there is a reference to the Anthrax Vaccine Program or if the information released may impact the Anthrax Vaccine Program. This provision is not intended to restrict dissemination of corporate information or the release of any information related to this Contract to third parties conducting normal due diligence on the Contractor in connection with capital raising activities or other types of corporate reorganizations where such release may be required. The advance notice will allow the DoD time to facilitate a response to any potential inquiries resulting from the information release and to be alert to the possibility of the inadvertent release of information, which could be taken out of context.

End of Section C.

MODIFICATION P00005 TO CONTRACT W9113M-04-D-0002 PAGE 5 OF 5

AMENDMEN	NT OF SOLICIT	CATIO	N/MODIFICATION O	F CONTRACT	I. CONTRACT ID COD	Œ	PAGE OF PAGES
2. AMENDMENT/MODI		11110	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE	J DDO NO	6 BRAIDOT NO	l 2 ). (If applicable)
P00006	PKALION NO		01/04/04	N/A	ADQ. NO.	N/A	x (ii applicane)
6. ISSUED BY		CODE	W9113M	7. ADMINISTERED BY (If other	r than [lem 6]	CODE	S2101A
U.S. Army Space at ATTN: SMDC-CN 64 Thomas Johnson Frederick, MD 2170	Drive	nmand		DCMA Detroit-Grand R. 678 Front Street, NW Grand Rapids, MI 49504			
B. NAME AND ADDRES	S OF CONTRACTOR (No., st	rest, county, S	tate and ZIP Code)		(X)	9A. AMENDMI	ENT OF SOLICITATION NO.
3500 N.	Corporation Martin Luther King, Jr. , MI 48906	Blvd			х	9B. DATED (SI 10A. MODIFIC W9113M-0 10B. DATED (S	ATION OF CONTRACT/ORDER NO. 4-D-0002
CODE			FACILITY CODE			01/02/04	
CODE		11 THIS	S ITEM ONLY APPLIES TO	AMENDMENTS OF	SOLICITATIONS		
Offiers must acknowledge (a) By completing items 8 or (c) By separate letter or OF OFFERS PRIOR TO	receipt of this amendment prior and 1.5, and returning telegram which includes a refer THE HOUR AND DATE SPEC	to the hour according to the hour according to the sci rence to the sci IFIED MAY	14. The hour and due specified for receipt to 4. The hour and due specified in the solicitation or so arm of the amendment; (b) By acknowledging re discituation and amendment sumbers. FAIL MRESILIT IN REJECTION OF YOUR OFF are solicitation and the satestatement, and is or a solicitation and the satestatement, and is or	of Offers is extend anded, by one of the following met ceipt of this amendment on each cop are OF YOUR ACKNOWLEDGE 38. If by virtue of this amendmen	ed, is no hods: py of the offer submitted; MENT TO BE RECEIVED t your desire to change an	extended.	
12. ACCOUNTING AND Not applicable	APPROPRIATION DATA (If	required)					
			EM ONLY APPLIES TO MO FIES THE CONTRACT/OR				
CHECK ONE	A. THIS CHANGE OR NO. IN ITEM 10A.	DER IS ISSU	ED PURSUANT TO: (Specify authority) T	HE CHANGES SET FORTH IN I	TEM 14 ARE MADE IN T	THE CONTRACT	ORDER
	B. THE ABOVE NUM ITEM 14, PURSUA	BERED CON NT TO THE .	TRACT/ORDER IS MODIFIED TO REFI AUTHORITY OF FAR 43,103(b).	ECT THE ADMINISTRATIVE C	HANGES (such as change	s in paying office	appropriation date, etc.) SET FORTH IN
X	C. THIS SUPPLEMEN FAR 52.212-4	TAL AGREE	MENT IS ENTERED INTO PURSUANT	TO AUTHORITY OF:			
	D. OTHER (Specify ty	pe of modifica	tion and authority)				
E, IMPORTANT	: Contractor is i	not, 🔀 i	s required to sign this docum	ent and return1co	pies to the issuing	office.	
See Page 2.			by UCF section headings, including solicit erenced in Item 9A or 10A, as heretofore ch				
	OF SIGNER (Type or print)	Secondent (e)	M MANUEL PAR ON THEM, OR RESERVED CO.	16A. NAME AND TITLE OF Lynn M. Selfridge		ER (Type or prin	0
15B, CONTRACTOR/OF	FEROR	15C, DATI	SIGNED	16B. UNITED STATES OF A	AMERICA	16C. DATE S	SIONED
/s/ Robert G. Krame (Signature of person autho		2/3/05		is/ Lynn M. Selfridge (Signature of Contracting Off	icer)	2/8/05	
				•		•	

NSN 7540-01-152-8070 Previous edition appeable STANDARD FORM 30 (REV. 10-83) Prescribed by GSA FAR (48 CFR) 53.243

- A. This modification adds the following functions to this contract (previously provided under DAMD17-97-D-0003):
  - (1) Maintain current level of security at BioPort's production facility in Lansing, MI that is used to produce and store the Government's purchase of Anthrax Vaccine Adsorbed.
  - (2) Printing labels, labeling of vials and packaging for shipment of AVA produced under this contract.
  - (3) Potency testing on stability lots produced under this contract.
  - (4) Stability test consisting of chemistry, sterility, and safety, on the doses produced under this contract:
- B. The effective date for the above cited additional functions is January 02, 2004.
- C. Consideration for incorporation of the additional functions cited above is provided by revising the dose price for each performance periods comprising the contract as follows.

Contract Line Item No.	Old I	Price/dose	Adjuste	ed Price/dose
0001	\$	[**]	\$	[**]
0002	\$	[**]	\$	[**]
0003	\$	[**]	\$	[**]

- D. The minimum and maximum quantities included in the Section B of the contract do not change as a result of this modification.
- E. The contractor agrees to process revised payment requests upon receipt of a modification to delivery orders 0001 and 0002 without additional dose price increases.

Funding for the additional functions in paragraph A(1) through A(4) shall be provided on modifications to delivery order number 0001 and 0002.

G. All other terms and conditions of the contract remain unchanged and in full force and effect.

Modification P00006 to W9113M-04-D-0002, page 2 of 2

AMENDMEN	NT OF SOLICIT	ATIO	N/MODIFICATION O	F CONTRACT	L CONT	RACT ID COL	DE.	PAGE O	F PAGES
2. AMENDMENT/MODE 01	FICATION NO		3. EFFECTIVE DATE 02/16/05	4. REQUISITION/PURCHASE N/A	REQ. NO.		5. PROJECT NO N/A	). (If applicable)	
6. ISSUED BY	COL	DE .	W9113M	7. ADMINISTERED BY (If other	er than Item	6)	CODE	S2303A	
U.S. Army Space at ATTN: SMDC-CM 64 Thomas Johnson Frederick, MD 2170	Drive	mand		DCMA Grand Rapids Riverview Center Buildi 678 Front Street, NW Grand Rapids, MI 49504					
8. NAME AND ADDRES	S OF CONTRACTOR (No., stre	eet, county, S	tate and ZIP Code)			(X)	9A. AMENDME	INT OF SOLICITATE	ON NO.
3500 N.BioPort Cor Lansing, MI 48906	poration Martin Luther	King Jr. I	Blvd				9B. DATED (SE	Е ГІЕМ 11)	
						х		ATION OF CONTRAI I-D-0002-0001	CD'ORDER NO.
								01/02/04	
CODE 1HNOB		11 77777	FACILITY CODE  S ITEM ONLY APPLIES TO		50110	T. I. T. CO.			
Offers must acknowledge: (a) By completing items 8 or (c) By separate letter or OF OFFERS PRIOR TO 1	d solicitation is amended as set for receipt of this amendment prior to and 1.5, and returning	orth in Item 1 to the hour an copies α ence to the so FIED MAY I	4. The hour and date specified for receipt to d date specified in the solicitation or as am if the amendment; (b) By acknowledging re histation and amendment numbers. FALL SESILIT TO REDECTION OF YOUR OFFI ESSILIT TO REDECTION OF YOUR OFFI e solicitation and this amendment, and is re	of Offices is extended, by one of the following met ceipt of this amendment on each to URE OF YOUR ACKNOWLEDGER. If by virtue of this amendment	ed, hods: ppy of the of MENT TO! t your desire	is no fer submitted; BE RECEIVED to change an	t extended.		
12. ACCOUNTING AND See Block 14, below	APPROPRIATION DATA (If re v.	equired)							
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			TRACT/ORDER IS MODIFIED TO REFI AUTHORITY OF FAR 43.163(b).	ECT THE ADMINISTRATIVE C	HANGES (	such as change	s in paying office,	appropriation date, etc	.) SET FORTH IN
X	C. THIS SUPPLEMENT FAR 52.212-4	TAL AGREE	MENT IS ENTERED INTO PURSUANT	TO AUTHORITY OF:					
	D. OTHER (Specify type	e of modifica	tion and authority)						
E. IMPORTANT	Contractor is n	ot, 🛚 is	s required to sign this docum	ent and return1_ co	pies to	the issuin	g office.		
14. DESCRIPTION OF A	MENDMENT/MODIFICATION	(Organized	by UCF section headings, including solicit	ation/contract subject matter where	feasible.)				
This instrument mo 2005.	difies delivery order nun	nber 0001	issued under the provisions of c	ontract W9113M-04-D-00	02, as a 1	result of co	ntract modific	ation P00006 dat	ed February 8,
			rax vaccine (the DoD's Anthrax ng, and the provision of security						beling,
	all terms and conditions of the d OF SIGNER.(Type or print)	locument refe	renced in Item 9A or 10A, as heretofore ch	anged, remains unchanged and in f			ER (Type or print	)	
Robert G. Kramer, 1	President & CEO			Lynn M. Selfridge					
15B. CONTRACTOR/OF	P 15.100.700	15C. DATE	SECOLET	16B. UNITED STATES OF A	AMERICA		16C. DATE S	RENED	
/s/ Robert G. Krame (Signature of person autho	tr	2/17/05		/s/ Lynn M. Selfridge (Signature of Contracting Off	licer)	_	2/17/05		

NSN 7540-01-152-8070 Previous edition umsable STANDARD FORM 30 (REV. 10-83) Prescribed by GSA FAR (48 CFR) 53.243 Section B of delivery order no. 0001 is revised as follows:

The total price of delivery order no. 0001 is increased front \$29,722,975.80 by \$2,685,576.60 to \$32,408,552.40.

 $Section \ G \ of \ delivery \ order \ no. \ 0001 \ is \ revised \ to \ increase \ the \ obligated \ dollar \ amount \ to \ \$32,408.552.40.$ 

There are no revisions to the accounting and appropriation data or the ACRN cited in Section G of delivery order no. 0001.

All other terms and conditions of the delivery order remain unchanged and in full force and effect.

Modification 01 to Delivery Order 0001 to Contract No. W9113M-04-D-0002 Page 2 of 2

AMENDME	NT OF SOLICIT	ATIO	N/MODIFICATION O	OF CONTRACT	J. CONT	RACT ID COI	DE	PAGE 1	OF PAGES
2. AMENDMENT/MODI 01	FICATION NO		3. EFFECTIVE DATE 02/16/05	4. REQUISITION/PURCHASE N/A	REQ. NO.		5. PROJECT NO N/A	D. (If applicable)	
6. ISSUED BY	CC	DE	W9113M	7. ADMINISTERED BY (If other	er than Iten	1 б)	CODE	S2303A	
U.S. Army Space a ATTN: SMDC-CN 64 Thomas Johnson Frederick, MD 217	Drive	nmand		DCMA Grand Rapids Riverview Center Buildi 678 Front Street, NW Grand Rapids, MI 49504					
	SS OF CONTRACTOR (No., str	seet, county, S	State and ZIP Code)			(X)	9A. AMENDM	ENT OF SOLICITA	TION NO.
BioPort Corporatio 3500 N. Martin Lut Lansing, MI 48906							9B. DATED (SI	EE ITEM 11)	
						x		ATION OF CONTR 4-D-0002-0002	
							10B. DATED (S	SEE ITEM 11) 01/02/04	
CODE 1HOB6			FACILITY CODE						
		11. THE	S ITEM ONLY APPLIES TO	AMENDMENTS OF	SOLIC	ITATION:	<u>s</u>		
_			14. The hour and date specified for receipt			is no	t extended.		
_			nd date specified in the solicitation or as am						
OF OFFERS PRIOR TO	r telegram which includes a refe THE HOUR AND DATE SPEC	rence to the sc TFIED MAY	of the amendment; (b) By acknowledging re slicitation and amendment numbers. FAID RESULT IN REJECTION OF YOUR OFF he solicitation and this amendment, and is re	URE OF YOUR ACKNOWLEDGE ER. If by virtue of this amendmen	MENT TO t your desi	BE RECEIVED re to change an	D AT THE PLAC offer already subt	E DESIGNATED Fo nitted, such change r	OR THE RECEIPT may be made by
12. ACCOUNTING AND See Block 14, below	APPROPRIATION DATA (If w.	required)							
			EM ONLY APPLIES TO MO IFIES THE CONTRACT/OR						
CHECK ONE	A. THIS CHANGE OR NO. IN ITEM 10A.	DER IS ISSU	TED PURSUANT TO: (Specify authority) 1	THE CHANGES SET FORTH IN I	TEM 14 A	RE MADE IN	THE CONTRACT	ORDER	
	B. THE ABOVE NUM ITEM 14, PURSUA	BERED CON	TRACT/ORDER IS MODIFIED TO REFI AUTHORITY OF FAR 43,103(b).	LECT THE ADMINISTRATIVE C	HANGES	(such as change	es in paying office	, appropriation date,	etc.) SET FORTH IN
X	C. THIS SUPPLEMEN FAR 52.212-4	TAL AGREE	MENT IS ENTERED INTO PURSUANT	TO AUTHORITY OF:					
	D. OTHER (Specify ty)	pe of modifica	ation and authority)						
E. IMPORTANT	: Contractor is 1	not, 🛛 i	s required to sign this docum	ent and return1_ co	pies to	the issuing	g office.		
14. DESCRIPTION OF A	MENDMENT/MODIFICATIO	N (Organized	by UCF section headings, including solicit	ation/contract subject matter where	feasible.)				
This instrument mo 2005.	difies delivery order nu	mber 0002	issued under the provisions of c	ontract W9113M-04-D-00	02, as a	result of cor	ntract modific	ation P00006 d	ated February 8,
packaging for ships	ment, stability testing, po	otency test	arax vaccine (the DoD's Anthrax ing, and the provision of security erenced in Isem 9A or 10A, as heretofore cl	at the BioPort Lausing, M	II facilit	y. The revi:	sed dose price	is S[**].	labeling,
15A. NAME AND TITLE Robert G. Kramer,	OF SIGNER (Type or print) President & CEO			16a. NAME AND TITLE OF Lynn M. Selfridge	F CONTR.	ACTING OFFIC	CER (Type or prin	1)	
15B. CONTRACTOR/OF	FEROR	15C. DATI	E SIGNED	16B. UNITED STATES OF A	AMERICA	i.	16C. DATE S	SIGNED	
/s/ Robert G. Kram	er	2/17/05		/s/ Lvnn.M. Selfridge		_	2/17/05		
(Signature of person author	orized to sign)			(Signature of Contracting Off	icer)				

NSN 7540-01-152-8070 Previous edition unusable STANDARD FORM 30 (REV. 10-83) Prescribed by GSA FAR (48 CFR) 53.243 Section B of delivery order no. 0002 is revised as follow:

The total price of delivery order no. 0002 is increased from \$36,196,254.90 by \$674,559.60 to \$36,870,814.50.

Section G of delivery order no. 0002 is revised to increase the obligated dollar amount to \$36,870,814.50.

There are no revisions to the accounting and appropriation data or the ACRN cited in Section G of delivery order no. 0002.

All other terms and conditions of the delivery order remain unchanged and in full force and effect.

Modification 01 to Delivery Order 0002 to Contract No. W9113M-04-D-0002 Page 2 of 2

# Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

		TRACT/ORDER FOR			1. REQU	JISITION NUM	BER		PAGE 1		
2, CONTRACT N		3. AWARD/EFFECTIV		4. ORDER NUMBER	5 SOLIC	TTATION NUMB	FP		6. SOLIC	10	N
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3500 North Mar		ing, Jr. Blvd.			P.O. Box	x 15580 (404) 49		revention (1381	0)		
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27a. SOLICITAT	ION INCORP	ORATES BY REFERENCE	Allowance E FAR 52.2		nt: \$122,737 2.212-3 AND 5		ACHED.		ARE A		ATTACHED.
27b. CONTRACT.	PURCHASE	ORDER INCORPORATE	S BY REFE	RENCE FAR 52.212-4.	FAR 52.212-5	IS ATTACHED.	ADDENI	DA ARE	ARE NOT		CHED.
TO ISSUING	OFFICE. CO	RED TO SIGN THIS DOO NTRACTOR AGREES TO	O FURNISE	AND DELIVER ALL	ITEMS SET	DATED		TRACT: REFER YOUR OFFER	ON SOLIC		
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/s/ Robert	G. Kramer				,	s/ Lorenzo J, Fa	giano				
			-								
30b. NAME AND	TITLE OF SI	GNER (Type or print)	30e, DA1	E SIGNED	31b. NAME	OF CONTRACTE	NG OFFIC	ER (Type or pris	11)		31c. DATE SIGNED
		ident & CEO	5/5	05		zo J. Falgiano	1 4 4				May 05 2005
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					36. NR ACC	OUNT NUMBER	39. S/R	VOUCHER NU	MISEK	40. P	ALD BY
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					43a page :	DECED.	ana mo-	TAL CONTEASS	rne.		
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# TABLE OF CONTENTS

Section	Document/Clause/Provision	Page No.
A	Standard Form 1449	1
В	Continuation of SF1449 (Block 19 — 24)	2
C	Contract Clauses	3
D	Contract Documents, Exhibits or Attachments	9
	Page i	

# SECTION B — CONTINUATION OF SF1449

Contract Schedule

AVA available doses for the period May 2005 — December 2005, as projected in Table E.1 of the final revised proposal dated March 8, 2005.

ITEM NO.	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0001	BioThrax Vaccine	[**] Doses	\$[**]	\$ 75,237,000.00
	Anthrax Vaccine Adsorbed (AVA)			
	BioThrax®			
AVA available do	oses for the period January 2006 — September 2006, as projected in Ta	able E.1 of the final revised proposal dated Marc	h 8, 2005.	
ITEM NO.	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0002	BioThrax Vaccine	[**]	\$[**]	\$ 47,500,000.00
	Anthrax Vaccine Adsorbed (AVA)	Doses		
	BioThrax®			
OPTION I*				
OF HON I"				
ITEM NO.	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0003	BioThrax Vaccine	5,000,000	TBD	TBD*
	Anthrax Vaccine Adsorbed (AVA)	Doses		
	BioThrax <sup>®</sup>			
	<del></del>			
	g execution of the contract, the government agrees to meet with the con rmance period has been agreed upon at contract execution the clauses			A. Since the option price nor
the perior	i mance period has been agreed upon at contract execution the clauses	Tound at FAR 32.217-7 and 32.217-9 are not men	uucu.	
	TOTAL: 5,000,000 Doses		\$	122,737,000.00
There are no claus	ses/provisions included in this section.			
There are no claus	ses/provisions included in this section.			
		Page 2		

# SECTION C — CONTRACT CLAUSES

FAR SOURCE TITLE AND DATE

52.212-4 Contract Terms and Conditions — Commercial Items (Oct 2003)

52.243-1 Changes — Fixed Price

F.O.B. Origin, Contractor's Facility

# Addendum to 52.212-4, Contract Terms and Conditions — Commercial Items (Oct 2003)

# C.1.1 Method of Delivery

52.247-30

- a. Delivery of the BioThrax Vaccine shall be F.O.B.Origin, Contractor's Facility.
- b. The USG will receive and transport product from the manufacturer monthly, on or about the 15th of each month or such mutually acceptable date, during the life of the contract.
- c. Inspection/Acceptance: Prior to acceptance of the product by the Strategic National Stockpile (SNS), the contractor shall provide approximately 2 week advanced notification of the amount of product that will be available, so that the USG may plan for the necessary logistics. Notice of availability of product with supporting documentation shall be provided to the Project Officer, Walter Lange at (202)401-4848.
- d. Acceptance of the product shall be deemed to have occurred after USG inspection and in accordance with C.1.2 below, and upon delivery of the FDA-released product to the USG designated carrier on the monthly transport date as provided in (b.) above. Contractor will invoice the USG immediately upon acceptance.

(End of Clause)

# **C.1.2 Packing Requirements**

The product will be delivered to the Government's carrier in boxes, on pallets, at Contractor's facility on the designated pick up days. The pallets will be stacked according to the load plan (Attachment D.2) and stretch wrapped on a pallet, after government inspection, to prevent shifting/damage during transit. (Note: Attachment D.2 is based on theoretical 180,000 dose lot size; actual loading may vary slightly based upon lot yield). Contractor is not required to deliver the product in any other configuration under this contract. Contractor will store the product in validated cold rooms at 2-8 degrees Celsius until turned over to the USG designated carrier. In accordance with the FOB origin clause, the USG will be responsible for cold storage conditions (i.e. — maintaining the product at 2-8 degrees Celsius) after pick up by the USG designated carrier.

(End of Clause)

# C.1.3 Excusable Delay

FAR 52.212-4 Contract Terms and Commercial Provisions, Part (f) is amended as follows:

(f) Excusable delays. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence such as, acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. Furthermore, the Contractor will not be in default under this contract if it is unable to deliver AVA doses in accordance with any delivery schedule because of the action or inaction of the FDA, except to the extent that such action or inaction is a direct consequence of the negligence or willful misconduct of the Contractor. Additionally, the Contractor will not be in default of this contract in the event that deliveries are delayed as a result of another Government agency placing an order for AVA doses that is determined to have priority over this contract under the Defense Priority Allocation System or under any other reasonable legal justification. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement or any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(End of Clause)

# C.2 FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders — Commercial Items (May 2004)

- (a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clause, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items: 52.233-3, Protest after Award (Aug 1996)(31 U.S.C 3553).
- (b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the contracting officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer shall check as appropriate.]

- 🗵 (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Jul 1995), with Alternate I (Oct 1995)(41 U.S.C. 253g and 10 U.S.C. 2402).
- o (2) 52.219-3, Notice of Total HUBZone Set-Aside (Jan 1999)(15 U.S.C. 657a).
- o (3) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Jan 1999) (if the offeror elects to waive the preference, it shall so indicate in its offer)(15 U.S.C. 657a).
- o (4) (i) 52.219-5, Very Small Business Set-Aside (June 2003)(Pub. L. 103-403, section 304, Small Business Reauthorization and Amendments Act of 1994).
- o (ii) Alternate I (Mar 1999) of 52.219-5.
- o (iii) Alternate II (June 2003) of 52.219-5.
- o (5) (i) 52.219-6, Notice of Total Small Business Aside (June 2003) (15 U.S.C. 644).
- o (ii) Alternate I (Oct 1995) of 52.219-6.
- o (6) (i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003)(15 U.S.C. 644).
- o (ii) Alternate I (Oct 1995) of 52.219-7.
- o (7) 52.219-8, Utilization of Small Business Concerns (Oct 2000) (15 U.S.C. 637(d)(2) and (3)).
- o (8) (i) 52.219-9, Small Business Subcontracting Plan (Jan 2002)(15 U.S.C. 637 (d)(4)).
- o (ii) Alternate 1 (Oct 2001) of 52.219-9.
- o (iii) Alternate II (Oct 2001) of 52.219-9.
- o (9) 52.219-14, Limitations on Subcontracting (Dec 1996)(15 U.S.C. 637(a)(14)).
- o (10) (i) 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (June 2003)(Pub. L. 103-355, section 7102, and 10 U.S.C. 2323) (if the offeror elects to waive the adjustment, it shall so indicate in its offer).
- o (ii) Alternate I (June 2003) of 52.219-23.
- o (11) 52.219-25, Small Disadvantaged Business Participation Program Disadvantaged Status and Reporting (Oct 1999)(Pub. L. 103-355, section 7102, and 10 U.S.C. 2323).

o (12) 52.219-26, Small Disadvantaged Business Participation Program – Incentive Subcontracting (Oct 2000)(Pub. L. 103-355, section 7102, and 10 U.S.C. 2323). o (13) 52.222-3, Convict Labor (June 2003)(E.O. 11755).

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- ☑ (14) 52.222-19, Child Labor Cooperation with Authorities and Remedies (Jan 2004) (E.O. 13126).
- ☑ (15) 52.222-21, Prohibition of Segregated Facilities (Feb 1999).
- ☑ (16) 52.222-26, Equal Opportunity (Apr 2002)(E.O. 11246).
- 🗵 (17) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Dec 2001)(38 U.S.C. 4212).
- ☑(18) 52.222-36, Affirmative Action for Workers with Disabilities (Jun 1998)(29 U.S.C. 793).
- 🗵 (19) 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Dec 2001)(38 U.S.C. 4212).
- o (20) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (Aug 2000)(42 U.S.C. 6962(c)(3)(A)(ii)).
- o (ii) Alternate I (Aug 2000) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)).
- o (21) 52.225-1, Buy American Act Supplies (June 2003)(41 U.S.C. 10a-10d).
- o (22) (i) 52.225-3, Buy American Act —Free Trade Agreement Israeli Trade Act (Jan 2004)(41 U.S.C. 10a-10d, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, Pub. L. 108-77,108-78).
- o (ii) Alternate I (Jan 2004) of 52.225-3.
- o (iii) Alternate II (Jan 2004) of 52.225-3.
- o (23) 52.225-5, Trade Agreements (Jan 2004)(19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
- 🗵 (24) 52.225-13, Restrictions on Certain Foreign Purchases (Oct 2003) (E.o.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- o (25) 52.225-15, Sanctioned European Union Country End Products (Feb 2000)(E.O. 12849).
- o (26) 52.225-16, Sanctioned European Union Country Services (Feb 2000)(E.O. 12849).
- o (27) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002)(41 U.S.C. 255(f), 10 U.S.C. 2307(f)).
- o (28) 52.232.30, Installment Payments for Commercial Items (Oct 1995)(41 U.S.C. 255(f), 10 U.S.C. 2307(f)).
- 🗵 (29) 52.232-33, Payment by Electronic Funds Transfer Central Contractor Registration (Oct. 2003)(31 U.S.C. 3332).
- o (30) 52.232-34, Payment by Electronic Funds Transfer Other Than Central Contractor Registration (May 1999)(31 U.S.C. 3332).
- o (31) 52.232-36, Payment by Third Party (May 1999)(31 U.S.C. 3332).
- ☑ (32) 52.233-4, Applicable Law for Breach of Contract Claim.
- o (33) 52.239-1, Privacy or Security Safeguards (Aug 1996)(5 U.S.C. 552a).
- o (34) 52.244-2, Subcontracts

 $o~(35)~(i)~52.247-64, Preference~for~Privately~Owned~U.S.-Flag~Commercial~Vessels~(Apr~2003)\\ (46~U.S.C.~1241~and~10~U.S.C.~2631).$ 

o (ii) Alternate I (Apr 1984) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

- o (1) 52.222-41, Service Contract Act of 1965, as Amended (May 1989)(41 U.S.C. 351, et seq.).
- o (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 1989)(29 U.S.C. 206 and 41 U.S.C. 351, et seq.).
- o (3) 52.222-43, Fair Labor Standards Act and Service Contract Act Price Adjustment (Multiple Year and Option Contracts) (May 1989)(29 U.S.C.206 and 41 U.S.C. 351, et seq.).
- o (4) 52.222-44, Fair Labor Standards Act and Service Contract Act Price Adjustment (Feb 2002)(29 U.S.C. 206 and 41 U.S.C. 351, et seg.).
- o (5) 52.222-47, SCA Minimum Wages and Fringe Benefits Applicable to Successor Contract Pursuant to Predecessor Contractor Collective Bargaining Agreements (CBA) (May 1989)(41 U.S.C. 351, et seq.).
- (d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records Negotiation.
- (1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.
- (2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7,

Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

- (3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.
- (e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c) and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in paragraphs (i) through (vi) of this paragraph in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause —
- (i) 52.219-8, Utilization of Small Business Concerns (Oct 2000)(15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$500,000 (\$1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (ii) 52.222-26, Equal Opportunity (Apr 2002)(E.O. 11246).
- (iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Dec 2001)(38 U.S.C. 4212).
- (iv) 52.222-36, Affirmative Action for Workers with Disabilities (June 1998)(29 U.S.C. 793).
- (v) 52.222-41, Service Contract Act of 1965, as Amended (May 1989), flow down required for all subcontracts subject to the Service Contract Act of 1965 (41 U.S.C. 351, et seq.)

(vi) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Apr 2003)(46 U.S.C. Appx 1241 and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64,

(2) While not required, the contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of Clause)

# C.3 FAR 52.212-5 Alternate I Contract Terms and Conditions Required to Implement Statutes or Executive Orders — Commercial Items — Alternate I (Feb 2000)

As prescribed in 12.301(b)(4), delete paragraph (d) from the basic clause, redesignate paragraph (e) as paragraph (d), and revise the reference to "paragraphs (a), (b), (c), or (d) of this clause" in the redesignated paragraph (d) to read "paragraphs (a), (b), and (c) of this clause".

(End of Alternate)

#### C.4 Indemnification

The United States Government agrees that vaccine delivered under this contract will not be used in humans unless indemnification has been approved in accordance with FAR Subpart 50.4 that is mutually agreeable to both parties. As a requirement of indemnification, the Contractor will apply to the Department of Homeland Security (DHS) for liability protection under the terms of the SAFETY ACT (6 U.S.C. 441 to 444; see also 6 C.F.R. part 25).

(End of Clause)

# C.5 Insurance Related to SAFETY Act Application

Should the United States Government require the contractor to obtain additional insurance in connection with making application under the SAFETY Act in accordance with C.4 of the contract, the requirement to obtain additional insurance shall be deemed a change in accordance with FAR 52.243-1. FAR 52.243-1 is hereby incorporated for this purpose. All other changes will be governed by FAR 52.212-4(c).

(End of Clause)

#### C.6 Dissemination of Information

No information related to the performance or content of this contract or the data obtained or generated under this contract shall be released or otherwise publicized without prior written approval of the Contracting Officer, which approval shall not be unreasonably withheld or delayed; provided, however, that no such written approval shall be required for release of information concerning this Contract to Contractor's lenders in connection with Contractor's financing activities, to third parties performing due diligence on Contractor in connection with Contractor's capital raising activities or proposed mergers, acquisitions or other business combinations, or disclosure as may be required by law, rule, regulation, court ruling or similar order. In any event the Contractor shall notify the government prior to the release of any information associated with this contract. Clearance for any press release related specifically to this contract must be approved by the Office of Public Affairs, Office of the Secretary of DHHS.

(End of Clause)

#### C.7 Prohibition on Contractor Involvement with Terrorist Activities

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to Executive Order 13224 and Public Law 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must also be included in all subcontracts issued to support performance under this contract.

(End of Clause)

# C.8 Invoice Submission (July 1999)

The Contractor shall submit an original and one (1) copy of contract invoices to the address shown below:

Centers for Disease Control and Prevention Procurement and Grants Office Attn: Linda F. Williams, Contract Specialist 2920 Brandywine Road, Room 3120 Atlanta, Ga. 30341

(b) The contractor shall submit one (1) copy of each invoice to our Financial Management Office:

Centers for Disease Control and Prevention FMO

PO Box 15580 Atlanta, GA 30333

- (c) The Contractor agrees to include (as a minimum) the following information on each invoice:
  - (1) Contractor's Name & Address
  - (2) Contractor's Tax Identification Number (TIN)
  - (3) Contract Number
  - (4) Invoice Number
  - (5) Invoice Date
  - (6) Contract Line Item Number
  - (7) Quantity
  - (8) Unit Price & Extended Amount for each line item
  - (9) Total Amount of Invoice
  - (10) Name, title and telephone number of person to be notified in the event of a defective invoice
  - (11) Payment Address or Electronic Funds Transfer (EFT) banking information.
  - (12) Material Receiving Report Signed by USG Representative.

(End of Clause)

# C.9 Government Assistance to Contractor in Litigation

In the event that a claim or suit for damages is brought against the Contractor by a third party arising out of it's performance of this contract, the Government will provide reasonable and timely access to documents, potentially relevant to the Contractor's assertion of defenses to any dispute with a third party, including, but not limited to a claim for bodily injury or other damages allegedly arising out of the use or ingestion of any product delivered to the Government under this contract. In addition, the Government will consider any request from the Contractor, to assist the Contractor in litigation, including a request to support the Contractor's assertion of appropriate defenses, including, but not limited to, the government contractor defense. If and when appropriate, the Government will file papers in support of the Contractor's assertion of its defenses in such disputes. The USG will assist the Contractor in resolving the Contractor's liability concerns related to this contract and will not take any public position adversely affecting the Contractor's requirement for full indemnification before the vaccine may be used in humans consistent with this Contract.

(End of Clause)

# C.10 Data Rights

Data submitted by the Contractor, whether in this proposal, during negotiations, or after award shall be solely for the purpose of negotiation of an award or, after award, administering the contract. All data submitted shall be considered proprietary and confidential and shall not be distributed outside of the Government or for use, other than specified above, without the advance written consent of the Contractor.

(End of Clause)

# C.11 Notification of Utilization

The USG agrees to notify the Contractor of any ultimate use of the Government owned vaccine provided by the Contractor to the SNS. This information is necessary for the investigation of adverse event claims and adverse event reporting

(End of Clause)

# SECTION D — CONTRACT DOCUMENTS, EXHIBITS OR ATTACHMENTS

# Section D — List Of Attachments

Item 1	Description Statement of Work	Attachment D.1
2	BioPort Load Plan	D.2
3	ACH Vendor/Miscellaneous Payment Enrollment Form	D.3
	Page 12	

# STATEMENT OF WORK

Acquisition of Licensed Anthrax Vaccine Adsorbed (BioThrax ®) for the Strategic National Stockpile (SNS)

# **D.1 Background and Need**

The Federal Response Plan of the Department of Homeland Security designates the Department of Health and Human Services (HHS) as the lead agency for public health and medical response to manmade or natural disasters. In 2002, HHS established the Office of Public Health Emergency Preparedness (OPHEP). This office is responsible for the implementation of a comprehensive HHS strategy to protect from, and be prepared to respond to, acts of bioterrorism and other public health emergencies threatening the civilian population. The Office of Research and Development Coordination (ORDC) in OPHEP has the primary responsibility within HHS to contract for large-scale manufacturing and delivery of licensed and licensable products to the Strategic National Stockpile (SNS) in preparation for response to a public health emergency.

Recent, significant changes in both the nature, regularity, and degree of the threat posed by the use of infectious agents as weapons of biological warfare have generated increased concern for the safety of the general American populace. Following the deliberate exposure of citizens of the United States to *Bacillus anthracis* (*B. anthracis*) spores in 2001, there is an urgent need to stockpile appropriate and effective medical countermeasures to safeguard against this potential threat. The USG has established a requirement for the procurement of licensed Anthrax Vaccine Adsorbed to meet this urgent need.

The Department of Health and Human Services intends to negotiate a sole source procurement with BioPort Corporation under the authority of FAR 6.302-1, Only One Responsible Source and No Other Supplies or Services will Satisfy Agency Requirements.

# **D.2 Project Identification and Purpose**

Provide 5 million doses of U.S. licensed Anthrax Vaccine Adsorbed (BioThrax®) in multi-dose vials to be delivered in appropriately packaged containers under controlled and secure conditions to the SNS.

AVA SOW Page 1 of 3

Attachment D.1, Contract No. 200-2005-11811

# **D.3 Specific Technical Requirements**

The Contractor shall provide the necessary qualified personnel, facilities, material, equipment (except Government property) and services to produce, test, bottle, package, and prepare for pick up in accordance with BioPort's Standard Operating Procedures and BioPort's Food and Drug Administration Biologics License and all federal government, and statutory requirements applicable to the manufacture, formulation, filling, and testing of BioThrax for the SNS in accordance with requirements as outlined below:

Task 1 Vaccine Production and cGMP Compliance

- a) The Contractor shall manufacture AVA in accordance with current GMP guidelines. The Contractor shall deliver 5 million doses of Final Drug Product (FDP) in 5 mL multi-dose vials, to the SNS within 18 months of contract award. AVA shall be made available for delivery not more than 60 days after the date of the FDA release, with the exception of lots [\*\*] and [\*\*].
- b) The Contractor shall provide primary and secondary points of contact who will be available 24 hours per day, seven days per week to be notified in case of a public health emergency.

Task 2 — Potency, Stability, and Container/Closure Integrity Testing of Finished Vaccine

The Contractor shall perform all requisite assays and release tests, including but not limited to potency, identity, and stability testing in accordance with the FDA approved Biologic License Application (BLA)(License Number 1260, BL 103821).

AVA SOW Page 2 of 3

Attachment D.1, Contract No. 200-2005-11811

# **D.4 Reporting Requirements**

The Contractor shall submit to the Contracting Officer and to the Project Officer progress reports covering the work accomplished during each reporting period. These reports are subject to the technical inspection and requests for clarification by the Project Officer. These shall be brief and factual and prepared in accordance with the following format:

- (1) Monthly Progress Reports: On the fifteenth of each month for the previous calendar month, the Contractor shall submit a Monthly Progress Report to the Project Officer and the Contracting Officer. A monthly report will not be required for the period when the final report is due. The Contractor shall submit one copy of the Monthly Progress Report electronically via e-mail. Any attachments to the e-mail report shall be submitted in Microsoft Word or WordPerfect 9 or compatible version. Such reports shall include the following specific information:
- a. The contract number and title, the period of performance being reported, the contractor's name and address, the author(s), and the date of submission;
- b. Section I An introduction covering the purpose and scope of the contract effort;

Section II — The report shall detail, document, and summarize the results of work done in performance of requirements of this contract during the period covered, and include a summary of work planned for the next reporting period. This shall include the information listed below that is applicable for the performance period during the month being reported:

Production capacity assessment problems and recommendations to include:

- 1. Raw material procurement status;
- 2. Inventory report of product manufactured and delivered to the USG under this contract.
- 3. Quality control testing and purity;
- 4. Quality control potency assessment;
- 5. FDA inspections and consultation results or recommendations;
- 6. Security assessment, problems and recommendations;
- 7. Physical storage monitoring and calibration reports for manufactured products.
- 8. Overall project assessment, problems encountered and recommended solutions, etc.

Section III — An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if behind planned progress, what corrective steps are planned. The project plan and delivery schedule will be updated in each Monthly Report and compared to the baseline plan and delivery schedule.

AVA SOW Page 3 of 3

# ACH VENDOR/MISCELLANEOUS PAYMENT ENROLLMENT FORM

This form is used for Automated Clearing House (ACH) payments with an addendum record that contains payment-related information processed through the Vendor Express Program. Recipients of these payments should bring this information to the attention of their financial institution when presenting this form for completion. See reverse for additional instructions.

# PRIVACY ACT STATEMENT

The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 U.S.C. 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to vendor's financial institution. Failure to provide the requested information may delay or prevent the receipt of payments through the Automated Clearing House Payment System.

		AGENCY INFORMATIO	N	
FEDERAL PROGRAM AGENCY				
AGENCY IDENTIFIER:	AG	GENCY LOCATION CODE (ALC):	ACH FORMAT: o CCD+ o CTX	
ADDRESS:				
CONTACT PERSON NAME:				TELEPHONE NUMBER:
ADDITIONAL INFORMATION:				
		PAYEE/COMPANY INF	ODMATION	
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ADDRESS				
CONTACT PERSON NAME:				TELEPHONE NUMBER: ( )
		FINANCIAL INSTITUTION	INFORMATION	
NAME:		THANCIALINGTHON	IN ORMATION	
ADDRESS:				
ACH COORDINATOR NAME:				TELEPHONE NUMBER:
NINE-DIGIT ROUTING TRANSIT NUM	BER:			,
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(Could be the same as ACH Coordinator)				( )
AUTHORIZED FOR LOCAL REPRODU	JCTION			SF 3881 (Rev. 2/2003)

SF 3881 (Rev. 2/2003) Prescribed by Department of Treasury 31 U S C 3322; 31 CFR 210

# **Instructions for Completing SF 3881 Form**

Make three copies of form after completing. Copy 1 is the Agency Copy; copy 2 is the Payee/Company Copy; and copy 3 is the Financial Institution Copy.

- 1. Agency Information Section Federal agency prints or types the name and address of the Federal program agency originating the vendor/miscellaneous payment, agency identifier, agency location code, contact person name and telephone number of the agency. Also, the appropriate box for ACH format is checked.
- 2. Payee/Company Information Section Payee prints or types the name of the payee/company and address that will receive ACH vendor/miscellaneous payments, social security or taxpayer ID number, and contact person name and telephone number of the payee/company. Payee also verifies depositor account number, account title, and type of account entered by your financial institution in the Financial Institution Information Section.
- 3. Financial Institution Information Section Financial institution prints or types the name and address of the payee/company's financial institution who will receive the ACH payment, ACH coordinator name and telephone number, nine-digit routing transit number, depositor (payee/company) account title and account number. Also, the box for type of account is checked, and the signature, title, and telephone number of the appropriate financial institution official are included.

# **Burden Estimate Statement**

The estimated average burden associated with this collection of information is 15 minutes per respondent or recordkeeper, depending on individual circumstances. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the Financial Management Service, Facilities Management Division, Property and Supply Branch, Room B-101, 3700 East West Highway, Hyattsville, MD 20782 and the Office of Management and Budget, Paperwork Reduction Project (1510-0056), Washington, DC 20503.

. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4 REOUSI	TION/P	URCHASE REQ. NO.	5 PROI	ECT NO (if applicable).
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ISSUED BY CO		7. ADMINI	STEREI	BY (If other than Item	8) CODE	
enters for Disease Control and Prevent equisition & Assistance Branch 8, Teat 920 Brandywine Road, Room 3120 tlanta, GA 30341-5539						
NAME AND ADDRESS OF CONTRA	CTOR (No., street, county, State an	nd Zip Code)	9A.	AMENDMENT OF SO	LICITATION	NO.
IOPORT CORPORATION 500 N. MARTIN LUTHER KING, JR. ANSING, MI 48906-2933	BLVD.			DATED (See Item 11)	CONTRACT	ORDER NO.
			200	-2005-11811		
		2	X 10E	3. DATED (See Item 13)		
DDE 026489018	FACILITY CODE			05/2005		
The above numbered solicitation is am	11. THIS ITEM ONLY APPLI				vtandad	is not extended. Offers must
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# MEMORANDUM OF DECISION

SUBJECT: Authority under the residual powers provisions of Public Law 85-804 to include Indemnification Clause in Contract No. 200-2005-11811, awarded May 5, 2005 to BioPort Corporation.

BioPort Corporation (BioPort) has requested that the Department of Health and Human Services (HHS) indemnify it against risks associated with supplying anthrax vaccine adsorbed (AVA) pursuant to Office of Public Health Emergency Preparedness Contract No. 200-2005-11811 (the Contract).

I adopt as applicable to the Contract the findings of former Acting Secretary of the Army Brownlee with respect to unusually hazardous risks contained in the second, fourth, and fifth sentences of the second paragraph of his September 28, 2004 memorandum of decision authorizing indemnification of BioPort (attached). I note that the Food and Drug Administration affirmed the conclusion referenced by former Acting Secretary Brownlee in a December 19, 2005 final order. I further adopt, with respect to AVA acquired under the Contract, the definition of unusually hazardous risks contained in TAB A, section a, appended to that memorandum. The use of this definition is for the purposes of this contract indemnification matter only. It has no bearing on, and is unrelated to, any determination by the Food and Drug Administration (FDA) concerning the safety or effectiveness of AVA or any other product.

This indemnification shall include BioPort, its affiliates (including, but not limited to Emergent BioSolutions Inc.), subsidiaries, divisions, and organizational units, together with their officers, directors, employees, agents, successors and assigns; provided, that with respect to successors or assigns responsible for the performance of any executory contract subject to this memorandum, this indemnification shall include only those successors or assigns with whom BioPort has entered into a Government-approved novation agreement, or, where appropriate, as to whom a change-of-name-agreement has been executed in accordance with the Federal Acquisition Regulation (FAR).

I adopt the findings of the Acting Secretary as to the availability, cost and terms of private insurance to specifically cover these risks, as well as self-insurance. Based on this evaluation, and except as otherwise provided herein, all liabilities of BioPort arising from the above-described unusually hazardous risks with respect to AVA acquired under the Contract shall be subject to indemnification. Accordingly, except with regard to BioPort's workers' compensation insurance or as deemed necessary by the Department of Homeland Security should BioPort receive certification under the SAFETY Act, the Government will not require that Contractor purchase or maintain any insurance coverage as a condition of the indemnification hereby authorized.

#### Page 2 - BioPort Corp./Memorandum of Decision

Based on my findings that: (1) AVA serves as a significant bioterrorism countermeasure; and (2) the Contract provides that the Government will not administer the vaccine to human subjects until I have approved a request for indemnification; I further find that the use of an indemnification clause in the contract to cover the unusually hazardous risks defined above will facilitate the national defense. Because BioPort is licensed by the FDA to produce AVA, I further determine that BioPort is in compliance with applicable Government safety requirements.

The Government retains the right to closely monitor any and all litigation of claims arising out of the Contract between BioPort and HHS, including any and all dispute resolution proceedings or settlement discussions involving claims. As a condition of indemnification, BioPort shall fully cooperate with the Government's efforts to effect such monitoring.

"Claim" or "claims" shall mean claims arising out of the Contract between BioPort and HHS for relief of any sort relating to the unusually hazardous risks as defined above asserted in court, arbitration or dispute resolution proceedings, and claims or demands presented to the Contractor without the institution of formal proceedings. Reference to "claims," "losses," or "damages" include all claims (as defined above), losses or damages that are identified on or after the date of this memorandum.

"Contractor" means BioPort, its affiliates (including without limitation Emergent BioSolutions Inc.), subsidiaries, divisions, and organizational units.

"Indemnify" means to indemnify and hold harmless.

Legal fees and expenses incurred by Contractor are subject to indemnification to the extent that the Secretary determines these amounts to be just and reasonable. These legal fees and expenses specifically include, but are not limited to, any and all costs (including reasonable legal fees and expenses) relating to invoking the protections of the SAFETY Act and/or defending its applicability, legality and/or constitutionality, to the extent that such costs (1) are not covered by any insurance the contractor is required to obtain to meet SAFETY Act qualification requirements, and (2) are incurred in connection with the defense of a claim or claims as defined herein. Further, HHS agrees to consider and pay promptly all submissions for reimbursement by Contractor for all reasonable legal fees and expenses that are incurred in connection with the foregoing or otherwise subject to indemnification and to make prompt payment therefore consistent with the requirement for HHS to obtain supplemental appropriations, if applicable, and the legal standards on HHS under the Anti-Deficiency Act.

In view of the foregoing and pursuant to the authority vested in me by the residual power provisions of Public Law 85-804 (50 U.S.C. §§ 1431-1433, 1435) and Executive Order 10789, as amended, I hereby authorize the Contracting Officer to modify the Contract to include the indemnification clause set forth at FAR § 52.250-1 in the Contract, provided that: (1) the Contract defines unusually hazardous risks as set forth above, and (2) the indemnification clause shall be so interpreted as to effectuate the policies set forth at FAR § 50.102.

# Page 3 — BioPort Corp./Memorandum of Decision

As a condition of this indemnification, BioPort shall submit to the Secretary of Homeland Security an application for the designation of AVA as a qualified anti-terrorism technology (QATT) under section 862(b) of the Homeland Security Act of 2002 (6 U.S.C. § 442(b)). In the event that the Secretary of Homeland Security designates AVA as a QATT, this indemnification shall remain effective according to its terms with respect to such residual indemnified liabilities on the part of BioPort as may remain or survive following application of the SAFETY Act, provided that BioPort has complied with the SAFETY Act and its implementing regulations.

Should the Secretary of Homeland Security decline to designate AVA as a QATT, this indemnification shall remain in effect according to its terms. See 68 Fed. Reg. 59684, 59694 (Oct. 16, 2003).

As permitted by FAR 50.403-2(d) and FAR 52.250-1(e), and when justified by the circumstances, I authorize the Contracting Officer to permit BioPort to provide for indemnification of its first and second-tier subcontractors, provided that the indemnification is limited to the unusually hazardous risks defined in this Memorandum of Decision and that the Contracting Officer approves BioPort's request for subcontractor indemnification in writing.

It is not possible to determine the actual or estimated cost to the government as the result of the use of this indemnification clause, inasmuch as the liability of the government, if any, will depend upon the occurrence of incidents within the definition of unusually hazardous risks.

/s/ Michael O. Leavitt Michael O. Leavitt

# TAB A

# DEFINITION OF UNUSUALLY HAZARDOUS RISKS AND LIMITATIONS ON COVERAGE

# a. Definition of Unusually Hazardous Risks.

Release (or alleged release) of an infectious agent or toxic material into the environment in connection with activities undertaken pursuant to the contract that results (or allegedly results), either directly or indirectly, in human exposure to or environmental damage by an infectious material or toxic material involved with the production or testing of vaccines pursuant to the contract. Such activities may include, but are not limited to: (1) storage, use, testing, or handling of the live vaccine products, their intermediate precursors or infectious agents or toxins that are used as challenge materials for test of the products or intermediates; (2) transportation of such substances; and (3) disposal of such substances.

Adverse reaction (or alleged adverse reaction) in a human from administration of a vaccine or other material used in the production or testing of the vaccine, in conjunction with or as a result of the performance of the contract, or administration of a vaccine produced, tested, or delivered under the contract.

The term adverse reaction includes anaphylaxis and other foreseeable and unforeseeable adverse reactions. Such reactions include, but are not limited to: (1) reactions directly attributable to and resulting from the administration of the vaccine or other material involved with the vaccine production or testing (to include challenge materials); (2) reactions that manifest long after exposure, but which are directly attributable to and resulting from the administration of the vaccine or other material involved with the production, or testing of the vaccine; (3) the failure of the vaccine to perform as intended or otherwise confer immunity; or (4) performance by the vaccine in a manner not intended.

#### b. Limitations on Coverage.

Notwithstanding any other provision in the indemnification clause or Memorandum of Decision, BioPort Corporation and its subcontractors shall not be indemnified against grossly negligent or criminal behavior on the part of BioPort Corporation's or its subcontractors' directors, officers, or managers who have supervision over, or direction of, all or substantially all of the operations at any one plant or separate locations where the contract or a subcontract is being performed.

Attachment No. 4 to Contract W9113M-04-B-0002

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AMEND	MENT OF SOLIC	TATION/	MODIFICATION O	F CONTRACT	1. CONTRACT ID COD	E	PAGE OF PAG	ies 2	
2. AMENDMEN Medification	NT/MODIFICATION NO.	3. E	FFECTIVE DATE	4. REQUISITION/PURCHASE	REQ. NO.	5. PROJECT NO	). ([f applicble)	3	
6. ISSUED BY		CODE		7. ADMINISTERED BY (If oth	er than Item 6)	CODE			
Department of Health & Human Services OS/OPHEP/ORDC 200 Independence Ave., S.W. Room 636G Washington, D.C. 20201									
8. NAME AND	ADDRESS OF CONTRACTOR	l (No., street, county	r, State and ZIP Code)		(X)	9A. AMENDMI	ENT OF SOLICIATION NO.		
BioPort Corpo 3500 N. Marti Lansing, MI	in Luther King, Jr. Blvd.					9B. DATED (SE 10A. MODIFIC HHSO100200 10B. DATED (S	ATION OF CONTRACT/ORDER 600019C	R NO.	
CODE			FACILITY CODE						
		11. THI	S ITEM ONLY APPLIE	S TO AMENDMENTS	OF SOLICITATI	ONS			
The above numbered solicitation is amended as set forth in hem 14. The hour and date specified for receipt of Offers  is extended,  Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:  (a) By completing items 8 and 15, and returning						THE sange may			
12. ACCOUNT	ING AND APPROPIRATION D	ATA (If required)							
TIN: 383412	788 CAN	1991535	Appropriation: 756	50140 O.C.	25.2A	\$120,000,000	0.00		
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			IFIES THE CONTRACT						
CHECK ONE	A. THIS CHANGE OR NO, IN ITEM 10A.	DER IS ISSUED PU	JRSUANT TO: (Specify authority) T	THE CHANGES SET FORTH IN I	TEM 14 ARE MADE IN T	HE CONTRACT	ORDER		
	B. THE ABOVE NUMBERED CONTRACTORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.182(b).							RTH IN	
X									
	FAR 52.243-1, Changes  D. OTHER (Specify type of modification and authority)								
E. IMPORTANT: Contractor is not, is required to sign this document and return1_ copies to the issuing office.									
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section beading), including officiation/contract subject matter where feasible.)  The purpose of this modification is to modify the statement of work, apply the indemnification to the modified contract number, and purchase an additional 5 million doses of AVA as reflected on page 2 through 3.  I. The total contract amount is increased by \$120,000,000 from \$122,737,000 to \$242,737,000									
2. The total a	llotted amount is increased l	by \$120,000,000	from \$122,737,000 to \$242,737 eptember 30, 2006 to September	7,000					
			referenced in Item 9A or 10A, as her						
	ND TITLE OF SIGNER (Type or	r print)		16A. NAME AND TITLE O	F CONTRACTING OFFIC	E.K. (Type or print	)		
	mer, President & CEO	15C, DATE SIGN	ED	Brian K. Goodger  16B. UNITED STATES OF	AMERICA	16C, DATE S	WINED		
/s/ Robert G.		5/4/06	- mar	/s/ Brian K. Goodger	ACCOUNTY OF	5/4/06	enr a naille		
(Signature of per	rson authorized to sign)			(Signature of Contracting Of	ficer)				

NSN 7540-01-152-8070 Postcious addition transplate STANDARD FORM 30 (REV. 10-83) Prescribed by GSA FAR (48 CFR) 53.243

# The contract is hereby modified as follows:

# SECTION B

# **Contract Schedule**

AVA available doses for the period May 8, 2006 — May 5, 2007.

ITEM NO.	SUPPLIES / SERVICES	QTY / UNIT	UNIT PRICE	EXTENDED PRICE
0004	BioThrax Vaccine	5,000,000	\$[**]	\$120,000,000.00
	Anthrax Vaccine Adsorbed	Doses		
	(AVA) BioThrax®		FFP	

TOTAL: 5,000,000 Doses \$120,000,000.00

# ${\tt SECTION} \: {\tt C} - {\tt CONTRACT} \: {\tt CLAUSES}$

# C.1.1 Method of Delivery

b. The USG will receive and transport product from the manufacturer approximately bi-monthly. A first delivery of approximately [\*\*] doses shall be available for inspection and acceptance immediately after award of the contract modification. The contractor shall invoice and be paid upon acceptance of the first delivery. Upon acceptance of the first delivery at the manufacturer's location, the manufacturer shall store the USG vaccine in cGMP conditions in segregated storage until the first scheduled shipment on or about August 15. Subsequent deliveries and shipments shall occur as follows:

Estimated "Delivery Dates"	Target Quantities to be Delivered (Inspection and Acceptance)	Target Quantities to be Shipped to SNS Location
Immediately after Contract Award	[**]	[**]
August 15, 2006	[**] — [**]	[**] — [**]
October 15, 2006	[**] — [**]	[**] — [**]
December 16, 2006	[**] — [**]	[**] — [**]
February or March, 2007 (balance to be delivered by May 5, 2007 at the latest)	[**] — [**]	[**] — [**]

d. Except for the acceptance of the first delivery, acceptance of the product shall be deemed to have occurred after USG inspection and in accordance with C.1.2, and upon delivery of the FDA-released product to the USG designated carrier on the periodic transport dates as provided in (b.) above. Contractor will invoice the USG immediately upon acceptance.

(End of Clause)

# C.4 Indemnification

The indemnification granted under contract number 200-2005-11811, modification 0001, dated 2/23/2006, applies to this contract (HHSO100200600019C).

# C.8 Invoice Submission (July 1999)

(a) The Contractor shall submit an original and one (1) copy of contract invoices to the address shown below:

Department of Health & Human Services Office of Research & Development Coordination Attn: Brian K. Goodger, Contracting Officer 200 Independence Ave. S.W. Room 636-G Washington, DC 20201

# C.12 Risk of Loss

Under paragraph (j) of FAR clause 52.212-4, risk of loss of or damage to vaccine under Item 0004 shall pass to the Government upon acceptance by the Government, except to the extent provided in FAR 52.212-4(a) regarding nonconforming items. The Contractor remains responsible for ensuring that during the Contractor's storage of the product that all doses shall remain in compliance with FDA cGMP guidelines. In the event that the Contractor or its subcontractor fails to comply with FDA cGMP guidelines for storage of the product, the Contractor shall replace those units of product not stored in compliance with FDA guidelines.

# ${\tt SECTION\,D-CONTRACT\,DOCUMENTS, EXHIBITS\,OR\,ATTACHMENTS}$

# Section D — List Of Attachments

 Item
 Description
 Attachment

 1
 Revised Statement of Work (modified on page 2, Task 1)
 D.1, 3 pages

All Other Terms & Conditions of the Contract Remain Unchanged.

Page 3

# STATEMENT OF WORK

Acquisition of Licensed Anthrax Vaccine Adsorbed (BioThrax®) for the Strategic National Stockpile (SNS)

### **D.1 Background and Need**

The Federal Response Plan of the Department of Homeland Security designates the Department of Health and Human Services (HHS) as the lead agency for public health and medical response to manmade or natural disasters. In 2002, HHS established the Office of Public Health Emergency Preparedness (OPHEP). This office is responsible for the implementation of a comprehensive HHS strategy to protect from, and be prepared to respond to, acts of bioterrorism and other public health emergencies threatening the civilian population. The Office of Research and Development Coordination (ORDC) in OPHEP has the primary responsibility within HHS to contract for large-scale manufacturing and delivery of licensed and licensable products to the Strategic National Stockpile (SNS) in preparation for response to a public health emergency.

Recent, significant changes in both the nature, regularity, and degree of the threat posed by the use of infectious agents as weapons of biological warfare have generated increased concern for the safety of the general American populace. Following the deliberate exposure of citizens of the United States to *Bacillus anthracis* (*B. anthracis*) spores in 2001, there is an urgent need to stockpile appropriate and effective medical countermeasures to safeguard against this potential threat. The USG has established a requirement for the procurement of licensed Anthrax Vaccine Adsorbed to meet this urgent need.

The Department of Health and Human Services intends to negotiate a sole source procurement with BioPort Corporation under the authority of FAR 6.302-1, Only One Responsible Source and No Other Supplies or Services will Satisfy Agency Requirements.

# **D.2 Project Identification and Purpose**

Provide 5 million doses of U.S. licensed Anthrax Vaccine Adsorbed (BioThrax®) in multi-dose vials to be delivered in appropriately packaged containers under controlled and secure conditions to the SNS

# **D.3 Specific Technical Requirements**

The Contractor shall provide the necessary qualified personnel, facilities, material, equipment (except Government property) and services to produce, test, bottle, package, and prepare for pick up in accordance with BioPort's Standard Operating Procedures and BioPort's Food and Drug Administration Biologics License and all federal government, and statutory requirements applicable to the manufacture, formulation, filling, and testing of BioThrax for the SNS in accordance with requirements as outlined below:

Task 1 Vaccine Production and cGMP Compliance

- a) The Contractor shall manufacture AVA in accordance with current GMP guidelines. The Contractor shall deliver 5 million doses of Final Drug Product (FDP) in 5 mL multi-dose vials, to the SNS by May 5, 2007. No lots shall be accepted that have an expiration date before December 7, 2008.
- b) The Contractor shall provide primary and secondary points of contact who will be available 24 hours per day, seven days per week to be notified in case of a public health emergency.

Task 2 — Potency, Stability, and Container/Closure Integrity Testing of Finished Vaccine

The Contractor shall perform all requisite assays and release tests, including but not limited to potency, identity, and stability testing in accordance with the FDA approved Biologic License Application (BLA)(License Number 1260, BL 103821).

# **D.4 Reporting Requirements**

The Contractor shall submit to the Contracting Officer and to the Project Officer progress reports covering the work accomplished during each reporting period. These reports are subject to the technical inspection and requests for clarification by the Project Officer. These shall be brief and factual and prepared in accordance with the following format:

- (1) Monthly Progress Reports: On the fifteenth of each month for the previous calendar month, the Contractor shall submit a Monthly Progress Report to the Project Officer and the Contracting Officer. A monthly report will not be required for the period when the final report is due. The Contractor shall submit one copy of the Monthly Progress Report electronically via e-mail. Any attachments to the e-mail report shall be submitted in Microsoft Word or WordPerfect 9 or compatible version. Such reports shall include the following specific information:
- a. The contract number and title, the period of performance being reported, the contractor's name and address, the author(s), and the date of submission;
- b. Section I An introduction covering the purpose and scope of the contract effort;

Section II — The report shall detail, document, and summarize the results of work done in performance of requirements of this contract during the period covered, and include a summary of work planned for the next reporting period. This shall include the information listed below that is applicable for the performance period during the month being reported:

Production capacity assessment problems and recommendations to include:

- 1. Raw material procurement status;
- 2. Inventory report of product manufactured and delivered to the USG under this contract.
- Quality control testing and purity;
- 4. Quality control potency assessment;
- 5. FDA inspections and consultation results or recommendations;
- 6. Security assessment, problems and recommendations;
- 7. Physical storage monitoring and calibration reports for manufactured products.
- 8. Overall project assessment, problems encountered and recommended solutions, etc.

Section III — An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if behind planned progress, what corrective steps are planned. The project plan and delivery schedule will be updated in each Monthly Report and compared to the baseline plan and delivery schedule.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

#### FILLING SERVICES AGREEMENT

This Agreement is made this 18th day of March, 2002 (the "Effective Date"), by and between BioPort Corporation, a Michigan corporation having its principal office at 3500 North Martin Luther King Jr. Blvd., Lansing, MI 48906 ("BIOPORT") and HOLLISTER-STIER Laboratories LLC, a Delaware limited liability company having its principal office at 3525 North Regal Street, Spokane, WA 99207 ("HOLLISTER-STIER") (sometimes referred to in the singular as "Party" and collectively as the "Parties").

# RECITALS

WHEREAS, BIOPORT is engaged in the production and sale of vaccines;

WHEREAS, HOLLISTER-STIER is a contract filler in the pharmaceutical industry and experienced in the filling services of pharmaceuticals;

WHEREAS, BIOPORT has, as specified herein, several contracts with the United States Government for the production, testing and maintenance of Anthrax Vaccine Adsorbed ("AVA");

WHEREAS, BIOPORT produces AVA in bulk quantities and desires to fill this vaccine in vials at an FDA-licensed location; and

WHEREAS, BIOPORT desires to engage HOLLISTER-STIER directly to provide filling services, and HOLLISTER-STIER desires to be so engaged.

NOW, THEREFORE, the parties hereto agree as follows:

#### AGREEMENT

- **1.0 Definitions:** As used in this agreement, the following definitions shall apply:
- 1.1 "Act" shall mean the US Food, Drug and Cosmetic Act of 1934, and the regulations promulgated thereunder, as the same may be amended from time to time.
- 1.2 "Bulk Lot" shall mean each separate and distinct quantity of Bulk Product designated as a single batch or lot by BIOPORT and designated by lot number.
- 1.3 "Bulk Product" shall mean AVA in bulk form as manufactured by BIOPORT and shipped to HOLLISTER-STIER.
- 1.4 "Bulk Product Specification(s)" means the specifications for the composition, testing, packaging and labeling of the Bulk Product.
- 1.5 "Certificate of Analysis" and "COA" shall mean a document prepared in accordance with cGMP and certifying that a Filled Lot meets the Filling Process Specifications as referenced, signed and dated by a duly authorized representative of the Quality Assurance Department of HOLLISTER-STIER.
- 1.6 "cGMP" shall mean current Good Manufacturing Practices as such term is used in the Act.

- 1.7 "Confidential Information" shall mean any nonpublic information of BIOPORT that has been or will be communicated to HOLLISTER-STIER or any nonpublic information of HOLLISTER-STIER that has been or will be communicated to BIOPORT, including without limitation, trade secrets, business methods, operating procedures, manufacturing methods and processes, prices, product forecasts, actual orders, and customer information, whether in a written, oral or visual format; provided, however, that "Confidential Information" will not include any information that is: (a) already known to the receiving Party at the time of disclosure hereunder, as demonstrated by its written records; (b) now or hereafter becomes publicly known other than through acts or omissions of the receiving Party, or anyone to whom the receiving Party disclosed such information; (c) disclosed to the receiving Party on a nonconfidential basis by a third party under no obligation of confidentiality to the disclosing Party; or (d) independently developed by the receiving Party without reliance on the Confidential Information of the disclosing Party as shown by its written records.
- 1.8 "FDA" shall mean the United States Food and Drug Administration.
- 1.9 "Filled Lot" shall mean each separate and distinct quantity of Filled Product processed under continuous conditions from a [\*\*] Bulk Lot and that is designated as a single batch or lot by HOLLISTER-STIER and designated by a lot number.
- 1.10 "Filled Product" shall mean vials filled by HOLLISTER-STIER with Bulk Product in accordance with all Filling Process Specifications and other requirements of this Agreement.
- 1.11 "Filling Process Specification(s)" means the requirements and statement of procedures for filling, testing, packaging, labeling, storage, and shipping Filled Product, as set forth in [\*\*], as altered or amended pursuant to Section 4.12. The Filling Process Specifications do not include matters covered by the Bulk Product Specifications.
- 1.12 "Good Faith Annual Estimate" shall have the meaning described in Section 5.2.
- 1.13 "Health Authority" means a regulatory authority having jurisdiction over the manufacture or sale of Bulk Product or Filled Product, including but not limited to the Canadian Health Protection Branch, the European Medicines Evaluation Agency, the FDA and any other relevant national regulatory agency in any nation, and "Health Authorities" shall mean collectively all such regulatory authorities.
- 1.14 "Percentage Yield" means the ratio of the Yield to the Theoretical Yield with respect to a particular Bulk Lot, expressed as a percentage.
- 1.15 "Term Year" means (a) the period between the Effective Date and the end of the calendar year in which the Effective Date occurs (the "First Term Year") and (b) any one of the four next following calendar years.
- 1.16 "Theoretical Yield" means the number of vials of Filled Product that could be filled from a particular Bulk Lot based on the total amount of Bulk Product in such Bulk Lot.
- 1.17 "Yield" means the number of acceptable vials of Filled Product available for shipment to BIOPORT that were filled from a particular Bulk Lot.
- 2.0 ENGAGEMENT AND LICENSE. BIOPORT hereby engages HOLLISTER-STIER, on a nonexclusive basis, and HOLLISTER-STIER hereby accepts such engagement, to provide BIOPORT with filling services to produce Filled Product in accordance with the Filling Process Specifications and the other terms and conditions set forth in this Agreement, as ordered by BIOPORT in accordance with this Agreement. BIOPORT

hereby grants HOLLISTER-STIER a nonexclusive, royalty-free right and license to practice any and all patents, know-how, and other intellectual properties, proprietary rights and technologies (including without limitation as to access to or use or modification of any tangible materials) owned or controlled by BIOPORT that are necessary or useful in the performance by HOLLISTER-STIER of its activities under, and in preparation for, this Agreement.

- 3.0 REPRESENTATIONS AND WARRANTIES. BIOPORT and HOLLISTER-STIER each represent and warrant to the other as follows:
- 3.1 It has full power and authority to enter into this Agreement and consummate the transactions contemplated hereby.
- 3.2 Except as provided in Section 4.10, it has or shall obtain prior to performance hereunder such permits, licenses and authorizations of government or regulatory authorities as are necessary to own its respective properties, conduct its business and consummate the transactions contemplated hereby.
- 3.3 It is not currently debarred, suspended, or otherwise excluded by the United States from receiving Federal contracts.
- 3.4 All laboratory, scientific, technical and/or other data submitted by or on behalf of BIOPORT relating to the Bulk Product or by or on behalf of HOLLISTER-STIER relating to the Filled Product, shall, to the best of the submitter's knowledge, be true and correct and shall not contain any material falsification, misrepresentation or omission.
- 3.5 In performing its obligations or activities under or in connection with this Agreement, it shall comply with all applicable existing and future laws, rules and regulations of the United States and the States thereof; provided, however, that HOLLISTER-STIER may rely on BIOPORT's warranty that the Filling Process Specifications conform to all applicable laws, rules and regulations.
- 3.6 Each Party represents and warrants that neither it nor its employees or agents has made or will make any payments in connection with this Agreement or from funds paid or payable hereunder directly or indirectly to any officials or employees of any governmental agency or instrumentality.
- 3.7 HOLLISTER-STIER represents and warrants to BIOPORT as follows:
  - 3.7.1 HOLLISTER-STIER's performance of the filling services will not violate or misappropriate any patent, copyright, trademark, trade secret or other intellectual property right of any third party (other than as may be due to HOLLISTER-STIER's compliance with BIOPORT's instructions or other matters bearing on the Bulk Product or its filling that are the responsibility of BIOPORT as provided herein).
  - 3.7.2 The Filled Product shall when delivered to BIOPORT hereunder meet all Filling Process Specifications, be of good, merchantable and usable quality, free of defects in materials and workmanship, suitable for the purposes for which the Filled Product is to be used, and shall not be adulterated or misbranded within the meaning of the Act or other substantially similar laws and statutes; provided, however, that the foregoing shall not apply to the extent that any defect or deficiency is caused by the Bulk Product or any other materials or technologies provided by BIOPORT or is due to HOLLISTER-STIER's compliance with the Filling Process Specifications or any other instructions provided by BIOPORT.

- 3.7.3 Subject to obtaining the rights and authorizations that are the responsibility of BIOPORT pursuant to Section 4.10, HOLLISTER-STIER's manufacturing facilities for the Filled Product: (a) conform, and will conform throughout the term of this Agreement, in all material respects with applicable laws, regulations and approvals governing such facilities, including but not limited to the cGMP as defined by 21 Code of Federal Regulations Sections 210, 211, et seq., (b) will be adequate to produce at least [\*\*] Filled Lots per annum; and (c) shall conform to FDA requirements for a multiple product facility, including without limitation with respect to prevention of cross contamination of products.
- 3.7.4 HOLLISTER-STIER shall not, during the term of this Agreement, fill any penicillin-based products, beta-lactam-based products, live viral vaccines or spore forming products in the same small volume parenteral facility used to fill any of the Filled Products (the "Filling Suite").
- 3.7.5 All product contact parts used to fill the Filled Product will be dedicated solely to Filled Product or disposed after each use.
- 3.8 BIOPORT represents and warrants to HOLLISTER-STIER as follows:
  - 3.8.1 BIOPORT has the full power and authority to grant the licenses it grants under this Agreement and to engage HOLLISTER-STIER hereunder, and the granting of the licenses granted to HOLLISTER-STIER hereunder, and the exercise by HOLLISTER-STIER of the rights granted by BIOPORT under such engagement or licenses will not breach any obligation to or right of any third party.
  - 3.8.2 Neither the Bulk Product, the BIOPORT technology licensed hereunder, nor the use thereof by HOLLISTER-STIER, nor HOLLISTER-STIER's conduct of the filling services in conformity with the Filling Process Specifications, shall cause HOLLISTER-STIER to violate any law or infringe, violate or misappropriate any patent, copyright, trademark, trade secret or other intellectual property right of any third party.
  - 3.8.3 The Bulk Product shipped by BIOPORT to HOLLISTER-STIER shall be accompanied by a complete and accurate AVA Bulk Formulation Lot Approval for Filling Form (the "Approval for Filling Form"), duly signed by an authorized representative of BIOPORT's Quality Assurance Department, and be of good, merchantable and usable quality, free of defects in materials and workmanship, suitable for the purposes for which the Bulk Product is to be used, and shall not be adulterated or misbranded within the meaning of the Act. The Bulk Product does not and will not contain any select agent as defined in subsection (j) of 42 CFR section 72.6, unless the same is exempted under subsection (h) of such section 72.6 or Appendix A of 42 CFR part 72, as such provisions may be amended from time to time.
  - 3.8.4 BIOPORT shall not release any Filled Product for distribution, sale or use without conducting all testing and certifications thereof that are the responsibility of BIOPORT hereunder or under current health, safety and environmental regulations, laws, Health Authority rules and regulations, and industry standards.

THE WARRANTIES SET FORTH HEREIN ARE THE SOLE AND EXCLUSIVE WARRANTIES MADE BY EITHER PARTY UNDER THIS AGREEMENT, AND NEITHER PARTY MAKES ANY OTHER WARRANTIES EXPRESS OR IMPLIED OR ARISING BY LAW, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY ARISING FROM THE COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OF TRADE.

EXCEPT FOR THE INDEMNITY OBLIGATIONS SET FORTH IN THIS AGREEMENT OR FOR BREACHES OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH IN THIS AGREEMENT, UNDER NO CIRCUMSTANCES WILL EITHER PARTY BE LIABLE TO THE OTHER UNDER ANY CONTRACT, TORT, STRICT LIABILITY, NEGLIGENCE OR OTHER LEGAL OR EQUITABLE THEORY, FOR COVER OR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOST PROFITS IN CONNECTION WITH THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING WITHOUT LIMITATION THE BULK PRODUCT OR FILLED PRODUCT OR ANY SERVICES PROVIDED OR TO BE PROVIDED IN CONNECTION WITH THE BULK PRODUCT.

#### 4.0 COVENANTS

- 4.1 The sterile Bulk Product and all vials, stoppers, seals and other materials to be provided by BIOPORT pursuant to the Filling Process Specifications will be delivered to HOLLISTER-STIER at BIOPORT's expense and liability, along with BIOPORT's Approval for Filling Form for each Bulk Lot. BIOPORT shall deliver or cause to be delivered quantities of Bulk Product and such other items, and shall do so in a timely manner, sufficient for HOLLISTER-STIER to perform the filling services called for hereunder.
- 4.2 To the extent called for in the Filling Process Specifications, HOLLISTER-STIER shall conduct materials tests of each Bulk Lot, but no such testing (or failure so to test) will relieve BIOPORT of its responsibility hereunder to deliver the Bulk Product in conformity with the requirements of the Approval for Filling Form, as based on the Bulk Product Specifications. If such materials tests indicate that any of the Bulk Product does not meet the requirements of the Approval for Filling Form, as based on the Bulk Product Specifications, HOLLISTER-STIER will immediately so inform BIOPORT and BIOPORT will supply replacement Bulk Product that does conform to the Bulk Product Specifications.
- 4.3 For each Filled Lot filled by HOLLISTER-STIER, HOLLISTER-STIER shall perform the following testing for compliance with the Filling Process Specifications: final container sterility and gross visual inspection. Upon completion of such testing and review of manufacturing records, HOLLISTER-STIER shall submit to BIOPORT a COA listing the results of such testing and copies of all agreed upon records. Subject to HOLLISTER-STIER's prior consent (such consent not to be unreasonably withheld if either the same does not add to the costs of HOLLISTER-STIER's performance hereunder or BIOPORT agrees to bear all additional costs associated with the same), BIOPORT, may, from time to time, change the type of test(s) or the form of the records to be provided by HOLLISTER-STIER to BIOPORT for each Filled Lot.
- 4.4 BIOPORT is responsible for the release of the Filled Product for sale or distribution.
- 4.5 BIOPORT is responsible for the Stability Testing Program for the Filled Product.
- 4.6 BIOPORT is responsible for maintaining Retention Samples of Filled Product.
- 4.7 BIOPORT is responsible for compliance with the requirements of all Health Authorities concerning the reporting of any adverse reactions or other events ("Adverse Events") that may occur as the result of the manufacture, testing, sale or use of the Bulk Product or the Filled Product. HOLLISTER-STIER shall advise BIOPORT promptly of any Adverse Event, safety or toxicity problem reported to HOLLISTER-STIER regarding Filled Product.
- 4.8 Except as required by applicable law and/or regulations, or in order to seek approval of any Health Authority, neither Party shall make any use of the other Party's name,

whether in a press release, company profile, promotional or advertising material or otherwise, without the other Party's prior written approval.

- 4.9 BIOPORT and HOLLISTER-STIER shall provide to each other copies of all correspondence from Health Authorities related to the Bulk Product or Filled Product, including all inspection reports issued by Health Authorities during the term of this Agreement, provided, however, that BIOPORT shall only be required to provide such copies to the extent they relate to the filling process or the filling services of HOLLISTER-STIER. HOLLISTER-STIER shall provide informal notice within 24 hours by telephone of any such inquiry or inspection. All documents provided by HOLLISTER-STIER to any Health Authority, with respect to Filled Product or Bulk Product or its SVP facility, shall be provided to BIOPORT in advance for review and comment if feasible, and in no case shall such documents be provided to BIOPORT later than three (3) business days after such documents are provided to any Health Authority. To the extent permitted by law or regulation: (a) HOLLISTER-STIER shall promptly notify BIOPORT of all Health Authority inspections concerning the Filled Product or Bulk Product, and (b) BIOPORT shall have the right to be present for such inspection, at BIOPORT's risk and expense.
- 4.10 While HOLLISTER-STIER shall be responsible to obtain and maintain any generally-applicable FDA approvals of its facility as a licensed FDA facility (i.e., not specific to the manufacture of Filled Product or to the receipt, storage, shipping or handling of Bulk Product or Filled Product), BIOPORT shall be solely responsible at its risk and expense for obtaining all permits, licenses, and authorizations necessary for HOLLISTER-STIER to fill and ship the Filled Product under this Agreement. Filling operations are to be performed using appropriate safety measures and containment techniques as dictated by current health, safety and environmental regulations, laws, Health Authority rules and regulations, and industry standards
- 4.11 BIOPORT shall supply HOLLISTER-STIER with a Safety Sheet and the U.S. Department of Transportation Hazard Classification for the Bulk Product and Filled Product. HOLLISTER-STIER and BIOPORT shall cooperate reasonably to develop mutually-agreed safety procedures as amendments to the Filling Process Specifications, for the handling of the Bulk Product and Filled Product and treatment or disposal of wastes relating thereto that comply with all federal, and state environmental and occupational safety and health requirements.

  HOLLISTER-STIER shall, in accordance with BIOPORT's instructions, ship rejected Bulk Product or Filled Product to such destination as BIOPORT shall designate in writing. The expense for disposal or reclamation of rejected Bulk Product and waste shall be borne by BIOPORT, provided, however, that the expense for disposal of rejected Bulk Product or Filled Product without prior written consent from BIOPORT.
- 4.12 No changes to the Filling Process Specifications shall be made without the mutual written consent of BIOPORT and HOLLISTER-STIER. However, the Parties agree to amend the Filling Process Specifications at the times, and in accordance with the procedures, set forth in the Filling Process Specifications, in order, among other things, to alter the preliminary Percentage Yield called for under the Filling Process Specifications to reasonably reflect the Yields obtained by HOLLISTER-STIER in the initial Filled Lots during the term hereof.
- 4.13 HOLLISTER-STIER shall not make any changes or additions to or alter in any way its Filling Suite, or the equipment, testing procedures, validation, suppliers of raw materials and components, or documentation systems that relate to the Bulk Product or the Filled Product without the prior written consent of BIOPORT, which consent shall not be unreasonably withheld or delayed.

- 4.14 HOLLISTER-STIER shall provide BIOPORT with not less than thirty (30) days advance written notice of HOLLISTER-STIER's commencement of production or filling in the Filling Suite of any product that is not within one or more of the Product Classifications specified in the Filling Process Specifications. "Product Classifications" means those types and classes of products any of which are or have been produced or filled in the Filling Suite, including those as of or prior to the Effective Date and those of which HOLLISTER-STIER gives notice under this Section (all of which shall be deemed from that point forward to be added to the list of Prior Product Classifications in the Filling Process Specifications).
- 4.15 The Parties agree that the filling services under this Agreement shall be conducted at the HOLLISTER-STIER facility in Spokane, Washington.
- 4.16 Subject to the confidentiality provisions of Section 8, BIOPORT shall have the right, at its risk and expense, to have personnel on site (maximum of two people) observing operations during filling and other related activities.

#### 5.0 ORDERING AND SUPPLY OF FILLED PRODUCT

- 5.1 HOLLISTER-STIER agrees to meet all of BIOPORT's firm purchase orders for Filled Product, based on BIOPORT's forecasts for Filled Product as set forth in Section 5.2 of this Agreement.
- 5.2 BIOPORT and HOLLISTER-STIER shall cooperate in estimating and scheduling production of commercial orders.
  - 5.2.1 BIOPORT shall annually provide a Good Faith Annual Estimate of the timing and pace of its expected specific orders for Filled Product. The first such Good Faith Annual Estimate shall be given upon execution of this Agreement and shall cover orders during the remainder of the First Term Year, and subsequent Good Faith Annual Estimates shall be delivered to HOLLISTER-STIER on or before each November 1, with respect to the next following Term Year. The estimates in each Good Faith Annual Estimate shall be good faith forecasts to assist HOLLISTER-STIER in planning its production and shall be non-binding and without prejudice to BIOPORT's subsequent firm orders.
  - 5.2.2 Subject to Section 5.2.4, on or before the first day of each calendar month, BIOPORT shall provide a firm purchase order for the next following calendar month, thereby constituting a rolling monthly firm purchase order; provided, however, that during any Term Year in which BIOPORT is filling AVA itself (or is actively preparing to do so), or is obtaining or has contracted to obtain AVA filling services from any other source, BIOPORT shall, on or before the first day of each calendar month, provide a firm purchase order for the next three following calendar months, thereby constituting a rolling three-month firm purchase order.
  - 5.2.3 To the extent that BIOPORT requests that HOLLISTER-STIER fill more lots than are the subject of a firm purchase order, HOLLISTER-STIER shall accommodate such additional fill requests subject to its then-available production capacity.
  - 5.2.4 BIOPORT may, without charge or breach of this Agreement, cancel or delay any firm order for a Filled Lot or Filled Lots, provided that it gives HOLLISTER-STIER notice of such cancellation or delay prior to the acceptance of the Bulk Lot for such Filled Lot(s) by HOLLISTER-STIER in accordance with the incoming inspection requirements as set forth in the Filling Process Specifications. Where BIOPORT gives such notice of a delay, rescheduling of the delayed Filled Lot

shall be accommodated into HOLLISTER-STIER's schedule subject to its then-available production capacity. Following such arrival of the Bulk Lot for a Filled Lot covered by a firm order, BIOPORT may not cancel or delay such Filled Lot unless it pays HOLLISTER-STIER a fee (the "Order Change Fee") equal to [\*\*]% of the aggregate Lot Production Fee (determined under Article 6) for the Filled Lot(s) that are so cancelled or delayed by BIOPORT. The parties agree that the Order Change Fee is a reasonable fee (and not a penalty) to compensate HOLLISTER-STIER for disruptions in its personnel planning and facilities usage.

- 5.3 If BIOPORT believes that a Filled Lot as delivered to it by HOLLISTER-STIER does not conform to the Filling Process Specifications, BIOPORT shall promptly so notify HOLLISTER-STIER, specifying the grounds for BIOPORT's belief in as much detail as is available to BIOPORT. If HOLLISTER-STIER disagrees, the Parties shall use their best efforts to resolve such disputes amicably. If the parties are unable to resolve the dispute, the matter shall be referred for resolution to an independent laboratory or other recognized expert, agreed to by the parties, whose decision shall be final and binding. Any charges of such laboratory or expert shall be paid for by the party against whom the dispute is decided. If BIOPORT does not give HOLLISTER-STIER such a notice of non-conformity prior to the tenth (10th) business day following delivery of the COA for a given Filled Lot and the batch record for such Filled Lot, BIOPORT will be deemed to have accepted such Filled Lot.
- Where volumes of Bulk Product in excess of those anticipated under the Percentage Yields called for in the Filling Process Specifications do not meet the Filling Process Specifications or are made unusable or are otherwise destroyed in the course of the filling services for a Filled Lot, but the balance of such Filled Lot remains in conformity with this Agreement, BIOPORT shall AS ITS SOLE REMEDY THEREFOR, be entitled to a prorata price adjustment to reflect the shortfall (to the extent under such Percentage Yield) in the anticipated volume in such Filled Lot. As an example, if the Percentage Yield called for in the Filling Process Specifications for a Filled Lot is [\*\*]% and the actual Percentage Yield achieved for such Filled Lot is [\*\*]%, then the price for such Filled Lot (as otherwise determined under Article 6) would be reduced by [\*\*]% (representing [\*\*]% [\*\*]%).
- 5.5 If an entire Filled Lot is made unusable or is destroyed, either through the fault of HOLLISTER-STIER or otherwise because it does not meet the Filling Process Specifications, HOLLISTER-STIER shall promptly so inform BIOPORT or BIOPORT shall promptly so inform HOLLISTER-STIER, as the case may be, together with an explanation of the circumstances and HOLLISTER-STIER shall, AS BIOPORT'S SOLE REMEDY THEREFOR, (i) conduct the filling services for the replacement Bulk Lot without charge, including bearing the cost of vials, stoppers, seals and other costs associated with the filling and preparation for shipment of the Filled Product, provided that BIOPORT at its risk and expense (other than shipping costs) supplies the replacement Bulk Lot; (ii) conduct a non-conforming materials run without charge to BIOPORT, if reasonably so requested by BIOPORT; (iii) conduct, without charge to BIOPORT, appropriate additional training of personnel, development work and/or technical studies to address the causes underlying the failed fill as BIOPORT and HOLLISTER-STIER agree in good faith after consultation are called for under the circumstances; and (iv) pay for all destruction costs associated with the rejected material, including any shipment related expenses, any such destruction only to occur with BIOPORT's prior written consent.

#### 6.0 PRICE — PAYMENT

6.1 The initial price to be paid by BIOPORT for the filling services for each Filled Lot (the "Lot Production Fee") shall be [\*\*] dollars (\$[\*\*]); provided, however, that effective for Filled

Products shipped following the thirtieth day after the first and each subsequent anniversary of the Effective Date, the initial Lot Production Fee set forth above shall be increased to reflect increases (if any, but not decreases) since the Effective Date in the "Producer Price Index — Pharmaceutical Preparations" (code PCU2834) published by the US Bureau of Labor Statistics, or if the same is no longer published, the successor index published by the US BLS that is most similar thereto (the "Index").

- 6.2 All prices for Filled Product shall be on the basis of Filled Product being shipped F.O.B. HOLLISTER-STIER's plant in Spokane, Washington. Shipment of Filled Product shall be arranged by BIOPORT and the cost and liability of such shipment shall be borne by BIOPORT.
- 6.3 In addition to the prices for Filled Product specified under Section 6.1, and the matters described in Sections 4.3 and 4.10, certain additional costs specifically associated with HOLLISTER-STIER's performance and preparation for performance under this Agreement have been borne by BIOPORT and/or the U.S. Government under separate agreements, either as one-time costs or otherwise. Any future such additional costs shall be negotiated by the parties in good faith, and where appropriate BIOPORT shall assist HOLLISTER-STIER to obtain reimbursement therefor from the U.S. Government, either directly or through BIOPORT.
- 6.4 HOLLISTER-STIER will issue an invoice at such time as BIOPORT has accepted the Filled Lot pursuant to Section 5.3.
- 6.5 BIOPORT will be required to pay HOLLISTER-STIER for all Filled Product ordered during any period when Production and Testing Procedures have not been fully developed and validated, either initially or due to any agreed changes or modifications thereto.
- During periods when the cost for filling services is to be directly reimbursed by the Government to BIOPORT: (a) BIOPORT will include HOLLISTER-STIER's invoice amounts, with respect to Filled Product to be provided to the U.S. Government, in its invoice to the Government submitted on or before the 30th day of the month and shall pay HOLLISTER-STIER within ten (10) days of receiving payment from the Government; and (b) regardless of whether BIOPORT shall receive compensation from the Government, BIOPORT shall pay HOLLISTER-STIER a minimum of [\*\*]% of the invoiced amount within thirty (30) days of receipt of HOLLISTER-STIER's invoice and shall within 90 days of HOLLISTER-STIER's issuance of the invoice pay HOLLISTER-STIER the balance of the invoiced amounts if BIOPORT has not received payment from the Government due to any fault or deficiency in BIOPORT's performance, billing or documentation under its contract with the Government. During periods when the cost for filling services is to be included in the price of Filled Product to be provided by BIOPORT to the Government, and at all times with respect to Filled Product to be supplied to any BIOPORT customer other than the U.S. Government, BIOPORT shall pay HOLLISTER-STIER's invoices within thirty days of receipt of invoice.
- 6.7 The remittance address for payments to HOLLISTER-STIER hereunder is:

Hollister-Stier Laboratories LLC P.O. 201236 Dallas, Texas 75320-1236

AUDITS AND INSPECTIONS. HOLLISTER-STIER shall allow up to [\*\*] of BIOPORT's personnel (or its authorized representatives as approved for such purpose by HOLLISTER-STIER, which approval shall not be unreasonably withheld) access, during normal business hours up to two (2) times per Term Year (and not more than three days per time), to HOLLISTER-STIER's facilities for the purpose of conducting a quality

systems audit as such systems relate to the filling and packaging of the Filled Products. HOLLISTER-STIER's personnel shall provide such BIOPORT personnel or such approved authorized representatives with all necessary assistance, including access to documents and reports to the extent bearing on the filling services (including but not limited to validation documents), during such inspections. The failure to inspect shall not be deemed a waiver of any of BIOPORT's rights or of HOLLISTER-STIER's obligations under this Agreement.

- CONFIDENTIALITY. The parties acknowledge and agree that the terms and conditions of this Agreement shall remain confidential. The Parties acknowledge and agree that all Confidential Information of a Party shall be considered confidential and proprietary to such Party. Each Party agrees not to use any Confidential Information of the other Party for any purpose other than as permitted herein or required for the performance by such Party of its obligations hereunder. Each Party also agrees, during and following the term of this Agreement, not to disclose or provide any of the other Party's Confidential Information except to its personnel, contractors or consultants with a need to know the same for purposes of such Party's performance under this Agreement and to take reasonable precautions (at least as protective as those such Party takes to protect its own, and in no event less than reasonable precautions, to prevent the disclosure of the other Party's Confidential Information to any other third party or for any other purpose. Nothing herein shall prevent either Party from disclosing any Confidential Information of the other Party to the extent such disclosure is required by applicable law or regulation, or by order of any court or governmental body, provided that such Party gives the other Party such advance notice of the disclosure as may be practicable under the circumstances and assists with any reasonable attempts by such other Party to limit or to restrict such disclosure in accordance with applicable law.
- **9.0 AUTHORIZED CONTACTS.** The Parties will interact for purposes of this Agreement primarily through their designated primary contacts. HOLLISTER-STIER's primary contact for this Agreement is [\*\*], and BIOPORT's primary contact for this Agreement is [\*\*]. Either Party may change its primary contact from time to time by written notice from either the outgoing primary contact or from such Party's President.
- **TERM AND TERMINATION.** This Agreement will become effective as of the Effective Date and shall continue in effect until the end of the fifth Term Year (December 31, 2006), provided, however, that either party may terminate this Agreement in the event of a material breach by the other party of any one or more terms or obligations of this Agreement which is not remedied within ninety (90) days after receipt of written notice of the breach from the non-breaching party or, if such breach cannot reasonably be cured within such 90-day period, if the breaching party has failed to commence such cure within the 90-day period or to proceed diligently to prosecute such cure to completion within a reasonable time thereafter.
- 11.0 RELATIONSHIP OF PARTIES. With respect to the subject matter under this Agreement, the Parties are and remain independent contractors. This Agreement shall not be deemed to create a joint venture, partnership, association, or agency between the Parties. Neither Party hereunder is authorized to incur or create any obligation, express or implied, on behalf of the other Party or to bind the other Party in any manner whatsoever.
- 12.0 DISPUTES. All disputes arising under this Agreement that can not be settled amicably, shall be finally resolved by arbitration in Chicago, Illinois, before a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association then in effect, and any arbitral award thereon may be enforced by any court of competent jurisdiction. The prevailing Party in any arbitration shall be entitled to reimbursement from the other Party for the prevailing Party's attorneys fees and other costs and

expenses incurred in, and in preparation for, the arbitration and the enforcement of any judgment therefrom.

- 13.0 INSURANCE. BIOPORT and HOLLISTER-STIER each agree to maintain in force during the term of this Agreement product liability and other insurance coverage commensurate with industry standards and practices.
- 14.0 NO LIENS. HOLLISTER-STIER will not allow, directly or indirectly, create, incur, assume or permit to exist any lien or encumbrance of any kind on the Bulk Product or Filled Product.
- 15.0 NO SOLICITATION OF EMPLOYEES OR CUSTOMERS. Both Parties agree that, during the term of this Agreement, and for a period of twelve (12) consecutive months after termination of such Agreement, neither of the Parties will (a) directly induce or attempt to induce or otherwise counsel, advise, solicit or encourage any employee to leave the employ of the other Party or to accept employment with any other person or entity, (b) employ any person who, as of the time of such employment, had left the employ of the other Party within the previous six (6) months, and (c) actively solicit any customer, client, or business partner of the other Party to cease or reduce its relationship with that Party or induce or attempt to induce any such customer, client, or business partner may have with the other Party.

#### 16.0 INDEMNIFICATION.

- 16.1 Indemnification of BIOPORT. HOLLISTER-STIER shall indemnify, defend and hold BIOPORT and its directors, personnel, owners, and agents harmless from and against any and all damages, losses, obligations, deficiencies, liabilities, costs, expenses, penalties, claims and encumbrances, including without limitation, attorneys' fees and disbursements, resulting from or arising out of any third party claim or demand, including but not limited to a claim or demand for bodily injury or death, alleged to have arisen due to or in connection with any breach of warranty by HOLLISTER-STIER hereunder or otherwise due to or in connection with a manufacturing defect in any Filled Product manufactured by HOLLISTER-STIER otherwise than in accordance with the Filling Process Specifications.
- 16.2 Indemnification of HOLLISTER-STIER. BIOPORT agrees to indemnify, defend, and hold harmless HOLLISTER-STIER and its directors, personnel, owners, and agents from and against any and all damages, losses, obligations, deficiencies, liabilities, costs, expenses, penalties, claims and encumbrances, including, without limitation, attorneys' fees and disbursements, resulting from and arising out of any third party claim or demand, including but not limited to a claim or demand for bodily injury or death, alleged to have arisen due to or in connection with any breach of warranty by BIOPORT hereunder or otherwise due to or in connection with the production, use, sale, distribution, advertising and/or marketing of the Bulk Product or the Filled Product, except to the extent such claim or demand is the result of HOLLISTER-STIER's failure to manufacture Filled Product in accordance with the Filling Process Specifications.
- 16.3 Procedures. Subject to the requirements and procedures specified in FAR 52.250-1, where applicable, BIOPORT and HOLLISTER-STIER agree to give, and agree that their respective directors, personnel, owners, and agents shall give, to the Party that is obligated to indemnify pursuant to this Section 16: (a) prompt notice of any claim or suit coming within the scope of the indemnities in this Section, (b) all relevant facts in its possession or control, (c) the right to exclusively control the defense or settlement of any action unless the Party or person being indemnified reasonably determines that a conflict of interest exists with respect to such assumption of such control due to actual or

potential differing interests between the parties, and (d) its reasonable cooperation in the defense or settlement of any such action.

16.4 Limitation of Indemnification Liability. Neither party shall have any liability under this Section to the other or its directors, personnel, owners, and agents to the extent that damages, losses, obligations, deficiencies, liabilities, costs, expenses, penalties, claims and encumbrances result from the willful misconduct or gross negligence of the Party seeking indemnification (or whose directors, personnel, owners, and agents are seeking indemnification), or that of its officers directors, agents or employees.

# 17.0 LIMITATION OF LIABILITY.

Neither party shall be responsible to the other for payment of consequential, special or incidental damages. With the exception of a third party claim or demand for bodily injury or death alleged to have arisen due to or in connection with the manufacture of Filled Product by HOLLISTER-STIER otherwise than in accordance with the Filling Process Specifications, in no event shall HOLLISTER-STIER's liability under Section 16 hereof exceed the Lot Production Fee and the other costs as described in Section 5.4 hereof to be borne by HOLLISTER-STIER.

#### 18.0 FORCE MAJEURE.

If either Party's performance of its respective obligations hereunder is prevented or made unprofitable to it by fire, strike, lockouts, war, civil disturbances, acts of God, altered laws or regulations, or other similar or dissimilar events beyond the reasonable control of the Party, the Party will not be liable to the other Party for damages or for breach of this Agreement. The Party being able to perform may, at its sole option, either (a) terminate this Agreement if the other Party is or reasonably appears likely to be so prevented from performing for a period in excess of 120 days, (b) extend the term of this Agreement by a period equal in length to the period during which the other Party was unable to perform its obligations hereunder, or (c) waive such obligations.

# 19.0 SEVERABILITY

In the event that any one or more of the agreements, covenants, provisions or terms contained herein shall be declared invalid, illegal or unenforceable in any respect, the validity of the remaining agreements, covenants, provisions or terms contained herein shall in no way be affected, prejudiced or invalidated thereby.

# 20.0 PRIME CONTRACT FLOW DOWN

The following Federal Acquisition Regulations ("FAR") clauses are incorporated herein by reference:

The services being provided by HOLLISTER-STIER under this Filling and Packaging Agreement represent subcontracted work under U.S. Army Medical Research and Material Command contract DAMD17-98-C-8052. The following provisions in that contract are hereby incorporated by reference into this subcontract and made a part thereof except that where not inappropriate in the context of the clauses (e.g., it is agreed to be inappropriate to alter the meaning of "Government" or of "Contracting Officer" in clause 52.249-2, "Termination for Convenience of the Government" in this way, and clause 52.249-2 will only be applied to this Agreement if and to the extent that the Government exercises that clause to terminate BIOPORT's agreements with the Government, "Government" shall mean "BIOPORT", "Contracting Officer" shall mean "BIOPORT's representative", "Contractor" shall mean HOLLISTER-STIER, and other terms shall be appropriately revised to reflect that this is a subcontract:

# Federal Acquisition Regulation Clauses:

52.202-3	Gratuities (Apr 1984)
52.203-1	Officials Not To Benefit (Apr 1984)
52.203-5	Covenant Against Contingent Fees (Apr 1984)
52.203-6	Restrictions on Subcontractor Sales to the Government (Jul 1995)
52.203-7	Anti-Kickback Procedures (Jul 1995)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Jan 1997)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (Jun 1997)
52.211-15	Defense Priority and Allocation Requirements (Sep 1990)
52.215-2	Audit and Records — Negotiation (Aug 1996)
52.215-13	Subcontractor Cost or Pricing Data-Modifications (Oct 1997)
52.215-15	Termination of Defined Benefit Pension Plans (Oct 1997)
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions (Oct 1997)
52.215-19	Notification of Ownership Changes (Oct 1997)
52.219-8	Utilization of Small Business Concerns and Small Disadvantaged Business Concerns (Feb 1990)
52.222-3	Convict Labor (Aug 1996)
52.222-4	Contract Work Hours and Safety Standards Act — Overtime Compensation (Mar 1986)
52.222-20	Walsh-Healey Public Contracts Act (Dec 1996)
52.222-26	Equal Opportunity (Apr 1984)
52.222-35	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (Apr 1998)
52.222-36	Affirmative Action for Workers with Disabilities (Jun 1998)
52.222-37	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era (Apr 1998)
52.223-2	Clean Air and Water (Apr 1984)
52.223-6	Drug-Free Workplace (Jan 1997)
52.223-14	Toxic Chemical Release Reporting (Oct 1996)
52.225-10	Duty-Free Entry (Apr 1984)
52.225-11	Restrictions on Certain Foreign Purchases (Aug 1998)
52.226-2	Notice and Assistance Regarding Patent and Copyright Infringement (Aug 1996)

52.227-1	Authorization and Consent (Jul 1995)
52.242-12	Report of Shipment (REPSHIP) (Jul 1995)
52.243-1	Changes — Fixed-Price (Aug 1987)
52.249-2	Termination for Convenience of the Government (Fixed-Price) (Sep 1996)
52.249-8	Default (Fixed-Price Supply and Service) (Apr 1984)
52.249-14	Excusable Delays (Apr 1984)
52.250-1	Indemnification under Public Law 85-804 (4/84)

Copies of these clauses are available in applicable Government publications. Some clauses are no longer set forth in the current FAR and must be obtained from prior versions of the FAR.

# 21.0 CONDITION PRECEDENT TO AGREEMENT.

Except for the last sentence of this Section 21, this Agreement shall not be effective until the Contracting Officer under the contract DAMD98-C-8052 between BIOPORT and the U.S. Government ("8052") shall consent in writing to this Agreement as a subcontract to 8052 and shall approve pass-through indemnification to HOLLISTER-STIER under FAR clause 52.250-1 and that certain Memorandum of Decision of the Secretary of the Army dated November 15, 2000 ("Authority under Public Law (PL) 85-804 to include an Indemnification Clause in ... Contract No. DAMD17-98-C-8052 with BioPort Corporation (BioPort)," herein the "MOD"). The MOD is hereby incorporated into this Agreement by this reference. BIOPORT shall exert its continuing commercially reasonable best efforts to promptly secure such consent.

#### 22.0 DEPARTMENT OF DEFENSE CONTRACTS.

The following contract clauses are incorporated by reference from the Department of Defense (DOD) Federal Acquisition Regulations (DFARS) and apply with the same force and effect if given in full text to contracts placed by BIOPORT in connection with DOD contracts. In addition, all DFARS clauses required by the U.S. Government by statute, regulation or otherwise to be flowed down are hereby incorporated into this Agreement by this reference. In all the following clauses, "Contractor" and "Offeror" mean HOLLISTER-STIER and "Government" and "Contracting Officer" mean BIOPORT and/or Government. Unless otherwise provided, the clauses are those in effect as of the date of this Contract.

Defense Federal Acquisition Regulation Clauses:

252.203-7000	Statutory Prohibition on Compensation to Former Department of Defense Employees (Dec 1991)
252.203-7001	Special Prohibition on Employment (Jun 1997)
252.203-7002	Display of DOD Hotline Poster (Dec 1991)
252.204-7000	Disclosure of Information (Dec 1991)
252.223-7004	Drug-Free Work Force (Sep 1988)
252.231-7000	Supplemental Cost Principles (Dec 1991)
252.243-7001	Pricing of Contract Modifications (Dec 1991)

Copies of these clauses are available in applicable Government publications. Some clauses are no longer set forth in the current DFAR and must be obtained from prior versions of the DFAR

# 23.0 NOTICES.

Subject to Section 6.7, all notices permitted or required by this Agreement or other communications to either Party by the other shall be in writing and shall be deemed given (a) upon personal delivery or (b) three (3) days after being deposited in the United States mail (first class, postage prepaid) or (c) the day after being given to a reputable carrier for overnight shipment, addressed as follows:

To HOLLISTER-STIER: Hollister-Stier Laboratories LLC

P.O. Box 3145

Spokane, Washington, 99220-3145 Attn: Anthony Bonanzino, President

To BIOPORT: BioPort Corporation

3500 North Martin Luther King Blvd.

Lansing, MI 48906

Attn: Robert G. Kramer, President

# 24.0 ENTIRE AGREEMENT.

This Agreement contains the entire agreement between the Parties with respect to the subject matter hereof and supersedes any prior agreements between them with respect to that subject matter, including without limitation the Filling and Packaging Services Agreement dated December 21, 2000.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed effectively as of the date first written above in two copies, each of which is deemed to be an original.

BIO	PORT CORPORATION		LLISTER-STIER BORATORIES LLC
Ву	/s/ Robert G. Kramer	Ву	/s/ Anthony Bonanzino
Its:	President	Its:	President
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#### AMENDMENT NO. 1 TO FILLING SERVICES AGREEMENT

This Amendment No. 1 to the Filling Services Agreement dated March 18, 2002, by and between Hollister-Stier Laboratories LLC, a Delaware limited liability company ("Hollister-Stier"), and BioPort Corporation, a Michigan corporation ("BioPort"), is made effective this 18th day of April 2003.

#### RECITALS

Hollister-Stier and BioPort deem it desirable and to be in the best interests of the parties to amend the Agreement as hereinafter described and, therefore, the parties agree as follows:

#### A. Amendment

Pursuant to Section 6.0 Price — Payment Paragraph 6.1 the price to be paid by BioPort for the filling services for each Filled Lot (the "Lot Production Fee") shall be [\*\*] dollars (\$[\*\*]) as of the effective date of this Amendment.

BIOPORT CORPORATION

# B. Remaining Agreement

Except as set forth in Section A. hereof, all other terms, provisions and conditions of the Agreement remain in full force and effect as of the date hereof.

In WITNESS WHEREOF, the parties have executed this Amendment No. 1 as of the date hereinabove stated, to be effective as of the date hereinabove stated.

# HOLLISTER-STIER LABORATORIES LLC

By: <u>/s/ Anthony D. Bonanzino</u> By: <u>/s/ Robert G. Kramer</u>

Name: Anthony D. Bonanzino, Ph. D.

Name: Robert G. Kramer

Title: President and CEO

Title: President & COO

Date: March 13, 2003 Date: June 4, 2003

#### AMENDMENT NO. 2 TO FILLING SERVICES AGREEMENT

This Amendment No. 2 to the Filling Services Agreement dated March 18, 2002, by and between Hollister-Stier Laboratories LLC, a Delaware limited liability company ("Hollister-Stier"), and BioPort Corporation, a Michigan corporation ("BioPort"), is made effective this 1st day of June 2004.

#### RECITALS

Hollister-Stier and BioPort deem it desirable and to be in the best interests of the parties to amend the Agreement as hereinafter described and, therefore, the parties agree as follows:

#### A. <u>Amendment</u>

Pursuant to Section 6.0 Price — Payment Paragraph 6.1 the price to be paid by BioPort for the filling services for each Filled Lot (the "Lot Production Fee") shall be [\*\*] dollars (\$[\*\*]) as of the effective date of this Amendment. This pricing adjustment is based off the successor PPI index series PCU3254 for Pharmaceutical Preparations Mfg. The new price is calculated by the net change in the index between the Preliminary index for March of 2004 (355.1) and the base year index of March 2002 (323.7). The net effective increase in successive years will be calculated in this same manner, using the preliminary March index net increase over the base year index of March 2002.

#### B. <u>Remaining Agreement</u>

Except as set forth in Section A. hereof, all other terms, provisions and conditions of the Agreement remain in full force and effect as of the date hereof.

In WITNESS WHEREOF, the parties have executed this Amendment No. 2 as of the date hereinabove stated, to be effective as of the date hereinabove stated.

# HOLLISTER-STIER LABORATORIES LLC

By: /s/ Anthony D. Bonanzino

Name: Anthony D. Bonanzino, Ph. D.

Title: President and CEO

Date: 05/17/2004

# BIOPORT CORPORATION

By: /s/ Robert G. Kramer

Name: Robert G. Kramer

Title: President

Date: 5/24/04

#### AMENDMENT No. 3 TO FILLING SERVICES AGREEMENT

This Amendment No. 3 to the Filling Services Agreement dated March 18, 2002, is made and entered into this 1st day of September, 2004, by and between BIOPORT CORPORATION, a Michigan corporation, having its principal place of business at 3500 North Martin Luther King Jr. Blvd., Lansing, Michigan 48906 ("BIOPORT"), and HOLLISTER-STIER LABORATORIES, LLC, a Delaware limited liability company, having its principal place of business at 3525 North Regal Street, Spokane, Washington 99207 ("HOLLISTER-STIER").

WHEREAS, BIOPORT and HOLLISTER-STIER entered into a Filling Services Agreement dated March 18, 2002 (the "Agreement"), as modified by Amendments dated April 18, 2003 and June 1, 2004; and

WHEREAS, pursuant to Modification P00065 to Contract DAMD17-91-C1139, the Department of Defense reimbursed BIOPORT for the cost of security at HOLLISTER-STIER in the amount of [\*\*] Dollars (\$[\*\*]), which amount BIOPORT in turn paid to HOLLISTER STIER, to cover security for the period of October 2003 through December 2003; and

WHEREAS, the Department of Defense has since agreed to reimburse BIOPORT for that portion of HOLLISTER-STIER's security costs that are both related to the security of Bulk Product and Filled Product, as those terms, are defined in the Filling Services Agreement, and only to the extent the Bulk Product and Filled Product are allocated to a contract between BIOPORT and the Department of Defense; and

WHEREAS, the Department of Defense has agreed to reimburse BIOPORT in the amount of [\*\*] Dollars (\$[\*\*]) per month for security for the period of July 2004 through December 2004. NOW, THEREFORE, BIOPORT and HOLLISTER-STIER agree as follows:

- 1. **<u>Definitions</u>**. The following definitions apply to this Amendment:
- "Monthly Security Costs" shall mean the portion of HOLLISTER-STIER's security costs each month that is associated with the services provided by HOLLISTER-STIER pursuant to the Filling Services Agreement.
- "Product Security Guard" shall mean the security guard provided by HOLLISTER-STIER to provide dedicated security directly in conjunction with the services provided by HOLLISTER-STIER pursuant to the Filling Services Agreement.
- "Timesharing Patrol" shall mean the use of security guards, other than Product Security Guards, to temporarily substitute for the Product Security Guard for short term breaks.
- 2. HOLLISTER-STIER agrees to employ adequate security for the Bulk Product and Filled Product, as those terms are defined in the Filling Services Agreement, during all times in which such Bulk Product and/or Filled Product are in the possession and/or control of HOLLISTER-STIER. Such security shall consist of a Product Security Guard, with additional

Timesharing Patrols to cover officer breaks.

BIOPORT CORPORATION

- 3. HOLLISTER-STIER agrees that any personnel providing such security services, either as Product Security Guard or Timesharing Patrol, shall be fully qualified to provide such services.
- 4. BIOPORT agrees to reimburse HOLLISTER-STIER for the Monthly Security Costs. Both Parties agree that, for the level of services now anticipated under the Filling Services Agreement, the Monthly Security Costs shall amount to [\*\*] Dollars (\$[\*\*]) per month for the time period of July 2004 through December 2004. This agreement creates no obligation for BIOPORT to pay for security services after 12/31/04. Any compensation for security services after 12/31/04 is subject to future agreement.
- 5. If HOLLISTER-STIER experiences or anticipates an increase in the Monthly Security Costs, it shall give such adequate advance written notice to allow BIOPORT to request an increase in reimbursement from the Department of Defense as necessary.
- 6. If, during the period of July 2004 through December 2004, BIOPORT determines that such security services are no longer required, or that it requires a reduction in such services, BIOPORT shall give HOLLISTER-STIER thirty (30) days written notice pursuant to pursuant to Paragraph 23.0 of the Filling Services Agreement, and BIOPORT shall not be required to reimburse HOLLISTER-STIER for any security services provided in excess of the services described in such written notice.

HOLLISTER-STIER

7. All other provisions of the Agreement, including all Exhibits or Addendums thereto, remain in full force and effect, and this Amendment is subject to the terms thereof.

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their duly authorized representatives as of the date and year first above written.

ABORATORIES, LLC
By: /s/ [Illegible] 9-4-04
Title: V.P. — ENG/VAL./PD.

#### AMENDMENT TO FILLING SERVICES AGREEMENT

This Amendment is made and entered into this 10th day of February, 2003, by and between BIOPORT CORPORATION, a Michigan corporation, having its principal place of business at 3500 North Martin Luther King Jr. Blvd., Lansing, Michigan 48906 ("BIOPORT"), and HOLLISTER-STIER LABORATORIES, LLC, a Delaware limited liability company, having its principal place of business at 3525 North Regal Street, Spokane, Washington 99207 ("HOLLISTER-STIER").

WHEREAS, BIOPORT and HOLLISTER-STIER entered into a Filling Services Agreement dated March 18, 2002 (the "Agreement"); and

WHEREAS, pursuant to Section 21.0 of the Agreement, the Agreement did not become effective until such date that the Contracting Officer under Contract DAMD17-98-C-8052 ("Contract 8052") between BIOPORT and the U.S. Government (the "Contracting Officer") would consent in writing to the Agreement as a subcontract to Contract 8052 and approve pass-through indemnification to HOLLISTER-STIER under FAR Clause 52.250-1 and the Memorandum of Decision of the Secretary of the Army dated November 15, 2000; and

WHEREAS, the Contracting Officer provided such consent and approved such pass-through indemnification to HOLLISTER-STIER by virtue of executing Modification P00036 to Contract 8052 on December 27, 2002, a copy of which is attached hereto; and

WHEREAS, BIOPORT and HOLLISTER-STIER now desire to acknowledge the Contracting Officer's actions as described above and desire to amend the Agreement.

NOW, THEREFORE, BIOPORT and HOLLISTER-STIER agree as follows:

- 1. Pursuant to the provisions of Section 21.0 of the Agreement, the effective date of the Agreement shall be December 27, 2002.
- 2. FAR Clause 52.250-1 and the Modification P00036 to Contract 8052, each of which are attached to this Amendment, are hereby incorporated by reference into the Agreement.
- 3. Section 16.2 of the Agreement (entitled "Indemnification of HOLLISTER-STIER") is amended by inserting the following clause in front of the first sentence: "Except to the extent Hollister-Stier is indemnified from and against liabilities by the United States Government as a result of pass-through indemnification pursuant to FAR Clause 52.250-1,".
- 4. All other provisions of the Agreement, including all Exhibits or Addendums thereto, remain in full force and effect, and this Amendment is subject to the terms thereof.

[signatures on following page]

IN WITNESS WHEREOF, the parties have caused this Amendme	ent to be executed by their duty authorized representatives as of the date and year first above written.	
BIOPORT CORPORATION	HOLLISTER-STIER LABORATORIES, LLC	
By: /s/ Robert G. Kramer Title: President	By: /s/ [Illegible] Title: Vice President	

2. AMENDMENT/MODIFICATION NO. Poecenber 27, 2002 4. REQUISITION/PURCHASE REQ. NO. N/A N/A  6. ISSUED BY CODE DASG60 7. ADMINISTERED BY (If other than Item 8) S2303A  CODE U.S. Army Space and Missile Defense Command Attn: SMDC -CM-CH (L. Selfridge) 64 Thomas Johnson Drive, 3nd Floor Frederick, MD 21702  8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and Zip Code) () 9A. AMENDMENT OF SOLICITATION NO.  BIOPORT CORPORATION 3500 N. MARTIN LUTHER KING, JR. BLVD.  LANSING, MI 48906  CODE 025489018 FACILITY CODE September 17, 1998  11. THIS TIEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS  The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for recipit of Offers   1 is extended   1 is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted, or (c) by separate letter or telegram which includes a reference to the solicitation and mandment numbers.  FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECITED MAY RESULT IN REJECTION OF YOUR OFFER. If Ity virtue of this amendment, and its received prior to the opening hour and date specified.  12. ACCOUNTING AND APPROPRIATION DATA (If required) N/A  13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.  A. HIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.	AMENDMENT OF SOLICITATION/MO	DDIFICATION OF CONTRACT			J. CONTRACT ID CO	DE	PAGE 1	OF	PAGES 2
CODE   DASG0	2 AMENDMENT/MODIFICATION NO	Docombox 27	4 DEOLIIS	TTION/DITE	CHASE BEO, NO.	S DD	-	6f an	
6. ISSUED BY CODE DASG60 C. T. ADMINISTERED BY (If other than Item 8) CODE DASG60 CODE DASG60 C. T. ADMINISTERED BY (If other than Item 8) CODE DCMC Detroit-Grand Rapids Attn: SMDC -CM-CH (L. Selfridge) 64 Thomas Johnson Drive, 3-s Floor Frederick, MD 21702 8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and Zip Code) BIOPORT CORPORATION 3500 N. MARTIN LUTHER KING, JR. BLVD. LANSING, MI 48906  DAMDIT-98-C-8052 100. DATED (See Item 11) September 17, 1998 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS The above numbered solicitation is amended as set forth in Item 14. The hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing liems 8 and 15, and returning. Copies of the amendment; by sectioned for the submitted; or (c) by separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE NPECIFIED MAY RESULT. IN REJECTION OF YOUR OFFER. If by virtue of this amendment, and is received prior to the opening hour and date specified.  13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.  A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.			4. KEQUIS			I	COJECT NO.	(i) ap	расионе)
U.S. Army Space and Missile Defense Command Attn: SMDC - CM-CH (L. Selfridge) 64 Thomas Johnson Drive, 34 Floor Frederick, MD 21702  8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and Zip Code)  10			7. ADMINISTERED BY (If other than Item 8) S2303/				S2303A		
Attn: SMDC - CM-CH (L. Selfridge) 64 Thomas Johnson Drive, 3rd Floor Frederick, MD 21702  8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and Zip Code)  8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and Zip Code)  8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and Zip Code)  98. DATED (See Item 11)  98. DATED (See Item 11)  100. MODIFICATION OF CONTRACT/ORDER NO.  A DAMD17-98-C-8052  101. THIS TIEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS  The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  1 is extended [1 is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returningcopies of the amendment and date specified in the solicitation or acknowledging receipt of this amendment prior to the hour and date specified in the solicitation and amendment numbers.  FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.  12. ACCOUNTING AND APPROPRIATION DATA (If required)  N/A  13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS,  15 MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.  A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				h	n! I-				
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B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43,103(b).						S (such	as changes i	s payi	ng office
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:	C. THIS SUPPLEMENTAL AGRE	EMENT IS ENTERED INTO PURS	SUANT TO AU	THORITY	OF:				
D. OTHER Specify type of modification and authority)  X Public Law 85-804 and Memorandum of Decision dated November 15, 2000 signed by the SECARMY									
E. IMPORTANT: Contractor [X] is not, [] is required to sign this document and returncopies to the issuing office.									
,	(12)	,							
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)	14. DESCRIPTION OF AMENDMENT/MO								
See Attached.									
Except as provided herein, all terms and conditions of the document referenced in Items 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.		ditions of the document referenced	in Items 9A or 1	l0A, as here	tofore changed, remains t	inchang	ged and in ful	l force	e and
15A. NAME AND TITLE OF SIGNER (Type or print)  16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)  Lynn M. Selfridge				F CONTRACTING OFF	ICER (	Type or print,	1		
Contracting Officer			Contracting	Officer					
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BY /s/ Lynn M. Selfridge. Dec 27, 2002		В				Ε	Dec 27, 2002		
(Signature of person authorized to sign) (Signature of Contracting Officer)				e of Contrac	ting Officer)	4000 A T	m i nn no		HAT 10 00:
NSN 7540-01-152-8070         30-105         STANDARD FORM 30 (REV. 10-83)           PREVIOUS EDITION UNUSABLE         Prescribed by GSA			30-105					.30 (R	EV. 10-83)

A. Pursuant to the authority granted by the Secretary of the Army to the Contracting Officer to include indemnification clauses in certain first-tier subcontracts awarded by the BioPort Corporation under contract DAMD17-98-C-8052, the following contract revisions is effected:

Hollister-Stier Laboratories LLC, as a first-tier subcontractor to the BioPort Corporation shall have FAR 52.250-1 incorporated into the subcontract. The Memorandum of Decision dated November 15, 2000 containing the definition of "Unusually Hazardous Risk" pertinent, in part, to the subcontract is delineated below and is added to Section J of the Contract.

Adverse Reaction (or alleged adverse reaction) in a human form from administration of a vaccine or other material used in the production or testing of the vaccine, in conjunction with or as a result of the performance of the Subcontract, or administration of a vaccine produced, tested, or delivered under the Prime Contract.

The term "adverse reaction" (or "alleged adverse reaction") includes anaphylaxis and other foreseeable and unforeseeable adverse reactions. Such adverse reactions include, but are not limited to: (1) reactions directly attributable to and resulting from the administration of the vaccine, or other material involved with the vaccine, production or testing (to include challenge materials); (2) reactions that manifest long after exposure, but which are directly attributable and resulting from the administration of the vaccine or other material involved with the production or testing of the vaccine; (3) failure of the vaccine to perform as intended or otherwise confer immunity; or (4) performance by the vaccine in a manner not intended.

Notwithstanding any other provision in the indemnification clause or the Memorandum of Decision, Hollister-Stier shall not be indemnified against grossly negligent or criminal behavior on the part of Hollister-Stier's directors, officers or managers who have supervision over or direction of, all or substantially all of the operations at any one plant or separate locations where the subcontract is being performed.

B. This modification is executed without cost to either party and is without effect to any other contract terms or conditions.

Modification P00036 to Contract DAMD17-98-C-8052 Page 2 of 2

#### 52.250 — Extraordinary Contractual Actions Provisions and Clauses.

#### 52.250-1 — Indemnification Under Public Law 85-804.

# Indemnification Under Public Law 85-804 (Apr 1984)

- (a) "Contractor's principal officials," as used in this clause, means directors, officers, managers, superintendents, or other representatives supervising or directing
  - (1) All or substantially all of the Contractor's business;
  - (2) All or substantially all of the Contractor's operations at any one plant or separate location in which this contrast is being performed; or
  - (3) A separate and complete major industrial operation in connection with the performance of this contract.
- (b) Under Public Law 85-804 (50 U.S.C. 1431-1435) and Executive Order 10789, as amended, regardless of any other provisions of this contract, the Government shall, subject to the limitations contained in the other paragraphs of this clause, indemnify the Contractor against
  - (1) Claims (including reasonable expenses of litigation or settlement) by third persons (including employees of the Contractor) for death; personal injury; or loss of, damage to, or loss of use of property;
  - (2) Loss of, damage to, or loss of use of Contactor property, excluding loss of profit; and
  - (3) Loss of, damage to, or loss of use of Government property, excluding loss of profit.
- (c) This indemnification applies only to the extent that the claim, loss, or damage
  - (1) arises out of or results from a risk defined in this contract as unusually hazardous or nuclear and
  - (2) is not compensated for by insurance or otherwise. Any such claim, loss, or damage, to the extent that it is within the deductible amounts of the Contractor's insurance, is not covered under this clause. If insurance coverage or other financial protection in effect on the date the approving official authorizes use of this clause is reduced, the Government's liability under this clause shall not increase as a result.
- (d) When the claim, loss, or damage is caused by willful misconduct or lack of good faith on the part of any of the Contractor's principal officials, the Contractor shall not be indemnified for
  - (1) Government claims against the Contractor (other than those arising through subrogation); or
  - (2) Loss or damage affecting the Contractor's property.
- (e) With the Contracting Officer's prior written approval, the Contractor may, in any subcontract under this contract, indemnify the subcontractor against any risk defined in this contract as unusually hazardous or nuclear. This indemnification shall provide, between the Contractor and the subcontractor, the same rights and duties, and the same provisions for notice, furnishing of evidence or proof, and Government settlement or defense of claims as this clause provides. The Contracting Officer may also approve indemnification of subcontractors at any lower tier, under the same terms and conditions. The Government shall indemnify the Contractor against liability to subcontractors incurred under subcontract provisions approved by the Contracting Officer.
- (f) The rights and obligations of the parties under this clause shall survive this contract's termination, expiration, or completion. The Government shall make no payment under this clause unless the agency head determines that the amount is just and reasonable. The Government may pay the Contractor or subcontractors, or may directly pay parties to whom the Contractor or subcontractors may be liable.
- (g) The Contractor shall
  - (1) Promptly notify the Contracting Officer of any claim or action against, or any loss by, the Contractor or any subcontractors that may be reasonably be expected to involve indemnification under this clause:
  - (2) Immediately furnish to the Government copies of all pertinent papers the Contractor receives;
  - (3) Furnish evidence or proof of any claim, loss, or damage covered by this clause in the manner and form the Government requires; and
  - (4) Comply with the Government's directions and execute any authorizations required in connection with settlement or defense of claims or actions.
- (h) The Government may direct, control, or assist in settling or defending any claim or action that may involve indemnification under this clause.

(End of Clause)

#### Amendment No. 4 To Filling Services Agreement

This Amendment No. 4 to the Filling Services Agreement dated March 18, 2002 is made and entered into this 17th day of May, 2006, by and between BioPort Corporation, a Michigan corporation, having its principal place of business at 3500 North Martin Luther King Jr. Blvd., Lansing, Michigan 48906 (BioPort), and Hollister-Stier Laboratories LLC, a Delaware limited liability corporation, having its principal place of business at 3525 North Regal Street, Spokane, Washington 99207 (Hollister-Stier).

# RECITALS

Hollister-Stier and BioPort deem it desirable and to be in the best interests of the parties to amend the Agreement as hereinafter described and, therefore, the parties agree as follows:

# A. Amendment

Pursuant to Section 10.0 Term and Termination — It is the desire of BioPort and Hollister-Stier to extend the term of this agreement from December 31, 2006 to December 31, 2007.

#### B. Remaining Agreement

Except as set forth in Section A. hereof, all other terms, provisions and conditions of the Agreement remain in full force and effect as of the date hereof.

In WITNESS WHEREOF, the parties have executed this Amendment No. 4 as of the date hereinabove stated, to be effective as of the date hereinabove stated.

Hollister-Stier L	ABORATORIES LLC	BioPort Corporation
Ву:	/s/ A. Bonanzino	By: /s/ Robert G. Kramer
Name:	/s/ A. Bonanzino	Name: Robert G. Kramer
Title:	President, CEO	Title: President & CEO
Date:	05/19/2006	Date: May 23, 2006

Confidential Materials omitted and filed separately with the Securites and Exchange Commission. Asterisks denote omissions.

#### BT VACCINE LICENSE AGREEMENT

THIS BT VACCINE LICENSE AGREEMENT (this "Agreement"), effective as of November 23, 2004, (the "Effective Date"), by and between Emergent BioSolutions, Inc., a corporation organized and existing under the laws of the State of Delaware ("Emergent"), and the Health Protection Agency, a governmental agency organized and existing under the laws of England ("HPA") (each of Emergent and HPA, a "Party").

#### WITNESSETH:

WHEREAS, Emergent, which is the parent company of BioPort Corporation, desires to develop and commercialize one or more pharmaceutical products comprising toxoid components, which products are designed for the prevention or treatment of illness caused by *C. botulinum* toxin;

WHEREAS, HPA is the owner or licensee of certain information and inventions necessary or useful for the commercialization of such pharmaceutical products;

WHEREAS, Emergent desires to receive from HPA, and HPA desires to grant to Emergent, licenses in and to such information and inventions owned or controlled by HPA, all on the terms and conditions set forth herein;

WHEREAS, HPA desires to reserve the right to make and sell such pharmaceutical products within certain limitations, as set forth herein;

WHEREAS, Emergent is the owner or licensee of certain information and inventions necessary or useful for the commercialization of such pharmaceutical products;

WHEREAS, HPA desires to receive from Emergent, and Emergent desires to grant to HPA, licenses in and to such information and inventions owned or controlled by Emergent, all on the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

#### ARTICLE I Definitions

Unless specifically set forth to the contrary herein, the following terms shall have the respective meanings set forth below:

1.1 "AAA Rules" shall have the meaning set forth in Section 11.7.2.

1.2 "Act" shall have the meaning set forth in Section 11.9.

- 1.3 "Affiliate" shall mean, (a) with respect to Emergent, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with Emergent, and (b) with respect to HPA, any Person that, directly or indirectly, through one or more intermediaries, is controlled by HPA. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, by application of applicable law, or otherwise, or (b) the ownership indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity); provided that, if local law restricts foreign ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests.
  - 1.4 "After-Acquired HPA Know-How" shall have the meaning set forth in Section 1.36.
  - 1.5 "Agreement" shall have the meaning set forth in the preamble hereto.
- 1.6 "Applicable Law" shall mean all laws, rules, regulations applicable to the Exploitation of the Licensed Products, including any such rules, regulations, guidelines, or other requirements of the Regulatory Authorities, that may be in effect from time to time in the Territory.
- 1.7 "BT Development Agreement" shall mean that certain BT Vaccine Development Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
  - 1.8 "BT Licensed Technology" shall mean, collectively, the BT Licensed Patents and the BT Licensed Know-How.
  - 1.9 "BT Licensed Know-How" shall mean, collectively, the HPA Know-How and Joint Know-How.
  - 1.10 "BT Licensed Patents" shall mean, collectively, the HPA Patents and the Joint Patents.
  - 1.11 "Business Day" shall mean any day other than a Saturday, Sunday, any public holiday and any bank holiday in either the United States or England.
  - 1.12 "Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
  - 1.13 "Calendar Year" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

- 1.14 "Clinical Trials" shall mean, with respect to a Licensed Product, all tests and studies in patients that are required by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise, for Regulatory Approval of such product.
- 1.15 "Combination Product" shall mean any form or dosage of pharmaceutical composition or preparation for use in humans which contains, in co-formulated combination with a Licensed Product, therapeutic or antigenic levels of one or more other active ingredients (i) that do not comprise toxoids that act to stimulate an immune response and are designed or intended for use in the Field and (ii) the Manufacture of which does not use, and which active ingredients do not incorporate, any BT Licensed Technology. A Combination Product shall be deemed to be a Licensed Product
- 1.16 "Commercially Reasonable Efforts" shall mean, with respect to the development, Manufacture or commercialization of a Licensed Product, the level of efforts and resources customarily applied in the research-based pharmaceutical industry to a product of similar commercial potential at a similar stage in its lifecycle, taking into consideration its safety and efficacy, its cost to develop, the competitiveness of alternative products, its proprietary position, the likelihood of regulatory approval, its profitability, and all other relevant factors. Commercially Reasonable Efforts shall be determined on a country-by-country basis for each Licensed Product.
  - 1.17 "Confidential Information" shall have the meaning set forth in Section 4.3.1.
- 1.18 "Control" shall mean, with respect to any item of Information and Invention, Patent, Trademark or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such Information and Invention, Patent, Trademark or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.
  - 1.19 "Dispute" shall have the meaning set forth in Section 11.7.1.
- 1.20 "Distribution Agreement" shall mean that certain Exclusive Distribution Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
  - 1.21 "Drug Master File" shall have the meaning set forth in the BT Development Agreement.
  - 1.22 "Effective Date" shall mean the date of this Agreement as set forth in the preamble hereto.
  - 1.23 "Emergent" shall have the meaning set forth in the preamble hereto.
  - 1.24 "Emergent Beneficiaries" shall have the meaning set forth in Section 11.9.
  - 1.25 "Emergent Information" shall have the meaning set forth in Section 4.1.2.

- 1.26 "Europe" shall mean the European Union, as it may be constituted from time to time
- 1.27 "Exploit" shall mean to make, have made, import, use, sell, or offer for sale, including to research, develop, register, modify, enhance, improve, Manufacture, have Manufactured, store, formulate, have used, export, transport, distribute, promote, market or have sold or otherwise dispose of.
- 1.28 "Exploitation" shall mean the making, having made, importation, use, sale, offering for sale or disposition of a product or process, including the research, development, registration, modification, enhancement, improvement, Manufacture, storage, formulation, optimization, import, export, transport, distribution, promotion or marketing of a product or process.
  - 1.29 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.
  - 1.30 "FFDCA" shall mean the United States Federal Food Drug and Cosmetic Act, as amended from time to time.
  - 1.31 "Field" shall mean the prevention or treatment of illness in humans caused by C. botulinum toxin.
- 1.32 "First Sale" shall mean, with respect to any Licensed Product, the first commercial sale of such Licensed Product in a country where use of such Licensed Product is authorized by the relevant Regulatory Authorities (even though Regulatory Approval for such Licensed Product may not have been granted in such country). Any sale of a Licensed Product to a governmental entity for stockpiling or other health-related purposes shall qualify, for purposes of this definition, as such a commercial sale.
  - 1.33 "FTE Rate" shall have the meaning set forth in the BT Development Agreement.
  - 1.34 "GAAP" shall mean United States generally accepted accounting principles, consistently applied.
  - 1.35 "HPA" shall have the meaning set forth in the preamble hereto.
- 1.36 "HPA Know-How" shall mean all Information and Inventions, to the extent not generally known, (a) that are listed on Schedule 1.36 to this Agreement, (b) that are developed by or on behalf of, or come into the possession or under the Control of, HPA or its Affiliates after the Effective Date during the term of this Agreement and are reasonably necessary for the research, development, manufacturing, use or sale of Licensed Products or any Improvements to the Licensed Products (the "After-Acquired HPA Know-How"), or (c) that are Improvements to any item in (a) or (b) above, but excluding in each case (x) any Information and Inventions to the extent claimed or covered by the HPA Patents or Joint Patents, and (y) any Joint Know-How. For the avoidance of doubt, HPA Know-How shall include all such (i) biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, manufacturing and quality control data and information related to the Licensed Products, and (ii)

assays and biological methodology necessary or useful for the Exploitation of the Licensed Products.

- 1.37 "HPA Patents" shall mean all of the Patents that HPA and its Affiliates own, have under license, have a right to acquire (by option or otherwise) or otherwise Control, as of the Effective Date and at any time during the term of this Agreement, that (a) are reasonably necessary for the research, development, manufacturing, use or sale of the Licensed Products or any Improvements thereto, (b) claim or cover any Licensed Products, or (c) are Improvements to any item in (a) or (b) above, but excluding the Joint Patents. Without limitation of the foregoing, HPA Patents shall include those Patents listed on Schedule 1.37 to this Agreement, and any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates, and any international or foreign equivalent of any Patent listed in Schedule 1.37.
  - 1.38 "HPA Products" shall have the meaning set forth in Section 3.3(c)(i).
  - 1.39 "HPA Technology" shall mean, collectively, the HPA Patents and the HPA Know-How.
- 1.40 "Improvement" shall mean any modification, variation or revision to a compound, product or technology or any discovery, technology, device, process or formulation related to such compound, product or technology, whether or not patented or patentable, including any enhancement in the efficiency, operation, Manufacture (including any manufacturing process), ingredients, preparation, presentation, formulation, means of delivery, packaging or dosage of such compound, product or technology, any discovery or development of any new or expanded indications for such compound, product or technology, or any discovery or development that improves the stability, safety or efficacy of such compound, product or technology.
- 1.41 "IND" shall mean an investigational new drug application filed with the FDA for authorization to commence human clinical trials, and its equivalent in other countries or regulatory jurisdictions in the Territory.
  - 1.42 "Indemnification Claim Notice" shall have the meaning set forth in Section 7.3.1.
  - 1.43 "Indemnified Party" shall have the meaning set forth in Section 7.3.1.
- 1.44 "Information and Inventions" shall mean all technical, scientific and other know-how, show-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer software, apparatuses, specifications, data, cell lines, seed stock and other biological materials, pre-clinical and clinical trial results, Manufacturing procedures, test procedures and purification and isolation techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed, and all Improvements, whether to the foregoing or otherwise, and other discoveries, developments, inventions, and other intellectual property (whether or not confidential, proprietary, patented or patentable), but excluding the Regulatory Documentation.

- 1.45 "Infringement Suit" shall have the meaning set forth in Section 9.4.1.
- 1.46 "In-License Agreements" shall have the meaning set forth in Section 8.3(b).
- 1.47 "Joint Know-How" shall have the meaning set forth in the BT Development Agreement.
- 1.48 "Joint Patents" shall have the meaning set forth in the BT Development Agreement.
- 1.49 "Joint Technology" shall mean, collectively, the Joint Patents and the Joint Know-How.
- 1.50 "Jurisdiction" shall mean the countries constituting Europe collectively and each other country in the Territory.
- 1.51 "Licensed HPA Patents" shall have the meaning set forth in Section 8.3(b).
- 1.52 "Licensed Product" shall mean a pharmaceutical product that (a) comprises one or more toxoid components that acts to stimulate an immune response, (b) is designed for use in the Field, (c) comprises, is comprised of (in whole or in part), or is Exploited using, HPA Technology or Joint Technology, and (d) is Manufactured by or on behalf of Emergent (or, in relation to a Sublicensee, Manufactured by or on behalf of such Sublicensee).
  - 1.53 "Losses" shall have the meaning set forth in Section 7.1.
  - 1.54 "Major Market" shall mean each of the United Kingdom, the United States, France, Germany, Italy, and Japan.
- 1.55 "Manufacture" and "Manufacturing" shall mean, with respect to a product or compound, the manufacturing, processing, formulating, packaging, labeling, holding and quality control testing of such product or compound.
- 1.56 "Marketing Authorization" shall mean a New Drug Application or Biologics License Application, each as defined in the FFDCA, and the regulations promulgated thereunder, and any corresponding foreign application, registration or certification, necessary or reasonably useful to market a Licensed Product in the Territory, but not including pricing and reimbursement approvals.
  - 1.57 "Minor Market" shall have the meaning set forth in Section 5.2.
- 1.58 "Net Sales" shall mean, for any period, the gross amount invoiced by Emergent, its Affiliates or its Sublicensees, as the case may be, for arm's-length sales of Licensed Products to Third Parties, after deducting (to the extent not already deducted from the amount invoiced or received): (a) normal and customary trade, quantity and cash discounts and sales returns and allowances, including (i) those granted on account of price adjustments, billing errors, rejected goods, damaged goods, returns and rebates, (ii) administrative and other fees and reimbursements and similar payments to wholesalers and other distributors, buying groups,

pharmacy benefit management organizations, health care insurance carriers and other institutions, (iii) allowances, rebates and fees paid to distributors and (iv) chargebacks; (b) freight, postage, shipping and insurance expenses to the extent that such items are included in the gross amount invoiced; (c) customs and excise duties and other duties related to the sales to the extent that such items are included in the gross amount invoiced; (d) rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental program; (e) sales and other taxes and duties directly related to the sale or delivery of Licensed Products (but not including taxes assessed against the income derived from such sale); (f) distribution expenses to the extent that such items are included in the gross amount invoiced; (g) any other similar and customary deductions that are consistent with GAAP, or in the case of non-United States sales, other applicable accounting standards (consistently applied); (h) any such invoiced amounts that are not collected by Emergent, its Affiliates or its Sublicensees, as the case may be, to Third Parties in connection with the Exploitation of Licensed Products. Any of the deductions listed above that involves a payment by Emergent, its Affiliates or its Sublicensees, as the case may be, shall be taken as a deduction in the Calendar Quarter in which the payment is accrued by such entity. Deductions pursuant to clause (h) above shall be taken in the Calendar Quarter in which such sales are no longer recorded as a receivable. For purposes of determining Net Sales, the Product(s) shall be deemed to be sold when invoiced and a "sale" shall not include transfers or dispositions for charitable or promotional purposes.

For purposes of calculating Net Sales, sales between or among Emergent, its Affiliates, and its Sublicensees shall be excluded from the computation of Net Sales, but sales by Emergent, its Affiliates or its Sublicensees to Third Parties (other than its Sublicensees) shall be included in the computation of Net Sales.

In the event that a Licensed Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the first paragraph of this Section by the fraction A/(A+B), where A is the average invoice price in such country of the Licensed Product containing as its sole active ingredient toxoid components that act to stimulate an immune response and are intended for use in the Field, if sold separately in such country, and B is the average invoice price in such country of the other therapeutically or antigenically active ingredients in the Combination Product, if sold separately in such country. If, in a specific country, such other therapeutically or antigenically active ingredients in the Combination Product are not sold separately, Net Sales shall be adjusted by multiplying actual Net Sales of such Combination Product calculated pursuant to the first paragraph of this Section by the fraction A/C, where A is the average invoice price in such country of the Licensed Product containing as its sole active ingredient toxoid components that act to stimulate an immune response and are intended for use in the Field, and C is the invoice price in such country of such Combination Product. If, in a specific country, the Licensed Product containing as its sole active ingredient toxoid components that act to stimulate an immune response and are intended for use in the Field is not sold separately, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product calculated pursuant to the first paragraph of this Section by the fraction (C-B)/C, where B is the average invoice price in such country of the other

therapeutically or antigenically active ingredients in the Combination Product and C is the invoice price in such country of the Combination Product. The invoice price for the Licensed Product containing as its sole active ingredient toxoid components that act to stimulate an immune response and are intended for use in the Field, and for each other therapeutically or antigenically active ingredient shall be for a quantity comparable to that used in such Combination Product and of the same class, purity and potency. If, in a specific country, neither a Licensed Product containing as its sole active ingredient toxoid components that act to stimulate an immune response and are intended for use in the Field nor the other therapeutically or antigenically active ingredients in such Combination Product is sold separately, a market price for such Licensed Product and such other therapeutically or antigenically active ingredients shall be negotiated by the Parties in good faith based upon the manufacturing costs, overhead and profit for such Combination Product and all similar substances then being made and marketed and having an ascertainable market price.

- 1.59 "Owned HPA Patents" shall have the meaning set forth in Section 8.3(b).
- 1.60 "Patents" shall mean (a) all patents and patent applications, (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, reexaminations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patents or patent application, and (c) any foreign or international equivalent of any of the foregoing.
  - 1.61 "PCT" shall mean the Patent Cooperation Treaty, opened for signature June 19, 1970, 28 U.S.T. 7645.
- 1.62 "Person" shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government (whether or not having a separate legal personality).
  - 1.63 "Prosecution Jurisdiction" shall have the meaning set forth in Section 9.2.1.
- 1.64 "rBOT Development Agreement" shall mean that certain rBOT Vaccine Development Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
- 1.65 "rBOT License Agreement" shall mean that certain rBOT Vaccine License Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
- 1.66 "Regulatory Approval" shall mean any and all approvals (including pricing and reimbursement approvals), governmental licenses, registrations or authorizations of any Regulatory Authority, necessary for the Exploitation of the Licensed Products in a country in the Territory, including any (a) approval of any Licensed Product (including any INDs, Marketing Authorizations and supplements and amendments thereto); (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); (c) labeling approval; and (d) technical, medical and scientific licenses.

- 1.67 "Regulatory Authority" shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of the Licensed Products in the Territory, but excluding HPA acting in its capacity as a Party.
- 1.68 "Regulatory Documentation" shall mean all applications, registrations, governmental licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests, relating to any Licensed Product, and all data contained in any of the foregoing, including all INDs, Marketing Authorizations, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files and Manufacturing records (including Manufacturing records maintained pursuant to Section 2.10.3 of the BT Development Agreement and any Drug Master Files prepared and filed by HPA).
  - 1.69 "Retained Rights" shall have the meaning set forth in Section 3.3(a).
  - 1.70 "Subject Product" shall have the meaning set forth in Section 5.5.
- 1.71 "Sublicense Income" shall mean consideration of any kind, including any fees, royalties, milestones or other payments (whether cash or non-cash), received by Emergent or any of its Affiliates from one or more Sublicensees in consideration of a grant of rights by Emergent to Sublicensee to Exploit any Licensed Product for use in the Field in a Minor Market, but excluding (a) amounts received at or below fair market value for equity in Emergent or any of its Affiliates, (b) equity received from a Sublicensee in exchange for monetary consideration at or above fair market value, or (c) amounts received in the form of a loan to Emergent or a repayment of a loan from Emergent.
- 1.72 "Sublicensee" shall mean a Third Party to which Emergent or any of its Affiliates grants a license or sublicense to Manufacture, and sell or otherwise Exploit any Licensed Product for use in the Field in one or more countries in the Territory. For the avoidance of doubt, a distributor, sales agent, marketing representative or other Person whose role is to import, promote and sell Licensed Products, but not to Manufacture, develop and/or secure Regulatory Approvals of such Licensed Products, shall not be deemed to be a Sublicensee.
  - 1.73 "Territory" shall mean all of the countries in the world.
  - 1.74 "Third Party" shall mean any Person other than Emergent, HPA and their respective Affiliates.
  - 1.75 "Third Party Claim" shall have the meaning set forth in Section 7.3.2.
- 1.76 "Trademark" shall include any word, name, symbol, color, designation or device or any combination thereof, including any trademark, trade dress, brand mark, trade name, brand name, logo or business symbol.

1.77 "U.K. Public Entity" shall mean any national, local, regional or provincial governmental agency of the United Kingdom, including any components of the National Health Service.

1.78 "Valid Claim" shall mean, with respect to a particular country, a claim of an issued and unexpired Patent in such country that (a) has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken or has been taken within the time allowed for appeal; (b) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise in such country; and (c) provides exclusive and enforceable rights with respect to the sale of the Licensed Product in such country.

# ARTICLE II Commercialization

- 2.1 Commercialization Activities. Emergent shall have the exclusive right to commercialize any and all Licensed Products in the Territory. HPA may commercialize any and all HPA Products only to the extent of its Retained Rights as more completely described in Section 3.3. Except as otherwise expressly provided herein Emergent shall be solely responsible for any costs and expenses it incurs in connection with its Exploitation of Licensed Products. HPA shall be solely responsible for any costs and expenses it incurs in connection with the exercise of the Retained Rights.
- 2.2 Communications with Regulatory Authorities. Emergent shall have the sole right to conduct all communications with regard to the Exploitation of the Licensed Products, with the Regulatory Authorities in countries in the Territory. Nothing in this Section 2.2 shall limit HPA's rights to communicate with Regulatory Authorities in the United Kingdom, or if necessary agencies of the European Commission, in connection with the Exploitation of HPA Products pursuant to its Retained Rights as more completely described in Section 3.3.
- 2.3 Regulatory Approvals. Emergent shall have the sole right to develop and implement the strategy for obtaining and maintaining Regulatory Approvals for Licensed Product throughout the Territory. In connection with the foregoing, Emergent shall be entitled to prepare and submit INDs, Marketing Authorizations and other filings, applications or requests made pursuant to or in connection with the Regulatory Approvals in its name or in the name of its designee, unless Applicable Law requires that a Regulatory Approval be granted solely or jointly in the name of HPA or its Affiliates, in which case HPA shall, or shall cause its Affiliates to, as applicable, take actions to effect the assignment of such Regulatory Approval to Emergent pursuant to Section 3.2, to the extent permitted by Applicable Law. Emergent shall further be entitled to prepare, file, maintain and hold all regulatory filings for Licensed Products and shall keep HPA informed of the initial filing, and final approval of, any application for Regulatory Approval of such Licensed Product(s) in the Territory. Upon the request of Emergent, HPA shall, and shall cause its Affiliates to, provide to Emergent or its designee all information in HPA's or its Affiliates' possession that is reasonably necessary to support any and all applications for Regulatory Approval of the Licensed Product(s) in the Territory, at Emergent's expense (charged at rates no less favorable than those charged by HPA to its largest non-governmental customers). Nothing in this Section 2.3 shall limit HPA's rights to develop and

implement the strategy for obtaining and maintaining Regulatory Approval for HPA Products pursuant to its Retained Rights as more completely described in Section 3.3.

- 2.4 Development and Use of Trademarks. Emergent shall have the sole right to determine the Trademarks to be used with respect to the Exploitation of Licensed Products and any and all Improvements thereto. Without the prior express written permission of HPA, Emergent shall not use, and shall not permit its Affiliates to use, the name of HPA or any of its Affiliates, or any Trademarks that is confusingly similar to, misleading or deceptive with respect to, or that dilutes any of the Trademarks owned, controlled or used by HPA or its Affiliates. Without the prior express written permission of Emergent, HPA shall not, and shall not permit its Affiliates to use the name of Emergent or any of its Affiliates, or any Trademark that is confusingly similar to, misleading or deceptive with respect to, or that dilutes any of the Trademarks owned, controlled or used by Emergent or any of its Affiliates.
- 2.5 Discretion. Subject to the terms of this Agreement, including Section 2.6, and the terms of the Distribution Agreement, the Parties acknowledge and agree that all decisions relating to Emergent's Exploitation and pricing of Licensed Products and any and all Improvements thereto, shall be within the sole discretion of Emergent. HPA acknowledges that Emergent is in the business of researching, developing, manufacturing, marketing and selling pharmaceutical products and nothing in this Agreement shall be construed as restricting such business or imposing on Emergent the duty to Exploit or otherwise commercialize any Licensed Product for which royalties are payable hereunder to the exclusion of, or in preference to, any other product, or in any manner other than in accordance with its normal commercial practices.
- 2.6 Diligence. The Parties acknowledge and agree that Emergent's development of the Licensed Products is subject to, and dependent upon, the availability of government funding for such product and clinical development activities; that the availability of such funding in general, and for Emergent specifically, is uncertain as of the Effective Date; that the timing and continuity of any such funding is also uncertain; and that any and all of these factors could result in significant delays in Emergent's Exploitation of the Licensed Products. Emergent agrees to use Commercially Reasonable Efforts (a) to respond to any solicitations and procurement proposals of government agencies in each Major Market (including, in the case of the United States, federal, state and local agencies), of which HPA gives notice to Emergent or of which Emergent is otherwise aware, that are directly applicable to one or more Licensed Products, and (b) to enter into procurement contracts and development contracts with such government agencies with respect to the Licensed Products; provided, however, that Emergent shall not be required to do so with respect to any Licensed Product if a Third Party has instituted, or in the good faith judgment of Emergent is reasonably likely to institute, an Infringement Suit with respect to the Exploitation of such Licensed Product in such Major Market. Emergent shall be deemed to have satisfied its obligations under this Section 2.6 if it files an IND with respect to one or more Licensed Products by the fifth anniversary of the Effective Date. In the event that Emergent fails to file an IND with respect to at least one Licensed Product by such date (the "Penalty Date,"), then it shall pay HPA [\*\*] Dollars (US S[\*\*]) within ten days after the Penalty Date, and an equal sum thereafter on an annual basis, within ten days after each anniversary of the Penalty Date, until such time as Emergent has filed an IND with respect to at least one Licensed Product; provided, however, that if Emergent files such an IND

Emergent shall pay HPA a lump sum equal to the difference between [\*\*] Dollars (US \$[\*\*]) and the aggregate amount previously paid by Emergent to HPA pursuant to this sentence; and provided, further, that Emergent shall not be required to make any payment in the event that Emergent's failure to file such IND by such date results directly from the failure by HPA to perform any of its obligations hereunder in a timely manner. Such payment shall be the sole remedy of HPA for any breach of this Section 2.6, and any breach of this Section 2.6 (other than a breach of such payment obligation) shall not be deemed a material breach of this Agreement for purposes of Section 10.5.

- 2.7 Records and Audits. HPA shall prepare and maintain complete and accurate records regarding its marketing and sales of HPA Products in the Field. Upon the written request of Emergent and not more than once in each Calendar Year, HPA shall permit an independent firm of internationally recognized standing that is expert in the field of vaccine or pharmaceutical products, selected by Emergent, and reasonably acceptable to HPA, to have access during normal business hours, and upon reasonable prior written notice, to such of the records of HPA as may be reasonably necessary to verify that HPA's sales of HPA Products in the Field are within the scope of the Retained Rights. The firm that conducts such audit shall disclose to Emergent and HPA only the details of any sales made by HPA beyond the scope of the Retained Rights. Emergent shall bear the cost of such audit unless HPA is determined to have made sales beyond the scope of the Retained Rights, in which case HPA shall bear such cost.
- 2.8 Cooperation of HPA. HPA shall cooperate with any and all reasonable requests for assistance from Emergent with respect to the commercialization of the Licensed Products, including by making its employees, consultants and other scientific staff available upon reasonable notice during normal business hours at their respective places of employment to consult with Emergent on issues arising during such commercialization. In addition, HPA shall promptly disclose to Emergent any and all After-Acquired HPA Know-How, subject to the rights of any Third Parties therein. Emergent shall reimburse HPA for any and all reasonable and verifiable direct out-of-pocket costs and expenses incurred by HPA in providing such assistance, provided that the rate charged for any employee costs shall not exceed the most favorable rates charged by HPA to its largest non-governmental customers.
- 2.9 Rights and Obligations. Any and all rights of Emergent under this Article II are intended, and shall be construed, to benefit such of its Affiliates and Sublicensees as and to the extent Emergent may, from time to time, designate. Further, Emergent shall have the right to satisfy any or all of its obligations under this Article II through one or more of its Affiliates or Sublicensees; provided, however, that Emergent shall remain liable to HPA for the performance of such obligations.

# ARTICLE III

#### License Grants and Assignments

- 3.1 Grants to Emergent. HPA hereby grants to Emergent and its Affiliates, and shall cause HPA's Affiliates to grant to Emergent and its Affiliates:
  - (a) an exclusive (even with regard to HPA and its Affiliates), perpetual and irrevocable (in each case subject to the provisions of Article X), royalty-bearing license, with the

right to grant sublicenses (through multiple tiers of sublicensees), under HPA's and its Affiliates' rights, title, and interest in and to the BT Licensed Technology, to Exploit Licensed Products and any and all Improvements thereto in the Field in the Territory (other than to make, have made, and use Licensed Products and any and all Improvements thereto in the Field in the United Kingdom and to sell or otherwise distribute Licensed Products and any and all Improvements thereto in the Field in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service)), which license shall be subject, in the case of the After-Acquired HPA Know-How, to any rights in such After-Acquired HPA Know-How granted by HPA to Third Parties prior to the creation of such After-Acquired HPA Know-How;

(b) a non-exclusive, perpetual and irrevocable (in each case subject to the provisions of Article X), royalty-bearing license, with right to grant sublicenses (through multiple tiers of sublicenses), under HPA's and its Affiliates' rights, title, and interest in and to the HPA Technology, to make, have made, and use Licensed Products and any and all Improvements thereto in the Field in the United Kingdom and to sell or otherwise distribute Licensed Products and any and all Improvements thereto in the Field in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service), which license shall be subject, in the case of the After-Acquired HPA Know-How, to any rights in such After-Acquired HPA Know-How granted by HPA to Third Parties prior to the creation of such After-Acquired HPA Know-How;

(c) an exclusive (even with regard to HPA and its Affiliates), perpetual and irrevocable (in each case subject to the provisions of Article X), royalty-bearing license and right of reference, with the right to grant sublicenses (through multiple tiers of sublicensees), under HPA's and its Affiliates' rights, title and interest in and to the Regulatory Documentation, to the extent not assigned to Emergent and its Affiliates pursuant to Section 3.2 or the BT Development Agreement, to Exploit Licensed Products and any and all Improvements thereto in the Territory (other than to make, have made, and use Licensed Products and any and all Improvements thereto in the Field in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service)); and

(d) a non-exclusive, perpetual and irrevocable (in each case subject to the provisions of Article X), royalty-bearing license and right of reference, with the right to grant sublicenses (through multiple tiers of sublicensees), under HPA's and its Affiliates' rights, title and interest in and to the Regulatory Documentation, to the extent not assigned to Emergent and its Affiliates pursuant to Section 3.2 or the BT Development Agreement, to make, have made, and use Licensed Products and any and all Improvements thereto in the Field in the United Kingdom and to sell or otherwise distribute Licensed Products and any and all Improvements thereto in the Field in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase

Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service).

3.2 Assignment of Regulatory Documentation. HPA hereby assigns to Emergent, and shall cause its Affiliates to assign to Emergent, all of HPA's and its Affiliates' rights, title and interest in and to all Regulatory Documentation, including, to the extent permitted by Applicable Law, all Regulatory Approvals, Controlled by HPA or its Affiliates as of the Effective Date and from time to time during the term of this Agreement; provided, however, that HPA shall not be required to assign any Regulatory Documentation that it may develop, at its expense, solely in connection with the exercise of the Retained Rights under Section 3.3. HPA shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such agreements, documents and instruments, as may be necessary under, or as Emergent may reasonably request in connection with, or to carry out more effectively, the purposes of this Section 3.2.

# 3.3 HPA's Retained Rights and Licenses.

- (a) Subject to the provisions of Article X, HPA hereby retains the right under all of HPA's and its Affiliates' rights, title and interest in and to the BT Licensed Technology and the Regulatory Approvals, to the extent not assigned to Emergent and its Affiliates pursuant to Section 3.2 or the BT Development Agreement, to make, have made, and use HPA Products in the Field in the United Kingdom and to sell or otherwise distribute HPA Products in the Field in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase HPA Products for the purpose of supplying such HPA Products to or for the National Health Service) (collectively, the "Retained Rights").
- (b) HPA shall not, and shall cause its Affiliates not to, assign, sell or otherwise transfer, or grant any license or right of reference under, any of the Retained Rights to any Affiliate of HPA or any Third Party.
  - (c) Emergent hereby grants to HPA and its Affiliates, solely for use in connection with HPA's (or its Affiliates') exploitation of the Retained Rights:
- (i) a non-exclusive, perpetual and irrevocable (in each case subject to the provisions of Article X), royalty-free license (without the right to grant sublicenses), under Emergent's and its Affiliates' rights, title, and interest in and to (A) the patents, patent applications and know-how identified on Schedule 3.3(c), and (B) any Information and Inventions owned by Emergent during the term of this Agreement, or Controlled by Emergent during the term of this Agreement and as to which Emergent does not have royalty obligations to a Third Party, that are incorporated into the Licensed Products, to make, have made, and use a recombinant product that (w) comprises one or more *C. botulinum* toxin fragments that acts to stimulate an immune response, (x) is designed for use in the Field, (y) comprises, is comprised of (in whole or in part), or is Exploited using, HPA Technology or Joint Technology, and is (z) Manufactured by or on behalf of HPA (hereinafter "HPA Products") and any and all Improvements thereto in the Field in the United Kingdom to meet the

requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase HPA Products for the purpose of supplying such HPA Products to or for the National Health Service); and

- (ii) a non-exclusive, perpetual and irrevocable (in each case subject to the provisions of Article X), royalty-free license and right of reference (without the right to sublicense), under Emergent's and its Affiliates' rights, title and interest in and to the Regulatory Documentation, to make, have made, and use HPA Products and any and all Improvements thereto in the Field in the United Kingdom and to sell or otherwise distribute HPA Products and any and all Improvements thereto in the Field in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase HPA Products for the purpose of supplying such HPA Products to or for the National Health Service).
- (d) Notwithstanding anything in this Agreement to the contrary, subject to the license grant to HPA in Section 3.3(c), as between the Parties, Emergent shall own and retain all right, title and interest in and to all Emergent intellectual property and technology described therein and licensed thereunder.

#### 3.4 Negative Covenant

- (a) HPA hereby covenants and irrevocably (subject to the provisions of Article X) agrees for itself and each of its Affiliates that it and each of them shall not directly or indirectly assert, authorize, pursue or induce any third party to assert or pursue, assist or cooperate with any third party in asserting or pursuing, or seek to obtain any recovery with respect to any legal or equitable cause of action, suit, claim, defense, offset, counterclaim, cross-claim or pleading or other proceeding of any sort whatsoever, participate in any proceeding or action, or make any allegations against Emergent or any Affiliate, sub-licensee, authorized manufacturer or authorized distributor asserting that the (i) manufacture, use, sale, offer for sale, importation, or exportation of any product, or (ii) act of authorizing others to manufacture, use, sell, offer for sale, import, or export any product, or (iii) provision of any service, or (iv) practice of any method, that is both
  - (A) conducted with respect to Licensed Products, and
- (B) covered by or includes, in whole or in part, directly or indirectly, or is performed or used in conjunction with any know-how, show-how, patent or patent application (including without limitation Information and Inventions) owned or Controlled prior to, on or following the Effective Date by HPA or any of its Affiliates,
- constitutes direct infringement, contributory infringement, inducement to infringe, or otherwise violates, misappropriates or infringes any legal right under any of such intellectual property of HPA or any of its Affiliates.
- (b) Emergent hereby covenants and irrevocably (subject to the provisions of Article X) agrees (for itself and each of its Affiliates) that it and each of them shall not directly or indirectly assert, authorize, pursue or induce any third party to assert or pursue, assist or

cooperate with any third party in asserting or pursuing, or seek to obtain any recovery with respect to any legal or equitable cause of action, suit, claim, defense, offset, counterclaim, cross-claim or pleading or other proceeding of any sort whatsoever, participate in any proceeding or action, or make any allegations against HPA or any Affiliate asserting that the (i) manufacture, use, sale, offer for sale, importation, or exportation of any product, or (ii) act of authorizing others to manufacture, use, sell, offer for sale, import, or export any product, or (iii) provision of any service, or (iv) practice of any method, that is both

- (A) conducted by HPA or its Affiliates solely in furtherance of the Exploitation of HPA Products under its Retained Rights under Section 3.3 and
- (B) covered by or includes, in whole or in part, directly or indirectly, or is performed or used in conjunction with any know-how, show-how, patent or patent application (including without limitation Information and Inventions) owned or controlled by Emergent or any of its Affiliates that have been incorporated into Licensed Products,

constitutes direct infringement, contributory infringement, inducement to infringe, or otherwise violates, misappropriates or infringes any legal right under any of such intellectual property of Emergent or any of its Affiliates.

(c) The Parties acknowledge that the restrictions contained in this Section 3.4 are reasonable, valid and necessary for the adequate protection of the Licensed Products and HPA Products businesses and that the Parties would not have entered into this Agreement without the protection afforded them by this Section 3.4.

# ARTICLE IV Confidentiality and Nondisclosure

# 4.1 Confidentiality Obligations.

- 4.1.1 <u>General Obligations</u>. Except as provided herein, the Parties agree that, during the term of this Agreement and for five (5) years after this Agreement's expiration or termination pursuant to Article X, each Party shall hold in strict confidence and shall not publish or otherwise disclose, directly or indirectly, to any Person (other than employees, Affiliates, legal counsel, consultants, auditors and advisors who, except in the case of legal counsel, are bound in writing by confidentiality and non-use obligations no less onerous than those set forth herein) any Confidential Information of the other Party. During such period, a Party (and its Affiliates) shall not use for any purpose, directly or indirectly, Confidential Information of the other Party or its Affiliates furnished or otherwise made known to it, except as permitted hereunder.
- 4.1.2 <u>Additional HPA Obligations</u>. HPA recognizes that by reason of Emergent's status as an exclusive licensee pursuant to this Agreement and the BT Development Agreement, Emergent has an interest in HPA's retention in confidence of certain information of HPA. Accordingly, HPA shall, and shall cause its Affiliates, officers, directors, employees and agents to, hold in strict confidence, and not publish or otherwise disclose, and not use directly or indirectly for any purpose, any information relating to the Licensed Product(s) or the Regulatory Documentation, including the Regulatory Approvals (collectively, the "Emergent Information"),

except to the extent that (a) the Emergent Information is in the public domain through no fault of HPA, its Affiliates, or any of their respective officers, directors, employees or agents, or (b) such disclosure is reasonably necessary for the performance of HPA's obligations hereunder or the exercise of the Retained Rights, provided that any Third Party to which HPA proposes to disclose any Emergent Information is bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article IV. For clarification, the disclosure by HPA to Emergent or by Emergent to HPA of Emergent Information shall not cause such information to cease to be subject to the confidentiality provisions of this Section 4.1.2.

- 4.2 Permitted Disclosures. Each Party may disclose Confidential Information or Emergent Confidential Information to the extent that such disclosure is:
- (a) Made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the receiving Party shall first have given notice to the disclosing Party and, insofar as permitted by applicable law, given the disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;
- (b) Otherwise required by law, in the opinion of legal counsel to the receiving Party as expressed in an opinion letter in form and substance reasonably satisfactory to the disclosing Party, which shall be provided to the disclosing Party at least two (2) business days prior to the receiving Party's disclosure of the Confidential Information pursuant to this Section 4.2(b);
- (c) Made by the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; <u>provided</u>, <u>however</u>, that reasonable measures shall be taken to assure confidential treatment of such information;
- (d) Made by Emergent to existing or potential acquirers or merger candidates; existing or potential pharmaceutical collaborators; investment bankers; existing or potential investors, venture capital firms or other financial institutions for purposes of obtaining financing; each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article IV;
- (e) Made by HPA to potential investors in any spin-off entity to which HPA intends to transfer its business relating to the Development Program (as defined in the BT Development Agreement) and the Exploitation of Licensed Products and HPA Products, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article IV: or

(f) Made by Emergent or its Affiliates or Sublicensees to Third Parties as may be necessary or reasonably useful in connection with the Exploitation of any Licensed Product, including subcontracting and sublicensing transactions in connection therewith.

# 4.3 Confidential Information.

- 4.3.1 <u>Defined</u>. "Confidential Information" of a Party shall mean all information and know-how and any tangible embodiments thereof provided by or on behalf of such Party to the other Party either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement, including data; knowledge; practices; processes; ideas; research plans; engineering designs and drawings; research data; manufacturing processes and techniques; scientific, manufacturing, marketing and business plans; and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business. For the avoidance of doubt, Confidential Information shall be deemed to include any and all information provided by one Party to the other Party relating to Licensed Products or HPA Products, and the terms of this Agreement.
- 4.3.2 Exclusions. Notwithstanding the foregoing, information or know-how of a Party shall not be deemed Confidential Information with respect to the receiving Party for purposes of this Agreement if such information or know-how: (a) was already known to the receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, at the time of disclosure to, or, with respect to know-how, discovery or development by, such receiving Party; (b) was generally available or known, or was otherwise part of the public domain, after its disclosure to, or, with respect to know-how, discovery or development by, such receiving Party; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to know-how, discovery or development by, such receiving Party through no fault of the receiving Party; (d) was disclosed to such receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the Party that Controls such information and know-how not to disclose such information or know-how to others; or (e) was independently discovered or developed by such receiving Party or its Affiliates, as evidenced by their written records, without the use of Confidential Information belonging to the Party that Controls such information and know-how.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of a Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of such Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of a Party merely because individual elements of such Confidential Information are in the public domain or in the possession of such Party unless the combination and its principles are in the public domain or in the possession of such Party.

**4.4 Use of Name.** Neither Party shall mention or otherwise use the name, symbol, trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this

Section shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law.

- 4.5 Press Releases; Publication. Each Party shall have the right to issue press releases and to make other public disclosures, presentations or publications with respect to this Agreement; provided, however, that no such press release or other public disclosure, presentation or publication shall disclose any Confidential Information of the other Party without the prior written consent of such other Party; and, provided further, that neither HPA nor any of its Affiliates, officers, directors, employees or agents shall be permitted to issue any Press release or make any other public disclosure, presentation or publication regarding any information, data or results pertaining to or resulting from the Emergent Information, without the prior written consent of Emergent. HPA agrees to acknowledge Emergent in all such publications or other public disclosures by coauthorship or acknowledgement, as appropriate according to customary practice for such research publications and disclosures.
- **4.6 Equitable Relief.** Each Party acknowledges and agrees that breach of any of the terms of this Article IV would cause irreparable harm and damage to the other Party and that such damage may not be ascertainable in money damages and that as a result thereof the non-breaching Party would be entitled to seek from a court equitable or injunctive relief restraining any breach or future violation of the terms contained herein by the breaching Party without the necessity of proving actual damages. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of law or equity, including money damages, which other remedies are subject to Section 11.7.

# ARTICLE V Payments and Reports

- **5.1 Payments to HPA for Sales of Licensed Products in Major Markets.** Subject to Sections 5.4, 5.5, and 10.6.2(b), the right of offset of Emergent under Section 7.4(b), and the other terms and conditions of this Agreement, in partial consideration of the licenses and other rights granted herein, Emergent, on a Licensed Product-by-Licensed Product and Major Market-by-Major Market basis, shall pay to HPA royalties in an amount equal to [\*\*] percent ([\*\*]%) of Net Sales of such Licensed Product by Emergent, its Affiliates, or its Sublicensees in such Major Market.
- **5.2 Payments to HPA for Sales of Licensed Products in Other Countries.** Subject to Sections 5.3, 5.4, 5.5, 10.6.2(b), the right of offset of Emergent under Section 7.4(b), and the other terms and conditions of this Agreement, in partial consideration of the licenses and other rights granted herein, Emergent, on a Licensed Product-by-Licensed Product and country-by-country basis for countries other than the Major Markets (each, a "Minor Market"), shall pay to HPA the following:
  - (a) royalties in an amount equal to:
    - (i) [\*\*] percent ([\*\*]%) of Net Sales of such Licensed Product by Emergent or its Affiliates (but not its Sublicensees) in such Minor Market; and

- (ii) until aggregate cumulative Net Sales of all Licensed Products by Emergent, its Affiliates, and its Sublicensees in all Major Markets and by Emergent and its Affiliates in all Minor Markets have reached [\*\*] Dollars (US \$[\*\*]), an additional [\*\*] percent ([\*\*]%) of Net Sales of such Licensed Product by Emergent or its Affiliates (but not its Sublicensees) in such Minor Market; and
- (b) an amount equal to [\*\*] percent ([\*\*]%) of the difference between (i) all Sublicense Income received by Emergent or any of its Affiliates from the Sublicensee(s) for such Minor Market in connection with the Exploitation of such Licensed Product in the Field in such Minor Market and (ii) all fully-loaded internal costs and out-of-pocket costs incurred by Emergent and its Affiliates in connection with the identification of, negotiation with, and training of such Sublicensee and its employees and agents, and all other project costs related to Emergent's and its Affiliates' support of such Sublicensee's efforts to Exploit such Licensed Product in the Field in such Minor Market, all of which costs shall be calculated in a manner consistent with Emergent's standard method of accounting.
- **5.3 Reduction in Royalties for Compulsory Licenses**. In the event that a court or a governmental agency of competent jurisdiction requires Emergent or one of its Affiliates to grant a compulsory license to a Third Party permitting such Third Party to make and sell a Licensed Product in a Minor Market, and the rate of royalty payable to Emergent or its Affiliate under such license is lower than the market rate of royalty for such license is or would be in such country, then all Net Sales of such Licensed Product by Emergent and its Affiliates in such country shall be excluded from the royalty calculations set forth in Section 5.2(a) and the rate of royalty to be paid by Emergent to HPA on such Net Sales shall be equal to [\*\*] percent ([\*\*]%) of the royalty rate under such compulsory license, during the time period when such compulsory license is in effect and being exercised.
- **5.4 Reduction in Royalties for Competition.** In the event that HPA or its Affiliates shall knowingly and materially assist any Third Party to develop or otherwise Exploit a Vaccine Product (as defined in the BT Development Agreement) designed or intended for the prevention or treatment of illness in humans caused by *C. botulinum* toxin that competes with any Licensed Product and achieves a market share of at least [\*\*] percent ([\*\*]%) in a country, then the rate of royalty applicable to such Licensed Product in such country under Section 5.1 or 5.2(a), as the case may be, shall be reduced by [\*\*] percent ([\*\*]%). For purposes of this Section 5.4, the provision by HPA to a Third Party of standard commercially available services on a fee-for-service basis (e.g., sample testing using customer supplied assays or commercially available assays) that do not involve a research component (e.g., assay development) shall not, standing alone, be deemed "material assistance" to such Third Party.
- **5.5 Royalty Term**. Emergent's royalty obligations under Sections 5.1 and 5.2 shall terminate, on a country-by-country basis, with respect to each Licensed Product (for purposes of this Section 5.5, each a "Subject Product"):
- (a) in the case of any country in Europe, on the later to occur of (i) the seventh (7th) anniversary of the First Sale of the first Licensed Product in any country in Europe and (ii) the expiration date in such country of the last to expire of any issued HPA Patents and Joint

Patents that includes at least one Valid Claim covering the sale of such Subject Product in such country; or

(b) in the case of any country not in Europe, on the later to occur of (i) the seventh (7th) anniversary of the First Sale of the first Licensed Product in such country and (ii) the expiration date in such country of the last to expire of any issued HPA Patents and Joint Patents that includes at least one Valid Claim covering the sale of such Subject Product in such country.

Upon termination of the royalty obligations of Emergent under this Section 5.5 in a country, the license grants to Emergent in Section 3.1 shall become fully paid-up with respect to such country.

5.6 Reports; Payments. Following the First Sale of a Licensed Product, Emergent shall furnish to HPA a written report for each Calendar Quarter showing (a) invoiced sales and Net Sales by Emergent and its Affiliates in the Territory, and by Sublicensees in the Major Markets, (b) the number of units of each Licensed Product sold on a country-by-country basis during the applicable Calendar Quarter, and (c) the calculation of amounts owed to HPA pursuant to Section 5.1 and 5.2 in such Calendar Quarter. Reports shall be due and amounts owed to HPA shall be due and payable sixty (60) days following the close of each Calendar Quarter. Emergent shall keep complete and accurate records in sufficient detail to enable the amounts payable hereunder to be determined.

#### 5.7 Audits

(a) Upon the written request of HPA and not more than once in each Calendar Year, Emergent shall permit an independent certified public accounting firm of internationally recognized standing selected by HPA, and reasonably acceptable to Emergent, to have access during normal business hours, and upon reasonable prior written notice, to such of the records of Emergent as may be reasonably necessary to verify the accuracy of the reports provided in accordance with Section 5.6, for any Calendar Year ending not more than twenty-four (24) months prior to the date of such request. The accounting firm shall disclose to Emergent and HPA only whether the financial statements and any related invoices are correct or incorrect and the specific details concerning any discrepancies. If such accounting firm concludes that Emergent owed additional amounts to HPA during such period, Emergent shall pay HPA the difference between the amount actually owed, as determined by the accounting firm, and the amount actually paid by Emergent, with interest from the date originally due at the prime rate, as published in *The Wall Street Journal*, Eastern United States Edition, on the last business day preceding such date, within thirty (30) days after the date on which such accounting firm's written report is delivered to HPA. If such accounting firm concludes that Emergent has underpaid HPA during such period, Emergent shall pay such difference to HPA within thirty (30) days after the date of delivery of such report. If, and only if, the amount of the underpayment is greater than five percent (5%) of the total actual amount owed as determined by the accounting firm, Emergent shall bear all costs related to such audit. In all other cases, HPA shall bear the cost of such audit.

- (b) Emergent shall include in each sublicense granted by it in a Major Market pursuant to this Agreement a provision requiring the Sublicensee to make reports to Emergent, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by HPA's independent accountant to the same extent required of Emergent under this Agreement. Upon the expiration of twenty-four (24) months following the end of any year, the calculation of amounts payable with respect to such year shall be binding and conclusive upon HPA, and Emergent and its Sublicensees shall be released from any liability or accountability with respect to amounts payable for such year.
- (c) HPA shall treat all information subject to review under this Article V in accordance with the confidentiality provisions of Article IV and shall cause its accounting firm to enter into a reasonably acceptable confidentiality agreement with Emergent obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.
- **5.8 Mode of Payment**. All payments to be made by a Party to the other Party under this Agreement shall be made in United States dollars and may be paid by check made to the order of the receiving Party or bank wire transfer in immediately available funds to such bank account designated in writing by the receiving Party from time to time. Payments shall be free and clear of any taxes (other than withholding and other taxes imposed on the receiving Party, which shall be for the account of such Party), fees or charges, to the extent applicable. With respect to payments in currencies other than United States dollars, payments shall be calculated based on currency exchange rates for the month in which the invoice is received. For each month and each currency, such exchange rate shall equal the arithmetic average of the daily exchange rates for such month listed in *The Wall Street Journal*, Eastern United States Edition, or, if not so available, as otherwise agreed by the Parties. Any delinquent payments shall accrue interest from the date on which payment was due, at the prime rate, as published in *The Wall Street Journal*, Eastern United States Edition, on the last Business Day preceding such date.

# ARTICLE VI

# Complaints, Adverse Event Reporting and Product Recall

- **6.1 Complaints**. Each Party shall maintain a record of any and all complaints it receives with respect to either the Licensed Products or the HPA Products. Each Party shall notify the other Party in reasonable detail of any such complaint received by it at the same time as such Party is required to first report such complaint to any Regulatory Authority, if such Party is required to report such complaint, and in any event in sufficient time to allow such other Party to comply with any and all regulatory and other requirements imposed upon it in any country in which the Licensed Products or the HPA Products, as the case may be, are being marketed or distributed.
- 6.2 Adverse Event Reporting. Each Party shall provide the other Party with all information necessary or desirable for such other Party to receive in order to comply with all Applicable Law relating to adverse event reporting with respect to the Licensed Products and the HPA Products. In furtherance hereof, Emergent and HPA shall each (a) develop appropriate adverse experience reporting procedures; (b) provide to the other Party any material information on the HPA Products or the Licensed Products, respectively, from pre-clinical or clinical

laboratory, animal toxicology and pharmacology studies, as well as serious or unexpected adverse experience reports from clinical trials and commercial experiences with the HPA Products or the Licensed Products, respectively; and (c) report and provide such information to the other Party in such a manner and time so as to enable such other Party to comply with all Applicable Law in countries in which such other Party has sought or will seek Regulatory Approval.

#### 6.3 Product Recall

- 6.3.1 Notification and Recall. Emergent and HPA shall each have the sole right to decide, in its discretion, whether to conduct a recall of any Licensed Product or HPA Product, respectively (except in the case of a government-mandated recall), and the manner in which any such recall shall be conducted.
- 6.3.2 <u>Recall Expenses</u>. Emergent and HPA shall each bear the expenses of any recall of any Licensed Product or HPA Product, respectively; <u>provided</u>, <u>however</u>, that HPA shall bear the expense of a recall to the extent that such recall resulted from any defect in the Manufacturing of any Licensed Product or any intermediate thereof supplied to Emergent by or on behalf of HPA, HPA's breach of its obligations hereunder or HPA's gross negligence or willful misconduct. Such expenses of recall shall include expenses for notification, destruction or return of the recalled Licensed Product, any refund to consumers of amounts paid for the recalled Licensed Product, and any royalties paid by Emergent to HPA with respect to such recalled Licensed Product.

### ARTICLE VII Indemnity

- 7.1 Indemnification of Emergent. Subject to Sections 7.3 and 7.4(b), HPA shall indemnify Emergent, its Affiliates and its and their respective directors, officers, employees and agents, and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) in connection with any and all suits, investigations, claims or demands (collectively, "Losses") arising from or occurring as a result of (a) any material breach by HPA of this Agreement, (b) any gross negligence or willful misconduct of HPA, its Affiliates or its other permitted subcontractors in performing HPA's obligations under this Agreement, or (c) the Exploitation of HPA Licensed Products, except for those Losses for which Emergent has an obligation to indemnify HPA pursuant to Section 7.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the
- **7.2 Indemnification of HPA**. Subject to Sections 7.3 and 7.4(b), Emergent shall indemnify HPA, its Affiliates and their respective directors, officers, employees and agents, and defend and save each of them harmless, from and against any and all Losses arising from or occurring as a result of (a) any material breach by Emergent of this Agreement, (b) the gross negligence or willful misconduct of Emergent, its Affiliates or its other subcontractors in performing Emergent's obligations under this Agreement, or (c) the Exploitation of Licensed Products by Emergent or any of its Affiliates, except for those Losses for which HPA has an

obligation to indemnify Emergent and its Affiliates pursuant to Section 7.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

# 7.3 Indemnification Procedure

- 7.3.1 Notice of Claim. The indemnified Party shall give the indemnifying Party prompt written notice (an "Indemnification Claim Notice") of any Losses or discovery of fact upon which such indemnified Party intends to base a request for indemnification under Section 7.1 or Section 7.2. In no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses. All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "Indemnified Party").
- 7.3.2 Third Party Claims. The obligations of an indemnifying Party under this Article VII with respect to Losses arising from claims of any Third Party that are subject to indemnification as provided for in Sections 7.1 or 7.2 (a "Third Party Claim") shall be governed by and be contingent upon the following additional terms and conditions:
- (a) Control of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify any Person seeking indemnification in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against any such claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by any indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, the indemnifying Party shall not be liable to the Indemnified Party or any other indemnified Party for any legal expenses subsequently incurred by such indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in its defense of the Third Party Claim with respect to such indemnified Party.
- (b) Right to Participate in Defense. Without limiting Section 7.3.2(a), any indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to retain counsel of its choice for such purpose; provided, however, that such

retention shall be at the indemnified Party's own expense unless (i) the employment thereof has been specifically authorized by the indemnifying Party in writing or (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 7.3.2(a) (in which case the Indemnified Party shall control the defense).

- (c) <u>Settlement</u>. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 7.3.2(a), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). The indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim in a manner that has a materially adverse effect on the indemnifying Party without the prior written consent of the indemnifying Party.
- (d) <u>Cooperation</u>. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each other indemnified Party to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.
- (e) Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

#### 7.4 LIMITATION OF LIABILITY.

(a) SUBJECT TO SECTIONS 7.1 AND 7.2, AND EXCEPT IN CIRCUMSTANCES OF GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, NONE OF EMERGENT, HPA OR ANY OF THEIR RESPECTIVE AFFILIATES SHALL BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING FOR LOST PROFITS, MILESTONES OR ROYALTIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (A) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT, OR (B) THE DEVELOPMENT, MANUFACTURE, USE OR SALE OF ANY PRODUCT DEVELOPED, MANUFACTURED OR MARKETED HEREUNDER. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS ATTEMPTING TO EXCLUDE OR LIMIT THE LIABILITY OF EITHER OF THE PARTIES OR THEIR RESPECTIVE AFFILIATES (A) FOR DEATH OR PERSONAL INJURY CAUSED BY THE NEGLIGENCE OF EITHER OF THE PARTIES, THEIR RESPECTIVE AFFILIATES, OR OF THE OFFICERS, EMPLOYEES OR AGENTS OF THE PARTIES OR THEIR RESPECTIVE AFFILIATES, (B) FOR FRAUD OR FRAUDULENT MISREPRESENTATION OR (C) FOR ANY MATTER IN RESPECT OF WHICH IT WOULD BE ILLEGAL FOR EITHER PARTY TO EXCLUDE OR ATTEMPT TO EXCLUDE ITS LIABILITY

(b) SUBJECT TO THE PRECEDING SENTENCE, BUT NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, IN NO EVENT SHALL THE COMBINED AGGREGATE LIABILITY OF EITHER PARTY UNDER THIS AGREEMENT, TAKEN TOGETHER WITH SUCH PARTY'S AGGREGATE LIABILITY UNDER THE BT DEVELOPMENT AGREEMENT, THE 1BOT LICENSE AGREEMENT, THE 1BOT DEVELOPMENT AGREEMENT AND THE DISTRIBUTION AGREEMENT, EXCEED THE COMBINED AGGREGATE AMOUNTS PAID BY EMERGENT TO HPA, WHETHER AS LUMP SUMS OR PERIODIC PAYMENTS OF ROYALTIES OR SUBLICENSE INCOME, UNDER THIS AGREEMENT, THE BT DEVELOPMENT AGREEMENT, THE 1BOT LICENSE AGREEMENT, THE 1BOT DEVELOPMENT AGREEMENT AND THE DISTRIBUTION AGREEMENT (THE "AGGREGATE AMOUNT"); PROVIDED, HOWEVER, THAT IN THE EVENT THAT EITHER PARTY (THE "LIABLE PARTY") SHALL BECOME LIABLE TO THE OTHER PARTY HEREUNDER OR THEREUNDER FOR AN AMOUNT (THE "TOTAL LIABILITY") LARGER THAN THE AGGREGATE AMOUNT CALCULATED AS OF THE DATE THAT THE TOTAL LIABILITY BECAME DUE AND PAYABLE, THE LIABLE PARTY SHALL PROMPTLY PAY SUCH OTHER PARTY A LUMP SUM EQUAL TO THE AGGREGATE AMOUNT AS SO CALCULATED; AND PROVIDED, FURTHER, THAT IF HPA IS THE LIABLE PARTY, EMERGENT SHALL THEREAFTER HAVE A RIGHT OF OFFSET WITH RESPECT TO ANY PAYMENT OBLIGATIONS OF EMERGENT TO HPA HEREUNDER AND THEREUNDER THAT BECOME DUE AND PAYABLE AFTER SUCH DATE, UNTIL SUCH TIME AS THE TOTAL AMOUNTS OFFSET BY EMERGENT EQUAL THE DIFFERENCE BETWEEN THE TOTAL LIABILITY AND SUCH LUMP SUM PAYMENT BY HPA; AND PROVIDED, FURTHER, THAT IF EMERGENT IS THE LIABLE PARTY, THEN THEREAFTER, AT SUCH TIMES AS EMERGENT SHALL MAKE PAYMENTS TO HPA THAT ARE OTHERWISE DUE AND PAYABLE HEREUNDER OR THEREUNDER.

EMERGENT SHALL PAY TO HPA AN EQUAL AMOUNT AS ADDITIONAL DAMAGES, UNTIL SUCH TIME AS THE TOTAL AMOUNTS SO PAID TO HPA AS ADDITIONAL DAMAGES EQUAL THE DIFFERENCE BETWEEN THE TOTAL LIABILITY AND SUCH LUMP SUM PAYMENT BY EMERGENT..

7.5 Insurance. Emergent shall use commercially reasonable efforts to obtain and maintain, with an insurance company of internationally recognized standing, such type and amounts of liability insurance covering the Exploitation of the Licensed Products, and HPA shall maintain such program of self-insurance covering the Exploitation of the HPA Products, as is normal and customary in the pharmaceutical industry generally for Parties similarly situated, and Emergent shall upon request provide HPA with a copy of such policies of insurance, along with any amendments and revisions thereto; provided, however, that Emergent shall promptly notify HPA in writing if, after using commercially reasonable efforts, Emergent is unable to obtain such insurance or if, after obtaining such insurance, Emergent is unable to maintain such insurance; and provided, further, that Emergent shall not be required to seek such insurance coverage to the extent that the relevant liabilities are covered by a government indemnity in favor of Emergent or precluded by applicable law.

# ARTICLE VIII Representations and Warranties

- 8.1 Representations and Warranties. Each Party hereby represents, warrants and covenants to the other Party as of the Effective Date as follows:
- (a) Such Party (i) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (ii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.
- (b) Such Party is not aware of any pending or threatened litigation (and has not received any communication) that alleges that such Party's activities related to this Agreement have violated, or that by conducting the activities as contemplated herein such Party would violate, any of the intellectual property rights of any other Person.
- (c) All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.
- (d) The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable law or regulation or any provision of the articles of incorporation, bylaws, limited partnership

agreement or any similar instrument of such Party, as applicable, in any material way, and (ii) do not conflict with, violate, or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

- **8.2** Additional Representations, Warranties and Covenants of Emergent. Emergent represents, warrants and covenants to HPA as of the Effective Date that Emergent is a corporation duly organized and in good standing under the laws of the State of Delaware, and has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.
  - 8.3 Additional Representations, Warranties and Covenants of HPA. HPA represents, warrants and covenants to Emergent as of the Effective Date that:
- (a) HPA is a governmental entity duly organized, validly existing and in good standing under the laws of England, and has full governmental power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.
- (b) HPA is the sole and exclusive owner of all right, title and interest in and to the Patents listed on Schedule 1.37 (the "Owned HPA Patents") and, except as provided in Schedule 1.37, such rights are not subject to any encumbrance, lien or claim of ownership by any Third Party. HPA is the sole and exclusive licensee of and Controls all right, title and interest in and to the Patents listed on Schedule 1.37 (the "Licensed HPA Patents") and, except as provided in Schedule 1.37, such rights are not subject to any encumbrance, lien or claim of ownership by any Third Party. True, complete and correct copies of all license agreements regarding the Licensed HPA Patents (the "In-License Agreements"), as amended to the date hereof, have been provided to Emergent. The Owned HPA Patents and the Licensed HPA Patents constitute all of the HPA Patents as of the Effective Date. During the term of this Agreement, HPA shall not encumber or diminish the rights granted to Emergent hereunder with respect to the HPA Patents, including by not (i) committing any acts or permitting the occurrence of any omissions that would cause the breach or termination of any In-License Agreement, or (ii) amending or otherwise modifying, or permitting to be amended or modified, any In-License Agreement. HPA shall promptly provide Emergent with notice of any alleged, threatened, or actual breach of any In-License Agreement. As of the date hereof, none of HPA, its Affiliates and, to the best of their knowledge, any Third Party is in breach of any In-License Agreement.
- (c) To the best knowledge of HPA, the HPA Patents existing as of the Effective Date are subsisting and are not invalid or unenforceable, in whole or in part, and the conception, development and reduction to practice of the Regulatory Documentation, the HPA Patents and HPA Know-How existing as of the Effective Date have not constituted or involved the misappropriation of trade secrets or other rights or property of any Third Party. There are no claims, judgments or settlements against or amounts with respect thereto owed by HPA or any of its Affiliates relating to the Regulatory Documentation, the HPA Patents, or the HPA Know-How. No claim or litigation has been brought or threatened by any Person alleging, and HPA is not aware of any possible claim, whether or not asserted, that (i) the HPA Patents are invalid or unenforceable or (ii) the Regulatory Documentation, the HPA Patents, or the HPA Know-How

or the disclosing, copying, making, assigning, licensing or Exploitation of the Regulatory Documentation, the HPA Patents, or the HPA Know-How, or products embodying the Regulatory Documentation, the HPA Patents, or the HPA Row-How, including the Exploitation of any Licensed Product, violates, infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party. To the best knowledge of HPA, Emergent's worldwide Exploitation of any Licensed Product pursuant to the exercise of the licenses granted by HPA to Emergent in this Agreement will not infringe any Patents Controlled by any Third Party.

- (d) Except for the license grants and assignment in Sections 3.1 and 3.2, neither HPA nor any of its Affiliates has, directly or indirectly, expressly or by implication, by action or omission or otherwise (i) assigned, transferred, conveyed or otherwise encumbered any right, title or interest in or to the Regulatory Documentation or the HPA Technology in the Field; (ii) granted any license or other right, title or interest in or to the Regulatory Documentation or the HPA Technology in the Field; or (iii) agreed to or is otherwise bound by any covenant not to sue for any infringement, misuse or otherwise with respect to the Regulatory Documentation or the HPA Technology in the Field.
- (e) HPA agrees not to, and agrees to cause its Affiliates not to, directly or indirectly, expressly or by implication, by action or omission or otherwise (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the HPA Technology or Joint Technology, (ii) grant any license or other right, title or interest in or to the HPA Technology or the Joint Technology in any manner, or (iii) agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to the HPA Technology or the Joint Technology, in each case ((i), (ii), and (iii)) that is inconsistent with the grants, assignments and other rights reserved to Emergent and its Affiliates under this Agreement and the BT Development Agreement.
- (f) HPA shall cause each of its Affiliates and any other Person conducting Development Activities on behalf of HPA hereunder to assign to HPA rights to any and all Information and Inventions that relate to the Licensed Product(s), such that Emergent shall, by virtue of this Agreement and the BT License Agreement, receive from HPA, without payment of additional consideration beyond that required by this Agreement and the BT Development Agreement, the licenses and other rights granted to Emergent and its Affiliates hereunder and under the BT Development Agreement.
  - (g) To the best of HPA's and its Affiliate's knowledge, there is no actual or threatened infringement by a Third Party of the Regulatory Documentation or the BT Licensed Technology.
- 8.4 Disclaimer of Warranties. EXCEPT FOR THOSE WARRANTIES SET FORTH IN THIS ARTICLE VIII, AND SUBJECT TO SECTION 7.4(a), EACH PARTY HEREBY DISCLAIMS ANY AND ALL WARRANTIES, CONDITIONS AND TERMS, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING (A) ANY WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, (B) ANY WARRANTY WITH RESPECT TO THE VALIDITY OR ENFORCEABILITY OF ANY PATENT OR OTHER INTELLECTUAL

PROPERTY, AND (C) ANY WARRANTY THAT THE PERFORMANCE OF ITS RIGHTS OR OBLIGATIONS HEREUNDER WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF ANY PERSON. SUBJECT TO SECTION 7.4(a), NO PARTY MAKES ANY REPRESENTATIONS HEREUNDER OTHER THAN THOSE SET FORTH EXPRESSLY HEREIN.

# ARTICLE IX Intellectual Property Provisions

**9.1 Ownership of HPA Technology and Emergent Technology**. Subject to the license grants to Emergent and its Affiliates in Sections 3.1(a) and 3.1(b), as between the Parties, HPA shall own and retain all right, title and interest in and to all HPA Technology.

# 9.2 Prosecution of HPA Patents

- 9.2.1 HPA Patents. Subject to Sections 9.2.3 and 9.2.4, HPA shall be responsible, at the shared expense of Emergent and such other Persons as may be granted licenses thereunder by HPA consistent with the limitations of this Agreement, for obtaining, prosecuting and maintaining the HPA Patents in the United States, Canada, the European Union, Australia and Japan (the "Prosecution Jurisdictions") and such other countries in the Territory as Emergent, in its sole discretion, may elect. HPA shall file, prosecute and maintain Patent applications to secure Patent rights for the patentable HPA Technology (except to the extent that a Third Party licensor has retained the right to do so, in which case HPA shall use its commercially reasonable efforts to cause such Third Party licensor to do so), in the Prosecution Jurisdictions and in such other countries as Emergent may from time to time designate in writing.
  - 9.2.2 Interference, Opposition, Reexamination and Reissue of HPA Patents. In addition to the other obligations imposed on HPA pursuant to this Section 9.2:
- (a) HPA shall promptly, and in any event within fifteen (15) days of such event, inform Emergent of any request for, or filing or declaration, any interference, opposition, or reexamination relating to any HPA Patents. Emergent and HPA shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Emergent shall have the right to review and approve any submission to be made in connection with such proceeding.
  - (b) HPA shall not institute any reexamination, or reissue proceeding relating to HPA Patents without the prior written consent of Emergent, which consent shall not be unreasonably withheld.
- (c) In connection with any interference, opposition, reissue, or reexamination proceeding relating to HPA Patents, Emergent and HPA shall cooperate fully and shall provide each other with any information or assistance that either may reasonably request. HPA shall keep Emergent informed of developments in any such action or proceeding, including, to the extent permissible, the status of any settlement negotiations and the terms of any offer related thereto.

#### 9.2.3 Cooperation.

- (a) In General. HPA shall regularly provide Emergent with copies of all Patent applications filed under this Section 9.2 and other material submissions and correspondence with any patent authorities, as applicable, in sufficient time to allow for review and comment by Emergent. In addition, HPA shall provide Emergent and its counsel with an opportunity to consult with HPA and its counsel regarding the filing and contents of any application, amendment, registration, submission, response or correspondence with any patent authorities, and HPA shall accede to reasonable requests of Emergent regarding the filing and prosecution of the HPA Patents. HPA agrees to retain counsel designated by Emergent for the purpose of filing, prosecuting and maintaining Patents with respect to any HPA Technology for which Patent protection is first sought after the Effective Date, at the shared expense of Emergent and such other Persons as may be granted licenses thereunder by HPA consistent with the limitations of this Agreement.
- (b) <u>Patent Term Restoration</u>. The Parties hereto shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable HPA Patents have issued. In the event that elections with respect to obtaining such patent term restoration are to be made, Emergent shall have the right to make the election and HPA agrees to abide by such election.
- 9.2.4 Election not to Prosecute. If HPA elects not (a) to pursue the filing, prosecution or maintenance of a HPA Patent in a Jurisdiction, or (b) to take any other action with respect to a HPA Patent in a Jurisdiction that is necessary or useful to establish or preserve rights thereto, then in each such case ((a) and (b)) HPA shall so notify Emergent promptly in writing and in good time to enable Emergent to meet any deadlines by which an action must be taken to establish or preserve any such rights in such HPA Patent in such Jurisdiction. Upon receipt of each such notice from HPA or if, at any time, HPA fails to initiate any such action within thirty (30) days after a request by Emergent that it do so (or within such shorter time as may be required to prevent the forfeiture of such HPA Patent, at its expense in such Jurisdiction. If Emergent shall have the right, but not the obligation, to pursue the filing or registration, or support the continued prosecution or maintenance, of such HPA Patent, at its expense in such Jurisdiction. If Emergent elects to pursue such filing or registration, as the case may be, or continue such support, then Emergent shall notify HPA of such election and HPA shall, and shall cause its Affiliates to, (i) reasonably cooperate with Emergent in this regard, and (ii) promptly release or assign to Emergent, without consideration, all right, title and interest in and to such HPA Patent in such Jurisdiction.

# 9.3 Enforcement of BT Licensed Patents

9.3.1 <u>Rights and Procedures</u>. If either Party determines that any HPA Patent is being infringed by a Third Party's activities and that such infringement could affect the exercise by Emergent of its rights and obligations under this Agreement, it shall notify the other Party in writing and provide it with any evidence of such infringement that is reasonably available. Emergent shall have the first right, but not the obligation, to attempt to remove such infringement by commercially appropriate steps, including filing an infringement suit or taking other similar action, at its own expense. If required by law in order for Emergent to prosecute

such suit, HPA shall join such suit as a Party, at Emergent's expense. HPA shall use its best efforts to obtain any consents required by Third Parties owning Licensed HPA Patents in order to authorize Emergent to take legal action to remove such infringement. In the event Emergent fails within one hundred and twenty (120) days following notice of such infringement, or earlier notifies HPA in writing of its intent not to take commercially appropriate steps to remove any infringement of any such HPA Patent, HPA may do so at its own expense; provided, however, that if HPA fails to bring such suit or otherwise terminate such infringement within one hundred and twenty (120) days of its first having the right to do so, Emergent shall be permanently relieved of its royalty prosecuting such suit, and (b) the date that such infringement is otherwise terminated. The Party not enforcing the applicable HPA Patent shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence, making its employees available at reasonable business hours, and joining the action to the extent necessary to allow the enforcing Party to maintain the action.

- 9.3.2 <u>Costs and Expenses</u>. Any amounts recovered by either Party pursuant to Section 9.3.1, whether by settlement or judgment, shall be used to reimburse the Parties for their reasonable costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses), with any remainder being retained by or paid to Emergent and being deemed "Net Sales" for which Emergent shall pay HPA a royalty under Section 5.1 or 5.2(a), as the case may be.
- 9.3.3 <u>Certification Under FFDCA</u>. HPA shall inform Emergent of any certification regarding any HPA Patents it has received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vii) (IV) or such similar laws as may exist in jurisdictions other than the United States and shall provide Emergent with a copy of such certification within five (5) days of receipt. HPA's and Emergent's rights with respect to the initiation and prosecution of any legal action as a result of such certification or any recovery obtained as a result of such legal action shall be as defined in Sections 9.3.1 and 9.3.2.
- 9.3.4 Certification Under Drug Price Competition and Patent Restoration Act. HPA and Emergent each shall immediately give notice to the other of any certification of which they become aware filed by a Third Party under the United States Drug Price Competition and Patent Term Restoration Act of 1984 claiming that HPA Patents covering Licensed Products are invalid or that infringement will not arise from the manufacture, use or sale of Licensed Products by such Third Party. If HPA or Emergent (depending on which Party is defending the HPA Patents in accordance with Section 9.3.1) decides not to bring infringement proceedings against the entity making such a certification, such Party shall give notice to the other Party of its decision not to bring suit within twenty-one (21) days after receipt of notice of such certification. The Party receiving such notice may then, but is not required to, bring suit against the Party that filed the certification. Any suit by Emergent or HPA shall either be in the name of Emergent or in the name of HPA, or jointly by Emergent and HPA. For this purpose, the Party not bringing suit shall execute such legal papers necessary for the prosecution of such suit as may be reasonably requested by the Party bringing suit.

# 9.4 Infringement of Third Party Rights.

- 9.4.1 Third Party Litigation. In the event that a Third Party institutes a patent, trade secret, trademark or other infringement suit against Emergent or its Affiliates or sublicensees during the term of this Agreement, alleging that the practice by Emergent of the HPA Technology in the exercise of its rights as licensee under this Agreement infringes one or more patent, trademark, trade secret or other intellectual property rights held by such Third Party (an "Infringement Suit"), then (i) as between the Parties, Emergent shall assume direction and control of the defense of claims arising therefrom (including the right to settle such claims at its sole discretion), and (ii) Emergent may withhold and deposit into an interest-bearing escrow account [\*\*] percent ([\*\*]%) of all amounts that Emergent would otherwise be obligated to pay to HPA pursuant to Article V (the "Escrowed Amount"), and Emergent's payment obligations to HPA under Article V shall be reduced accordingly, until such time as a final, non-appealable judgment is rendered with respect to such Infringement Suit by a court of competent jurisdiction, or the time permitted for appeal of a final, appealable judgment has lapsed (the "Final Judgment"). If Final Judgment is rendered in favor of Emergent (or its Affiliates or sublicensees, as the case may be), then Emergent shall pay to HPA, within ten days after the entry of such judgment, the full amount of the Escrowed Amount. If the Final Judgment is rendered partially or entirely in favor of such Third Party, then Emergent may apply the Escrowed Amount to the payment of its defense costs in connection with such Infringement Suit and to the payment of any award it is required to pay pursuant to such Final Judgment. If the Escrowed Amount exceeds such defense costs and award then Emergent, within ten (10) days following the date of the Final Judgment, shall remit to HPA the amount of such defense costs and award then Emergent would otherwise be required to pay to HPA pursuant to Article V until such time
- 9.4.2 Cooperation. In the event that a Third Party institutes a Patent, Trademark, trade secret or other infringement suit against Emergent or its Affiliates or Sublicensees during the term of this Agreement, HPA shall use, and shall cause its Affiliates and any Third Parties owning relevant HPA Patents to use commercially reasonable efforts to assist and cooperate with Emergent in connection with the defense of such suit
- 9.4.3 Retained Rights. Nothing in this Section 9.4 shall prevent either Party, at its own expense, from obtaining any license or other rights from Third Parties it deems appropriate in order to permit the full and unhindered exercise of its rights under this Agreement.

# ARTICLE X Term and Termination

10.1 Term and Expiration. This Agreement shall become effective as of the Effective Date and unless terminated earlier pursuant to Section 10.2, 10.3, 10.4, 10.5 or 10.9, the term of this Agreement shall continue in effect until expiration of all royalty obligations hereunder. Upon expiration of this Agreement, Emergent's licenses under Section 3.1 and HPA's licenses under Section 3.3 shall become fully paid-up, perpetual licenses, and the

covenants in Section 3.4(a) and 3.4(b) shall survive with respect to such intellectual property of HPA and Emergent, respectively, as has been incorporated into the Licensed Products or HPA Products, as the case may be, as of the date of expiration of this Agreement.

- 10.2 Termination by Emergent without Cause. Notwithstanding anything contained herein to the contrary, Emergent shall have the right to terminate this Agreement in its entirety or with respect to one or more countries at any time in its sole discretion by giving one hundred and eighty (180) days' written notice to HPA.
- 10.3 Termination by HPA in Certain Events. In the event that (a) Emergent terminates the BT Development Agreement without cause prior to performing its obligations under Section 3.4 thereof, (b) HPA terminates the BT Development Agreement pursuant to Section 11.3 thereof, or (c) Emergent challenges the validity of the HPA Patents, or knowingly and voluntarily assists a Third Party to do so, HPA shall have the right upon written notice to Emergent to terminate this Agreement.
- **10.4 Termination by Emergent for Material Breach by HPA under the BT Development Agreement.** In the event that Emergent terminates the BT Development Agreement pursuant to Section 11.4 thereof, Emergent shall have the right upon written notice to HPA to terminate this Agreement.
- 10.5 Termination of this Agreement by Either Party for Material Breach. Material failure by HPA to comply with any of its material obligations contained herein, or material failure by Emergent to make payments owed to HPA pursuant to this Agreement, shall entitle the Party not in default to give to the Party in default notice specifying the nature of the default, requiring the defaulting Party to make good or otherwise cure such default, and stating its intention to terminate if such default is not cured. In the event that Emergent is the notifying Party, Emergent shall have the right, in addition to all other remedies available to it by law, in equity or pursuant to this Agreement, to suspend payment of any amounts that it would otherwise owe to HPA hereunder until such time as the material breach of HPA is cured (whereupon such suspended amounts shall be paid). If a noticed default is not cured within thirty (30) days (the "Cure Period") after the receipt of such notice (or, if such default cannot be cured within such thirty (30)-day period, if the Party in default does not commence actions to cure such default within the Cure Period and thereafter diligently continue such actions), the Party not in default shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement in its entirety; provided, however, that any right to terminate under this Section 10.5 shall be stayed in the event that, during any Cure Period, the Party alleged to have been in default shall have initiated dispute resolution in accordance with Section 11.7 with respect to the alleged default, which stay shall last so long as the initiating Party diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings.

# 10.6 Consequences of Termination by Emergent.

10.6.1 Termination by Emergent without Cause. In the event that Emergent terminates this Agreement in its entirety pursuant to Section 10.2, as of the effective date of such

termination, the licenses granted by HPA to Emergent in Section 3.1, the licenses granted by Emergent to HPA in Section 3.3, and the covenants in Section 3.4 shall terminate.

- 10.6.2 <u>Termination by Emergent for Cause</u>. In the event that Emergent terminates this Agreement pursuant to Section 10.4 or 10.5, as of the effective date of such termination, the following terms and conditions shall apply:
- (a) for five (5) years after the effective date of such termination, HPA shall not compete with Emergent in the Field (subject to HPA's Retained Rights under Section 3.3), or grant to a Third Party a license under the BT Technology enabling such Third Party to Exploit a recombinant product that (i) comprises one or more *C. botulinum* toxin fragments, (ii) acts to stimulate an immune response, and (iii) is designed for use in the Field;
- (b) HPA shall compensate Emergent for any damages that Emergent suffers as a result of such breach, first, through a lump sum payment up to the maximum amount permitted under Section 7.4(b), and then pursuant to Section 7.4(b) through a set-off against Emergent's payment obligations under Article V, provided that upon the full payment of such compensation, the applicable royalty rate shall be reduced to [\*\*] percent ([\*\*]%) of the rate that would otherwise apply under the terms of Article V; and
- (c) The licenses granted by HPA to Emergent in Section 3.1, the royalty obligations of Emergent under Article V (as modified pursuant to subparagraph (b) above), the covenant in Section 3.4(a), and the provisions of Article IX shall survive such termination. The licenses granted by Emergent to HPA in Section 3.3 and the covenant in Section 3.4(b) shall terminate.
  - 10.6.3 Rights Cumulative. The rights and remedies in this Section 10.6 shall be cumulative and in addition to any other rights or remedies that may be available to Emergent.

# 10.7 Consequences of Termination by HPA.

- 10.7.1 <u>Termination by HPA</u>. In the event that HPA terminates this Agreement pursuant to Section 10.3 or 10.5, as of the effective date of such termination, the licenses granted by Emergent to HPA in Section 3.3, the licenses granted by HPA to Emergent in Section 3.1, and the covenants in Section 3.4 shall terminate.
  - 10.7.2 Rights Cumulative. The rights and remedies in this Section 10.7 shall be cumulative and in addition to any other rights or remedies that may be available to HPA.

# 10.8 Accrued Rights; Survival; Work in Progress; Return of Information.

10.8.1 <u>Accrued Rights</u>. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

- 10.8.2 <u>Survival</u>. In addition to any other Section of this Agreement which by its express terms survives, or provides for survival upon the termination or expiration of this Agreement, Sections 3.2, 5.7, 7.1, 7.2, 7.3, 7.4, 9.1, 10.6, 10.7, 10.10, 11.2, 11.3, 11.5, 11.6, 11.7, 11.8, 11.9, 11.14, 11.16, 11.17, and this Section 10.8, and Articles IV and VI, shall survive the termination or expiration of this Agreement for any reason.
- 10.8.3 Work-in-Progress. Upon termination of this Agreement by HPA pursuant to Section 10.7.1, Emergent shall be entitled, during the following ninety (90) days, to finish any work-in-progress and to sell any inventory of the Licensed Products that remains on hand as of the date of the termination, so long as Emergent pays HPA the royalties applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement.
- 10.8.4 Return of Information. Within ninety (90) days of the expiration or termination of this Agreement, each Party shall deliver to the other Party any and all data, files, records and other materials in its possession or under its Control that constitute the Confidential Information of such other Party, to which the first Party does not retain rights hereunder (except that each Party shall have the right to retain one copy of each of the foregoing solely for archival purposes) Except as may be provided otherwise in this Agreement, each Party shall cease using any technology of the other Party to which its license hereunder has terminated, except to the extent that such technology has entered the public domain or that such Party has secured rights under such technology through contract, agreement, arrangement or otherwise.
- 10.9 Termination upon Insolvency. Either Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a Party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.
- 10.10 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Emergent or HPA are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the United States Bankruptcy Code, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the

rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

# ARTICLE XI Miscellaneous

- 11.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, when such failure or delay is caused by or results from causes beyond the reasonable control of the non-performing Party, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority. The non-performing Party shall notify the other Party of such force majeure within ten (10) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for one-hundred and eighty (180) days after the date of the occurrence, the Parties shall meet and discuss in good faith how best to proceed.
- 11.2 Export Control Regulations. The rights and obligations of the Parties under this Agreement shall be subject in all respects to United States laws and regulations and the analogous laws and regulations of England, as shall from time to time govern the license and delivery of technology and products between the United States and the United Kingdom, including the United States Foreign Assets Control Regulations, Transaction Control Regulations and Expert Control Regulations, as amended, and any successor legislation issued by the Department of Commerce, International Trade Administration, Office of Export Licensing. Without in any way limiting the provisions of this Agreement, each party agrees that, unless prior authorization is obtained from the Office of Export Licensing, it shall not export, re-export, or transship, directly or indirectly, to any country, any of the technical data disclosed to it by the other party if such export would violate the laws of the United States or the regulations of any department or agency of the United States Government.
- 11.3 Assignment. Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate, charge, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder, nor purport to do any of the same; provided, however, that Emergent may, without such consent, assign the benefit of this Agreement and its rights hereunder to an Affiliate, to the purchaser of all or substantially all of its assets, or to any Third Party pursuant to or in connection with any agreement and plan of merger, acquisition, reorganization, or other similar corporate transaction; and provided, further, that HPA may, without such consent, assign the benefit of this Agreement and its rights hereunder to an Affiliate or to a Third Party pursuant to or in connection with a spin-off of its business relating to the Development Program (as defined in the BT Development Agreement) and the Exploitation of Licensed Products and HPA Products, provided however, that no such assignment may be made to any Third Party, or any

Person controlled by any Third Party, that is at the time of such assignment a competitor of Emergent in the Field; and provided, further, that notwithstanding any other provision of this Agreement, HPA may not assign or otherwise transfer in any manner to any Third Party any of the Retained Rights, any of the licenses granted to HPA in Section 3.3(c), or any rights of HPA under Section 3.4. Any attempted assignment in violation of the preceding sentence shall be void and of no effect. All validly assigned rights of the Parties shall be binding upon and inure to the benefit of and be enforceable by the permitted assigns of Emergent or HPA, as the case may be. No assignment validly made pursuant to this Section 11.3 shall relieve the assigning Party of any of its obligations under this Agreement, unless the other Party has given its prior consent thereto.

11.4 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) the Parties agree to attempt to substitute for any such illegal, invalid or unenforceable provision as legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof prohibited or unenforceable in any respect.

11.5 Notices. All notices or other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (promptly confirmed by personal delivery or courier as provided herein) or sent by internationally-recognized overnight courier, addressed as follows:

if to HPA, to: Health Protection Agency

Porton Down

Salisbury, Wiltshire SP4 0JG England Attention: Dr. David Rhodes Facsimile No.: +44-1980-61-22-41

with a copy to: Legal Department

Health Protection Agency

Porton Down

Salisbury, Wiltshire SP4 0JG England Facsimile No.: +44-1980-61-22-41

 $if to \ Emergent, to: \qquad Emergent \ Bio Solutions, Inc.$ 

300 Professional Drive

Gaithersburg, Maryland 20879 USA Attention: General Counsel Facsimile No.: +1-301-590-1252 with a copy to: Covington & Burling

One Front Street, 35th Floor San Francisco, California 94111 USA Attention: James C. Snipes, Esq. Facsimile No.: +1-415-591-6091

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication shall be deemed to have been given when delivered if personally delivered on a Business Day, when transmitted if sent by facsimile (in accordance with this Section 11.5) on a Business Day, and on the third (3rd) Business Day after dispatch if sent by internationally-recognized courier. It is understood and agreed that this Section 11.5 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

11.6 Governing Law. This Agreement shall be governed by and construed in accordance with English law, without reference to the rules of conflict of laws thereof. Subject to Section 11.7, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of (i) the courts of the State of New York and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) initiated by HPA and arising out of or relating to this Agreement, and (ii) the English courts located in London for any action, suit or proceeding (other than appeals therefrom) initiated by Emergent and arising out of or relating to this Agreement. The Parties agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts, respectively. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or the United States District Court for the Southern District of New York or the English courts located in London, as the case may be, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Each Party hereto further agrees that service of any process, summons, notice or document by internationally recognized courier to its address set forth above shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

# 11.7 Dispute Resolution

11.7.1 <u>Negotiation</u>. The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement (or any document or instrument delivered in connection herewith) (each, a "Dispute"). In the event that the Parties are unable to, within ten (10) days, to reach a resolution, such Dispute shall be referred to the chief executive officers of Emergent and HPA, or their respective successors, who shall attempt in good faith to reach a resolution of the Dispute. If the foregoing procedures fail to achieve a mutually satisfactory resolution within ten (10) days, then either Party may, by written notice to the other Party, elect to have the matter settled by binding arbitration pursuant to Section 11.7.2.

11.7.2 <u>Arbitration</u>. Any arbitration under this Agreement shall take place at a location to be agreed by the Parties; <u>provided</u>, <u>however</u>, that in the event that the Parties are unable to agree on a location for an arbitration under this Agreement within five (5) days of the demand therefor, such arbitration shall be held in New York, New York if HPA is the Party that first demanded such arbitration or in London, England if Emergent is the Party that first demanded such arbitration arbitration under this Agreement shall be administered by the American Arbitration Association under its Commercial Arbitration Rules then in effect (the "AAA Rules"). The Parties shall appoint an arbitrator by mutual agreement. If the Parties cannot agree on the appointment of an arbitrator within thirty (30) days of the demand for arbitration, an arbitrator shall be appointed in accordance with AAA Rules. The arbitrator shall have the authority to grant any equitable and legal remedies that would be available in any judicial proceeding instituted to resolve the Dispute submitted to such arbitration in accordance with this Agreement; <u>provided</u>, <u>however</u>, that the arbitrator shall not have the power to alter, amend or otherwise affect the terms or the provisions of this Agreement. Judgment upon any award rendered pursuant to this Section may be entered by any court having jurisdiction over the Parties other assets. The arbitrator shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrator's fees and any administrative fees of arbitration, unless the arbitrator shall otherwise allocate such costs, expenses and fees between the Parties. The Parties agree that all arbitration awards shall be final and binding on the Parties and their Affiliates. The Parties hereby waive the right to contest the award in any court or other forum. Except to the extent necessary to confirm

11.7.3 Interim Relief. Notwithstanding anything herein to the contrary, nothing in this Section 11.7 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, either prior to or during any arbitration hereunder, if necessary to protect the interests of such Party. This Section 11.7.3 shall be specifically enforceable.

11.8 Equitable Relief. HPA acknowledges and agrees that the restrictions set forth in Section 3.4 and Article IV of this Agreement are reasonable and necessary to protect the legitimate interests of Emergent and that Emergent would not have entered into this Agreement in the absence of such restrictions, and that any violation or threatened violation of any provision of Section 3.4 or Article IV will result in irreparable injury to Emergent. HPA also acknowledges and agrees that in the event of a violation or threatened violation of any provision of Section 3.4 or Article IV, Emergent shall be entitled to preliminary and permanent injunctive relief, without the necessity of proving irreparable injury or actual damages and without the necessity of having to post a bond, as well as to an equitable accounting of all earnings, profits and other benefits arising from any such violation. The rights provided in the immediately preceding sentence shall be cumulative and in addition to any other rights or remedies that may be available to Emergent. Nothing in this Section 11.8 is intended, or should be construed, to

limit Emergent's right to preliminary and permanent injunctive relief or any other remedy for a breach of any other provision of this Agreement.

- 11.9 No Benefit to Third Parties. Article II confers a benefit on those Persons referred to in Section 2.9 (the "Emergent Beneficiaries") and, subject to the remaining provisions of this Section 11.9, is intended to be enforceable by the Emergent Beneficiaries by virtue of the Contracts (Rights of Third Parties) Act 1999 (the "Act"). The Parties do not intend that any provisions of this Agreement, apart from those of Article II, should be enforceable by virtue of the Act by any person who is not a party to this Agreement. Notwithstanding the provisions of this Section 11.9, this Agreement may be rescinded or amended in any way and at any time by the Parties in accordance with its terms, without the consent of any of the Emergent Beneficiaries.
- 11.10 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm the rights and remedies of the other Party under this Agreement.
- 11.11 English Language. This Agreement shall be written and executed in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control. All notices and other disclosure required of the Parties hereunder shall be in English.
- 11.12 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section, Paragraph, Schedule or Exhibit shall mean references to such Article, Section, Paragraph, Schedule or Exhibit of this Agreement, (b) references in any section to any clause are references to such clause of such section, and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, as so varied, replaced or supplemented and in effect at the relevant time of reference thereto.
- 11.13 Independent Contractors. It is expressly agreed that HPA and Emergent shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither HPA nor Emergent shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other Party. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.
- 11.14 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or the failure to exercise, or any

delay in exercising a right or remedy provided by this Agreement or by law, or the waiver of a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

- 11.15 Counterparts. The Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 11.16 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties, and no rule of strict construction shall be applied against either Party.
- 11.17 Entire Agreement; Modifications. This Agreement, together with the BT Development Agreement, the rBOT Development Agreement, the rBOT License Agreement, and the Distribution Agreement, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understanding, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment, modification, release or discharge hereof shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

Emergent BioSolutions, Inc.		Health Protection Agency	
Ву:	/s/ Fuad El-Hibri Fuad El-Hibri	Ву:	/s/ Pat Troop Pat Troop
Title:	Chairman and CEO	Title:	CEO
			- 43 -

### Schedule 1.34

### HPA Know-How

In addition to the public domain information contained in patent filings and publications, HPA staff are able to provide know-how in the technologies listed below. Much of this knowledge is recorded in HPA Laboratory notebooks according to the site-wide quality system BS EN ISO 9001 (2002), however, substantial know-how in the area of recombinant botulinum toxin fragments exists at HPA in the form of its staff's knowledge, cumulative experience and training.

Molecular technologies:
• [\*\*]

Protein technologies:

[\*\*]

## Schedule 1.35 HPA Patents

## A. Owned HPA Patents

Patent No. Patent Type

[\*\*]

B. Licensed HPA Patents

Patent No. Patent Title HPA License Agreements Agreement Date

[\*\*]

## <u>Schedule 3.3(c)</u> Emergent Patents and Know-How

**Emergent Patents** 

None

Emergent Know-How

None

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

#### BT VACCINE DEVELOPMENT AGREEMENT

THIS BT VACCINE DEVELOPMENT AGREEMENT (this "Agreement"), effective as of November 23, 2004, (the "Effective Date"), by and between Emergent BioSolutions, Inc., a corporation organized and existing under the laws of the State of Delaware ("Emergent"), and the Health Protection Agency, a governmental agency organized and existing under the laws of England ("HPA") (each of Emergent and HPA, a "Party").

#### WITNESSETH ·

WHEREAS, Emergent, which is the parent company of BioPort Corporation, desires to develop one or more pharmaceutical products comprising toxoid components, which products are designed for the prevention or treatment of illness caused by *C. botulinum* toxin;

WHEREAS, HPA has expertise, intellectual property and biological materials that would be useful in the development of such products;

WHEREAS, Emergent desires to engage HPA to perform certain development activities with respect to such products, on the terms and conditions set forth below;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants of the parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, do hereby agree as follows:

### ARTICLE I Definitions

Unless specifically set forth to the contrary herein, the following terms shall have the respective meanings set forth below:

- 1.1 "AAA Rules" shall have the meaning set forth in Section 12.7.2.
- 1.2 "Act" shall have the meaning set forth in Section 12.9.
- 1.3 "Affiliate" shall mean, (a) with respect to Emergent, any Person that, directly or indirectly, through one or more intermediaries, controlls, is controlled by, or is under common control with Emergent, and (b) with respect to HPA, any Person that, directly or indirectly, through one or more intermediaries, is controlled by HPA. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, by application of applicable law, or otherwise, or (b) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity); provided that, if local law restricts foreign

ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests.

- 1.4 "Agreement" shall have the meaning set forth in the preamble hereto.
- 1.5 "Applicable Law" shall mean all laws, rules, regulations applicable to the Exploitation of the Licensed Products, including any such rules, regulations, guidelines, or other requirements of the Regulatory Authorities, that may be in effect from time to time in the Territory.
- 1.6 "BT License Agreement" shall mean that certain BT Vaccine License Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms
  - 1.7 "BT Licensed Know-How" shall have the meaning set forth in the BT License Agreement.
  - 1.8 "BT Licensed Patents" shall have the meaning set forth in the BT License Agreement.
  - 1.9 "BT Licensed Technology" shall have the meaning set forth in the BT License Agreement.
  - 1.10 "Business Day" shall mean any day other than a Saturday, Sunday, any public holiday and any bank holiday in either the United States or England.
  - 1.11 "Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
  - 1.12 "Calendar Year" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.
- 1.13 "Clinical Trials" shall mean, with respect to a Licensed Product, all tests and studies in patients that are required by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise, for Regulatory Approval of such product.
- 1.14 "Commercially Reasonable Efforts" shall mean, with respect to the development, Manufacture or commercialization of a Licensed Product, the level of efforts and resources customarily applied in the research-based pharmaceutical industry to a product of similar commercial potential at a similar stage in its lifecycle, taking into consideration its safety and efficacy, its cost to develop, the competitiveness of alternative products, its proprietary position, the likelihood of regulatory approval, its profitability, and all other relevant factors. Commercially Reasonable Efforts shall be determined on a country-by-country basis for each Licensed Product.
  - 1.15 "Confidential Information" shall have the meaning set forth in Section 6.3.1.

- 1.16 "Control" shall mean, with respect to any item of Information and Invention, Patent, Trademark or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such Information and Invention, Patent, Trademark or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.
- 1.17 "Development Activities" shall mean (a) those tests, studies and other activities set forth in, or required to be conducted in order to obtain the information set forth in, the Development Plan; and (b) such other tests, studies and other activities with respect to the Licensed Product(s) as may be agreed to in writing from time to time by the Parties.
  - 1.18 "Development Budget" shall have the meaning set forth in Section 3.1.
  - 1.19 "Development Plan" shall mean the list and schedule of activities contained in Schedule 1.19, as may be amended by the parties from time to time in accordance with Section 12.17.
  - 1.20 "Development Program" shall mean the Development Activities carried out by the parties pursuant to this Agreement.
  - 1.21 "Development Program Term" shall have the meaning set forth in Section 2.10.2
- 1.22 "Distribution Agreement" shall mean that certain Exclusive Distribution Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms
  - 1.23 "Dispute" shall have the meaning set forth in Section 12.7.1.
- 1.24 "Drug Master File" shall mean any drug master file filed with the FDA with respect to any Licensed Product or any intermediate thereof, and any equivalent filing in other countries or regulatory jurisdictions.
  - 1.25 "Effective Date" shall mean the date of this Agreement as set forth in the preamble hereto.
  - 1.26 "Emergent" shall have the meaning set forth in the preamble hereto.
  - 1.27 "Emergent Beneficiaries" shall have the meaning set forth in Section 12.9.
  - 1.28 "Emergent Information" shall have the meaning set forth in Section 6.1.2.
- 1.29 "Emergent Technology" shall mean any Information and Inventions owned or Controlled by Emergent during the term of this Agreement that are reasonably necessary for the performance by HPA of its designated Development Activities and as to which Emergent does not have royalty obligations to a Third Party.

- 1.30 "Exploit" shall mean to make, have made, import, use, sell, or offer for sale, including to research, develop, register, modify, enhance, improve, Manufacture, have Manufactured, store, formulate, have used, export, transport, distribute, promote, market or have sold or otherwise dispose of.
- 1.31 "Exploitation" shall mean the making, having made, importation, use, sale, offering for sale or disposition of a product or process, including the research, development, registration, modification, enhancement, improvement, Manufacture, storage, formulation, optimization, import, export, transport, distribution, promotion or marketing of a product or process.
- 1.32 "Facility" shall mean the vaccine production unit within HPA's pharmaceutical production center located at Porton Down, Salisbury, Wilshire, England, at which HPA shall conduct the Development Activities designated for HPA, or such other facilities as the Parties may mutually agree in writing.
  - 1.33 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.
  - 1.34 "FFDCA" shall mean the United States Federal Food Drug and Cosmetic Act, as amended from time to time.
  - 1.35 "Field" shall mean the prevention or treatment of illness in humans caused by C. botulinum toxin.
  - 1.36 "GAAP" shall mean United States generally accepted accounting principles, consistently applied.
- 1.37 "Good Manufacturing Practices" shall mean the current good manufacturing practices applicable from time to time to the Manufacturing of any Licensed Product or any intermediate thereof pursuant to Applicable Law.
  - 1.38 "HPA" shall have the meaning set forth in the preamble.
- 1.39 "Improvement" shall mean any modification, variation or revision to a compound, product or technology or any discovery, technology, device, process or formulation related to such compound, product or technology, whether or not patented or patentable, including any enhancement in the efficiency, operation, Manufacture (including any manufacturing process), ingredients, preparation, presentation, formulation, means of delivery, packaging or dosage of such compound, product or technology, any discovery or development of any new or expanded indications for such compound, product or technology, or any discovery or development that improves the stability, safety or efficacy of such compound, product or technology.
- 1.40 "IND" shall mean an investigational new drug application filed with the FDA for authorization to commence human clinical trials, and its equivalent in other countries or regulatory jurisdictions in the Territory.
  - 1.41 "Indemnification Claim Notice" shall have the meaning set forth in Section 8.3.1.

- 1.42 "Indemnified Party" shall have the meaning set forth in Section 8.3.1.
- 1.43 "Information and Inventions" shall mean all technical, scientific and other know-how, show-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer software, apparatuses, specifications, data, cell lines, seed stock and other biological materials, pre-clinical and clinical trial results, Manufacturing procedures, test procedures and purification and isolation techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed, and all Improvements, whether to the foregoing or otherwise, and other discoveries, developments, inventions, and other intellectual property (whether or not confidential, proprietary, patented or patentable), but excluding the Regulatory Documentation.
- 1.44 "Joint Inventions" shall mean any and all Information and Inventions that are (a) first conceived, discovered, developed or otherwise made jointly, as necessary to establish joint authorship, inventorship or ownership under applicable copyright or patent law, as the case may be, by or on behalf of, on the one hand, HPA or any of its Affiliates or their respective employees and agents, and, on the other hand, Emergent or any of its Affiliates or their respective employees and agents, during the term of this Agreement; (b) first conceived, discovered, developed or otherwise made, as necessary to establish authorship, inventorship or ownership under applicable copyright or patent law, as the case may be, by or on behalf of Emergent, its Affiliates or any of their respective employees and agents, either alone or jointly with a Third Party(ies), during the term of this Agreement, in connection with or arising from the Development Activities; or (c) first conceived, discovered, developed or otherwise made, as necessary to establish authorship, inventorship or ownership under applicable copyright or patent law, as the case may be, by or on behalf of, HPA, its Affiliates or any of their respective employees and agents, either alone or jointly with a Third Party(ies), during the term of this Agreement, in connection with or arising from the Development Activities.
- 1.45 "Joint Know-How" shall mean all Information and Inventions, to the extent not generally known, that are included in the Joint Inventions, but excluding any Information and Inventions to the extent claimed or covered by the Joint Patents.
  - 1.46 "Joint Patents" shall mean any Patents to the extent that such Patents claim or cover Joint Inventions.
  - 1.47 "Joint Technology" shall mean, collectively, the Joint Patents and the Joint Know-How.
  - 1.48 "Key Personnel" shall have the meaning set forth in Section 2.3.
- 1.49 "Licensed Product" shall mean a pharmaceutical product that (a) comprises one or more toxoid components that acts to stimulate an immune response, (b) is developed pursuant to this Agreement for use in the Field, and (c) comprises, is comprised of (in whole or in part), or is Exploited using, BT Licensed Technology.
  - 1.50 "Losses" shall have the meaning set forth in Section 8.1.

- 1.51 "Manufacture" and "Manufacturing" shall mean, with respect to a product or compound, the manufacturing, processing, formulating, packaging, labeling, holding and quality control testing of such product or compound.
- 1.52 "Marketing Authorization" shall mean a New Drug Application or Biologics License Application, each as defined in the FFDCA, and the regulations promulgated thereunder, and any corresponding foreign application, registration or certification, necessary or reasonably useful to market a Licensed Product in the Territory, but not including pricing and reimbursement approvals.
  - 1.53 "Master Services Agreement" shall mean that certain Master Services Agreement, dated as of March 17, 2004, by and between HPA and BioPort Corporation, an Affiliate of Emergent.
  - 1.54 "Minimum Commitment" shall have the meaning set forth in Section 3.4.
  - 1.55 "Party" shall have the meaning set forth in the preamble hereto.
- 1.56 "Patents" shall mean (a) all patents and patent applications, (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patents or patent application, and (c) any foreign or international equivalent of any of the foregoing.
- 1.57 "Person" shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government (whether or not having a separate legal personality).
- 1.58 "rBOT Development Agreement" shall mean that certain rBOT Vaccine Development Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
- 1.59 "rBOT License Agreement" shall mean that certain rBOT Vaccine License Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms
- 1.60 "Regulatory Approval" shall mean any and all approvals (including pricing and reimbursement approvals), governmental licenses, registrations or authorizations of any Regulatory Authority, necessary for the Exploitation of the Licensed Product(s) in a country in the Territory, including any (a) approval of any Licensed Product (including any INDs, Marketing Authorizations and supplements and amendments thereto); (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); (c) labeling approval; and (d) technical, medical and scientific licenses.
  - 1.61 "Regulatory Authority" shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus,

commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of the Licensed Product(s) in the Territory, but excluding HPA acting in its capacity as a Party.

- 1.62 "Regulatory Documentation" shall mean all applications, registrations, governmental licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests, relating to any Licensed Product, and all data contained in any of the foregoing, including all INDs, Marketing Authorizations, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files and Manufacturing records (including Manufacturing records maintained pursuant to Section 2.9.3 and any Drug Master Files prepared and filed by HPA).
  - 1.63 "Retained Rights" shall have the meaning set forth in Section 5.3.
  - 1.64 "Territory" shall mean all of the countries in the world.
  - 1.65 "Third Party" shall mean any Person other than Emergent, HPA and their respective Affiliates.
  - 1.66 "Third Party Claim" shall have the meaning set forth in Section 8.3.2.
- 1.67 "Trademark" shall include any word, name, symbol, color, designation or device or any combination thereof, including any trademark, trade dress, brand mark, trade name, brand name, logo or business symbol.
  - 1.68 "U.K. Public Entity" shall mean any national, local, regional or provincial governmental agency in the United Kingdom, including any component of the National Health Service.
- 1.69 "Vaccine Product" shall mean any pharmaceutical product containing one or more immunomodulators that acts to stimulate an immune response and is intended for the prevention or treatment of disease in humans.

#### ARTICLE II Development Program

- 2.1 In General. HPA shall perform, or cause to be performed, the Development Activities designated for HPA in the Development Plan, in accordance with the terms and conditions of this Agreement, including the Development Budget. The goal of the Development Plan shall be to develop one or more Licensed Products in accordance with this Agreement.
- 2.2 Conduct of Development Program. HPA shall conduct the Development Program (a) in good scientific manner, and in compliance in all material respects with all requirements of Applicable Law and agreed laboratory practices, and (b) using Commercially Reasonable Efforts to complete its designated Development Activities efficiently and

expeditiously, in accordance with the schedule set forth in the Development Plan and in compliance with the Development Budget.

2.3 Key Personnel. The Development Activities shall be conducted by each Party under the direction and supervision of one ore more scientists designated by such Party. The Parties shall also designate principal contacts with respect to the Development Program. HPA's scientific and technical personnel considered by Emergent to be central to the conduct of the Development Activities by HPA (the "Key Personnel") are listed on Schedule 2.3. HPA shall not substitute other persons for the Key Personnel or otherwise materially reduce the time commitment of any Key Personnel to the Development Program below the level listed for such Key Personnel in Schedule 2.3 without the prior written approval of Emergent, which approval shall not be unreasonably withheld.

#### 2.4 Coordination.

- 2.4.1 <u>Consultation</u>. During the Development Program Term, the primary contacts designated by the Parties shall discuss with each other the conduct and progress of the Development Program, by telephone or in person, not less frequently than weekly. Such discussions shall cover the status of the Development Activities, review relevant results and data, consider technical and other issues that have arisen, and review and advise on any scientific and budgetary matters relating to the Development Program.
- 2.4.2 Facility Visits. Emergent may arrange for a reasonable number of its employees and/or consultants to visit the Facility, at mutually agreed times, for the purpose of observing such Facility and meeting to discuss the Development Program work and its results with the employees of HPA.
- 2.4.3 <u>Oversight and Technology Transfer</u>. The Parties shall use good faith efforts to agree upon, in writing, suitable arrangements whereby (a) Emergent personnel can provide reasonable oversight of the Development Activities, and (b) Emergent personnel will be provided timely access to Key Personnel so as to fully understand the progress being achieved in the Development Program and to enable the prompt and effective transfer of technology from HPA to Emergent as contemplated by this Agreement.

## 2.5 Information Disclosure; Supply of Resources.

2.5.1 Information Disclosure. HPA shall, and shall cause its Affiliates to, disclose and make available to Emergent, in whatever form Emergent may reasonably request, (a) all Regulatory Documentation under the Control of HPA or its Affiliates, (b) all BT Licensed Know-How (subject, in the case of the After-Acquired HPA Know-How (as defined in the BT License Agreement), to the rights of any Third Parties therein), (c) all Joint Know-How (to the extent not known to Emergent), (d) any other Information and Inventions claimed or covered by any BT Licensed Patents or Joint Patents (to the extent not known to Emergent) or otherwise relating, directly or indirectly, to the Licensed Product(s), and (e) any and all Improvements thereto under the Control of HPA or its Affiliates, promptly after the Effective Date, and thereafter immediately upon the earlier of the conception, discovery, development, or making of such Regulatory Documentation, BT Licensed Know-How, Joint Know-How or other

Information and Inventions or Improvements; provided, however, that Emergent shall reimburse HPA for any reasonable and verifiable direct out-of-pocket costs and expenses incurred by HPA in making such disclosures, to the extent not covered in the Development Budget. Emergent may use such Regulatory Documentation and Information and Inventions solely in the exercise of its rights under the licenses granted to Emergent by HPA in Section 5.1 and in the BT License Agreement.

- 2.5.2 <u>Supply of Resources</u>. Subject to Emergent's payment obligations with respect to the Development Program pursuant to Section 3.1, HPA shall dedicate to the performance of the Development Activities, and make available to Emergent upon Emergent's request, at no cost to Emergent other than the costs provided for in the Development Budget, such (a) equipment, (b) quantities of cell lines, seed stocks, compounds, components (toxoid and otherwise) and other biological materials, and (c) other resources (including scientific, clinical, medical, regulatory, Manufacturing and other personnel), in each case as are reasonably necessary for the performance of the Development Activities; <u>provided</u>, <u>however</u>, that HPA's obligations under this Section 2.5.2 shall not include any obligation to provide to Emergent a commercial supply of Licensed Products.
- 2.6 Communications with Regulatory Authorities. Subject to the obligation of HPA to respond to any inspection or investigation by governmental or Regulatory Authorities in accordance with Section 2.8, Emergent shall have the sole right, in its sole discretion, to conduct all communications with the Regulatory Authorities with regard to the Development Activities; provided, however, that HPA in conjunction with Emergent may communicate with the governmental health and safety authorities in the United Kingdom with regard to its activities pursuant to this Agreement.

#### 2.7 Records and Reports

- 2.7.1 Records. HPA shall maintain records in good scientific manner and in sufficient detail for patent and regulatory purposes, and in compliance with Applicable Law, fully and properly documenting all work done and results achieved in the performance of the Development Program. Such records shall be retained by HPA for at least three (3) years after the termination of this Agreement, or for such longer period as may be required by Applicable Law. Upon request, HPA shall provide copies of the records it has maintained pursuant to this Section 2.7.1 to Emergent.
- 2.7.2 Copies and Inspection of Records. Emergent shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all records of HPA maintained pursuant to Section 2.7.1. Emergent shall maintain such HPA records and the information disclosed therein in confidence in accordance with Article VI.
- 2.7.3 Quarterly Reports. Within thirty (30) days following the end of each Calendar Quarter during which Development Program activities are being performed, HPA shall provide to Emergent a written progress report which shall describe the work performed to date on the Development Program, evaluate the work performed in relation to the goals of the Development Program and in relation to the Development Budget, and provide such other

information as may be required by the Development Plan or reasonably requested by Emergent relating to the Development Program.

2.8 Regulatory Inspections. If any governmental or Regulatory Authority (a) contacts HPA, any of its scientific staff or any other person performing Development Activities on HPA's behalf, with respect to the Development Activities, (b) conducts, or gives notice of its intent to conduct, an inspection at any facility of HPA used in the performance of its obligations hereunder, or (c) takes, or gives notice of its intent to take, any other regulatory action alleging improper or inadequate research practices (including the issuance of a "Notice of Inspectional Observations," "Warning Letter" or the equivalent) with respect to any activity of HPA, any of its scientific staff or any other person performing Development Activities on HPA's behalf, whether or not in connection with the services provided under this Agreement, HPA shall notify Emergent with five (5) Business Days of such contact or notice, or sooner if necessary to permit Emergent to be present at, or otherwise participate in, any such inspection or regulatory action with respect to the Development Activities, and shall supply Emergent with all information pertinent thereto. Emergent shall have the right to be present at and to participate in any such inspection or regulatory action with respect to the Development Activities. HPA shall provide Emergent with copies of all documentation issued by any governmental or Regulatory Authority in connection with such inspection or regulatory action and any response thereto proposed by HPA. No such responses shall contain any false or misleading information, or omit any information necessary to make such response not false or misleading, with respect to the Development Activities of HPA.

#### 2 9 Clinical Trials

- 2.9.1 Emergent's Rights. Emergent shall have the exclusive right, in its sole discretion, to initiate and conduct any and all Clinical Trials with respect to the Licensed Products, except for such Clinical Trials as HPA may conduct in the exercise of the Retained Rights.
- 2.9.2 <u>Supply; Drug Master Files</u>. In accordance with the Development Plan (including the product specifications and other requirements set out therein), HPA shall provide Emergent with clinical supplies of Licensed Products for any Clinical Trials that Emergent may conduct, in such quantities and at such times as Emergent shall reasonably request. HPA shall prepare and file with the FDA and such other Regulatory Authorities as Emergent may from time to time designate in writing, Drug Master Files with respect to any Licensed Product or any intermediate thereof manufactured or supplied to Emergent by or on behalf of HPA hereunder. HPA shall maintain each such Drug Master File during the Development Program Term in accordance with all Applicable Law and the Development Plan, including by filing any necessary amendments or modifications thereto. HPA shall provide to Emergent a copy of each such Drug Master File, including any amendments or modifications thereto.
- 2.9.3 <u>Manufacturing Records</u>. HPA shall maintain, or cause to be maintained, (a) all records necessary to comply with all Applicable Law relating to the Manufacture of the Licensed Products by HPA, (b) all Manufacturing records, standard operating procedures, equipment log books, batch records, laboratory notebooks and all raw data relating to the Manufacturing of Licensed Products hereunder, and (c) such other records as Emergent may

reasonably require to ensure compliance by HPA with the terms hereof. All such material shall be maintained for such period as may be required by Applicable Law or for such longer period as Emergent may reasonably require; provided, however, that all records relating to the Manufacturing, stability and quality control of each batch of Licensed Product shall be retained until at least the first (1st) anniversary of the end of the approved shelf life for all Licensed Product from such batch.

- 2.10 Development Program Term. Except as otherwise provided herein, the term of the Development Program shall commence on the Effective Date and continue until the second (2nd) anniversary thereof (the "Development Program Term"). The Parties may extend the term of the Development Program, and, as appropriate, amend the Development Plan and the Development Budget, by written mutual agreement.
- **2.11 Rights; Subcontracting.** Any and all rights of Emergent under this Article II are intended, and shall be construed, to benefit such of its Affiliates and sublicensees as and to the extent Emergent may, from time to time, designate. Emergent shall have the right to satisfy any or all of its obligations under this Article II through one or more of its Affiliates or subcontractors. HPA may subcontract one or more of its obligations hereunder, with the prior written consent of Emergent, which may be granted or withheld in the sole and absolute discretion of Emergent.
- 2.12 Future Cooperation. The Parties acknowledge that it is their mutual intent to work together where practicable on other projects in the Field, and that Emergent afford HPA a right of first negotiation with respect to those research and development activities in the Field that Emergent shall decide, in its sole discretion, to subcontract.

# ARTICLE III Development Funding

- 3.1 Emergent's Obligations. In consideration of HPA's performance of its designated Development Activities, Emergent shall pay HPA the amounts set forth on Schedule 3.1 with respect to such Development Activities (the "Development Budget"). Without limitation of the foregoing, the rate HPA charges Emergent for its employee costs incurred in the performance of the Development Activities shall be no greater than the standard rate per full-time equivalent (FTE) that HPA charges to its largest non-governmental customers. To the extent that this Agreement imposes obligations (other than payment obligations or customary administrative obligations) on HPA that are (i) not budgeted for in the Development Budget or covered in HPA's standard overhead charges and (ii) not expressly required to be performed at HPA's expense or at no cost to Emergent, then HPA shall promptly notify Emergent of the obligation and provide Emergent with its budget to perform such obligation based on rates no less favorable than those charged by HPA to its largest non-governmental customers. Emergent may elect in its sole discretion either to waive performance of the obligation or to pay HPA for the performance thereof under the agreed-upon budget.
- 3.2 Invoices and Payments. Within thirty (30) days after the end of each Calendar Quarter, HPA shall invoice Emergent for the amounts payable by Emergent pursuant to Section 3.1 for such Calendar Quarter, which invoice shall be accompanied by reasonable documentation

thereof. HPA shall promptly furnish Emergent with such other information in support of such invoice as Emergent may reasonably request. Each invoice shall be payable to HPA within thirty (30) days after receipt by Emergent of such invoice and supporting documentation and information. Any delinquent payments shall accrue interest from the date on which payment was due, at the prime rate, as published in *The Wall Street Journal*, Eastern United States Edition, on the last Business Day preceding such date.

- 3.3 Books and Records. HPA shall maintain complete and accurate books, records and accounts that, in reasonable detail, fairly reflect any reimbursable Development Program costs and expenses incurred by it or its Affiliates in conformity with GAAP. HPA shall retain such books, records and accounts until the later of (a) three (3) years after the end of the period to which such books, records and accounts pertain, and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law. Emergent shall have the right to review and audit such books, records and accounts in accordance with Article IV. Further, in the event that any amounts payable by Emergent hereunder shall be funded by one or more grants from the United States Government to Emergent, HPA agrees to comply with any and all terms and conditions of such grants.
- 3.4 Minimum Commitment of Emergent. Emergent agrees that on or prior to the second (2nd) anniversary of the Effective Date, it and its Affiliates shall expend an aggregate amount of at least [\*\*] dollars (\$[\*\*]) in support of the Development Activities (the "Minimum Commitment"); provided, however, that any amounts paid by Emergent pursuant to Section 3.1 and any amounts expended by Emergent or any of its Affiliates pursuant to the Master Services Agreement prior to or during such two (2) year period, shall be credited toward such Minimum Commitment in satisfaction of Emergent's obligations under this Section 3.4. Any failure by Emergent to satisfy the Minimum Commitment obligation shall not be deemed to be a breach of this Agreement and HPA's sole remedy in the event of such failure shall be to terminate this Agreement after such second (2nd) anniversary in accordance with Section 11.3.

## ARTICLE IV

4.1 Audit. In the event that the Parties mutually agree that HPA will undertake to perform services on behalf of Emergent pursuant to this Agreement on a cost or cost-plus reimbursement basis, then the provisions of this Section 4.1 shall apply. Upon the written request of Emergent and not more than once in each Calendar Year, HPA shall permit an independent certified public accounting firm of internationally recognized standing selected by Emergent, and reasonably acceptable to HPA, to have access during normal business hours, and upon reasonable prior written notice, to such of the records of HPA as may be reasonably necessary to verify the accuracy of the calculation of any amounts payable by Emergent hereunder, for any Calendar Year ending not more than twenty-four (24) months prior to the date of such request. The accounting firm shall disclose to HPA and Emergent only whether the financial statements and any related invoices are correct or incorrect and the specific details concerning any discrepancies. If such accounting firm concludes that Emergent has overpaid HPA during such period, HPA shall reimburse Emergent for the difference between the amount actually owed, as determined by the accounting firm, and the amount actually paid by Emergent, with interest from the date originally due at the prime rate, as published in *The Wall Street* 

Journal, Eastern United States Edition, on the last Business Day preceding such date, within thirty (30) days after the date on which such accounting firm's written report is delivered to HPA. If such accounting firm concludes that Emergent has underpaid HPA during such period, Emergent shall pay such difference to HPA within thirty (30) days after the date of delivery of such report. If, and only if, the amount of the overpayment is greater than five percent (5%) of the total actual amount owed as determined by the accounting firm, HPA shall bear all costs related to such audit. In all other circumstances, Emergent shall bear the cost of such audit.

4.2 Confidentiality. Emergent shall treat all information subject to review under this Article IV in accordance with the confidentiality provisions of Article VI and shall cause its accounting firm to enter into a reasonably acceptable confidentiality agreement with HPA obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

## ARTICLE V License Grants and Assignments

5.1 Grants to Emergent. HPA hereby grants to Emergent and its Affiliates, and shall cause HPA's Affiliates to grant to Emergent and its Affiliates:

(a) an exclusive (even with regard to HPA and its Affiliates), perpetual and irrevocable (in each case subject to the provisions of Article XI), royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicensees), under HPA's and its Affiliates' rights, title, and interest in and to the Joint Technology, to Exploit Vaccine Products and any and all Improvements thereto in the Territory (other than to make, have made, and use Vaccine Products and any and all Improvements thereto in the United Kingdom and to sell or otherwise distribute Vaccine Products and any and all Improvements thereto in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service));

(b) an exclusive (even with regard to HPA and its Affiliates), perpetual and irrevocable (in each case subject to the provisions of Article XI), royalty-free license and right of reference, with the right to grant sublicenses (through multiple tiers of sublicensees), under HPA's and its Affiliates' rights, title and interest in and to the Regulatory Documentation, to the extent not assigned to Emergent and its Affiliates pursuant to Section 5.4 or the BT License Agreement), to Exploit Vaccine Products and any and all Improvements thereto in the Territory for any purpose whatsoever (other than to make, have made, and use Vaccine Products and any and all Improvements thereto in the United Kingdom and to sell or otherwise distribute Vaccine Products and any and all Improvements thereto in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service)); and

(c) a non-exclusive, perpetual and irrevocable (in each case subject to the provisions of Article XI), royalty-free license, with right to grant sublicenses (through multiple tiers of sublicensees), under HPA's and its Affiliates' rights, title, and interest in and to the

Regulatory Documentation, to the extent not assigned to Emergent and its Affiliates pursuant to Section 5.4 or the BT License Agreement), to make, have made, and use Vaccine Products and any and all Improvements thereto in the United Kingdom and to sell or otherwise distribute Vaccine Products and any and all Improvements thereto in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service).

#### 5.2 Grant to HPA

- (a) Subject to the provisions of Article XI, Emergent hereby grants to HPA (but not its Affiliates) a nonexclusive, royalty-free license and right of reference (without the right to grant sublicenses) under all of Emergent's rights, title and interest in and to the Emergent Technology solely for use in the performance by HPA of its designated Development Activities.
- (b) HPA and its Affiliates shall have no right, express or implied, to the Emergent Technology in or outside the Field except as expressly provided in this Agreement (including Section 5.2(a)) or in a separate written agreement between Emergent, on the one hand, and HPA and/or its Affiliate(s), on the other hand. All rights of Emergent and its Affiliates in and to the Emergent Technology that are not expressly granted to HPA in this Agreement are retained by Emergent and its Affiliates.
- 5.3 HPA's Retained Rights. Subject to the provisions of Article XI, HPA hereby retains the right under all of HPA's and its Affiliates' rights, title and interest in and to the Joint Technology and the Regulatory Documentation, to the extent not assigned to Emergent and its Affiliates pursuant to Section 5.4 or the BT License Agreement, to make, have made, and use Vaccine Products and any and all Improvements thereto in the United Kingdom and to sell or otherwise distribute Vaccine Products and any and all Improvements thereto in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service) (collectively, the "Retained Rights"). HPA shall not, and shall cause its Affiliates not to, assign, sell or otherwise transfer, or grant any license or right of reference under, any of the Retained Rights to any Affiliate of HPA or any Third Party.
- 5.4 Assignment of Regulatory Documentation. HPA hereby assigns to Emergent, and shall cause its Affiliates to assign to Emergent, all of HPA's and its Affiliates' rights, title and interest in and to all Regulatory Documentation, including, to the extent permitted by Applicable law, all Regulatory Approvals, Controlled by HPA or its Affiliates as of the Effective Date and from time to time during the term of this Agreement; provided, however, that HPA shall not be required to assign any Regulatory Documentation that it may develop, at its expense, solely in connection with the exercise of the Retained Rights. HPA shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such agreements, documents and instruments, as may be necessary under, or as Emergent may reasonably request in connection with, or to carry out more effectively, the purposes of this Section 5.4.

### ARTICLE VI Confidentiality and Nondisclosure

### 6.1 Confidentiality Obligations.

- 6.1.1 <u>General Obligations</u>. Except as provided herein, the Parties agree that, during the term of this Agreement and for five (5) years after this Agreement's expiration or termination pursuant to Article XI, each Party shall hold in strict confidence and shall not publish or otherwise disclose, directly or indirectly, to any Person (other than employees, Affiliates, legal counsel, consultants, auditors and advisors who, except in the case of legal counsel, are bound in writing by confidentiality and non-use obligations no less onerous than those set forth herein) any Confidential Information of the other Party. During such period, a Party (and its Affiliates) shall not use for any purpose, directly or indirectly, Confidential Information of the other Party or its Affiliates furnished or otherwise made known to it, except as permitted hereunder.
- 6.1.2 Additional HPA Obligations. HPA recognizes that by reason of Emergent's status as an exclusive licensee pursuant to this Agreement and the BT License Agreement, Emergent has an interest in HPA's retention in confidence of certain information of HPA. Accordingly, HPA shall, and shall cause its Affiliates, officers, directors, employees and agents to, hold in strict confidence, and not publish or otherwise disclose, and not use directly or indirectly for any purpose, any information relating to the Licensed Product(s) or the Regulatory Documentation, including the Regulatory Approvals (collectively, the "Emergent Information"), except to the extent that (a) the Emergent Information is in the public domain through no fault of HPA, its Affiliates, or any of their respective officers, directors, employees or agents, or (b) such disclosure is reasonably necessary for the performance of HPA's obligations hereunder or the exercise of the Retained Rights, provided that any Third Party to which HPA proposes to disclose any Emergent Information is bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article VI. For clarification, the disclosure by HPA to Emergent to HPA of Emergent Information shall not cause such information to cease to be subject to the confidentiality provisions of this Section 6.1.2.
  - 6.2 Permitted Disclosures. Each Party may disclose Confidential Information or Emergent Confidential Information to the extent that such disclosure is:
- (a) Made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the receiving Party shall first have given notice to the disclosing Party and, insofar as permitted by applicable law, given the disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

- (b) Otherwise required by law, in the opinion of legal counsel to the receiving Party as expressed in an opinion letter in form and substance reasonably satisfactory to the disclosing Party, which shall be provided to the disclosing Party at least two (2) Business Days prior to the receiving Party's disclosure of the Confidential Information pursuant to this Section 6.2(b);
- (c) Made by the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; <u>provided</u>, <u>however</u>, that reasonable measures shall be taken to assure confidential treatment of such information;
- (d) Made by Emergent to existing or potential acquirers or merger candidates; existing or potential pharmaceutical collaborators; investment bankers; existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing; each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article VI;
- (e) Made by HPA to potential investors in any spin-off entity to which HPA intends to transfer its business relating to the Development Program and the Exploitation of Licensed Products and HPA Products (as defined in the BT License Agreement), each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article VI; or
- (f) Made by Emergent or its Affiliates or sublicensees to Third Parties as may be necessary or reasonably useful in connection with the Exploitation of any Licensed Product, including subcontracting and sublicensing transactions in connection therewith.

### 6.3 Confidential Information.

- 6.3.1 <u>Defined</u>. "Confidential Information" of a Party shall mean all information and know-how and any tangible embodiments thereof provided by or on behalf of such Party to the other Party either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement, including data; knowledge; practices; processes; ideas; research plans; engineering designs and drawings; research data; manufacturing processes and techniques; scientific, manufacturing, marketing and business plans; and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business. For the avoidance of doubt, Confidential Information shall be deemed to include any and all information provided by one Party to the other Party relating to Licensed Products, and the terms of this Agreement.
- 6.3.2 Exclusions. Notwithstanding the foregoing, information or know-how of a Party shall not be deemed Confidential Information with respect to the receiving Party for purposes of this Agreement if such information or know-how: (a) was already known to the receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, at the time of disclosure to, or, with respect to know-how, discovery or development by, such receiving Party; (b) was generally available or known, or was otherwise part of the public domain, at the time of its disclosure to, or, with respect to know-how, discovery or development by, such receiving Party; (c) became generally available or known, or otherwise became part of

the public domain, after its disclosure to, or, with respect to know-how, discovery or development by, such receiving Party through no fault of the receiving Party; (d) was disclosed to such receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the Party that Controls such information and know-how not to disclose such information or know-how to others; or (e) was independently discovered or developed by such receiving Party or its Affiliates, as evidenced by their written records, without the use of Confidential Information belonging to the Party that Controls such information and know-how.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of a Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of such Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of a Party merely because individual elements of such Confidential Information are in the public domain or in the possession of such Party unless the combination and its principles are in the public domain or in the possession of such Party.

- **6.4 Use of Name.** Neither Party shall mention or otherwise use the name, symbol, trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law.
- 6.5 Press Releases; Publication. Each Party shall have the right to issue press releases and to make other public disclosures, presentations or publications with respect to this Agreement; provided, however, that no such press release or other public disclosure, presentation or publication shall disclose any Confidential Information of the other Party without the prior written consent of such other Party; and, provided further, that neither HPA nor any of its Affiliates, officers, directors, employees or agents shall be permitted to issue any press release or make any other public disclosure, presentation or publication regarding any information, data or results pertaining to or resulting from the Emergent Information, without the prior written consent of Emergent. HPA agrees to acknowledge Emergent in all such publications or other public disclosures by coauthorship or acknowledgement, as appropriate according to customary practice for such research publications and disclosures.
- 6.6 Equitable Relief. Each Party acknowledges and agrees that breach of any of the terms of this Article VI would cause irreparable harm and damage to the other Party and that such damage may not be ascertainable in money damages and that as a result thereof the non-breaching Party would be entitled to seek from a court equitable or injunctive relief restraining any breach or future violation of the terms contained herein by the breaching Party without the necessity of proving actual damages. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of law or equity, including money damages, which other remedies are subject to Section 12.7.

#### ARTICLE VII Payments

All payments to be made by a Party to the other Party under this Agreement shall be made in United States dollars and may be paid by check made to the order of the receiving party or bank wire transfer in immediately available funds to such bank account designated in writing by the receiving Party from time to time. Payments shall be free and clear of any taxes (other than withholding and other taxes imposed on the receiving Party, which shall be for the account of such Party), fees or charges, to the extent applicable. With respect to payments in currencies other than United States dollars, payments shall be calculated based on currency exchange rates for the month in which the invoice is received. For each month and each currency, such exchange rates shall equal the arithmetic average of the daily exchange rates for such month listed in *The Wall Street Journal*, Eastern United States Edition, or, if not so available, as otherwise agreed by the Parties. Any delinquent payments shall accrue interest from the date on which payment was due, at the prime rate, as published in *The Wall Street Journal*, Eastern United States Edition, on the last Business Day preceding such date.

## ARTICLE VIII

- **8.1 Indemnification of Emergent.** Subject to Sections 8.3 and 8.4(b), HPA shall indemnify Emergent, its Affiliates and its and their respective directors, officers, employees and agents, and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) in connection with any and all suits, investigations, claims or demands (collectively, "Losses") arising from or occurring as a result of (a) any material breach by HPA of this Agreement, (b) any gross negligence or willful misconduct of HPA, its Affiliates or its other permitted subcontractors in performing HPA's obligations under this Agreement, or (c) the Manufacture of the Licensed Products by HPA pursuant to Section 2.9.2, except for those Losses for which Emergent has an obligation to indemnify HPA pursuant to Section 8.2, as to which Losses each party shall indemnify the other to the extent of their respective liability for the Losses.
- **8.2 Indemnification of HPA.** Subject to Sections 8.3 and 8.4(b), Emergent shall indemnify HPA, its Affiliates and their respective directors, officers, employees and agents, and defend and save each of them harmless, from and against any and all Losses arising from or occurring as a result of (a) any material breach by Emergent of this Agreement, or (b) the gross negligence or willful misconduct of Emergent, its Affiliates or its other subcontractors in performing Emergent's obligations under this Agreement, except for those Losses for which HPA has an obligation to indemnify Emergent and its Affiliates pursuant to Section 8.1, as to which Losses each party shall indemnify the other to the extent of their respective liability for the Losses.

#### 8.3 Indemnification Procedure

8.3.1 Notice of Claim. The indemnified Party shall give the indemnifying Party prompt written notice (an "Indemnification Claim Notice") of any Losses or discovery of fact upon which such indemnified party intends to base a request for indemnification under Section

- 8.1 or Section 8.2, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses. All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "Indemnified Party").
- 8.3.2 Third Party Claims. The obligations of an indemnifying Party under this Article VIII with respect to Losses arising from claims of any Third Party that are subject to indemnification as provided for in Sections 8.1 or 8.2 (a "Third Party Claim") shall be governed by and be contingent upon the following additional terms and conditions:
- (a) Control of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify any Person seeking indemnification in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against any such claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by any indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, the indemnifying Party shall not be liable to the Indemnified Party or any other indemnified party for any legal expenses subsequently incurred by such indemnified party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in its defense of the Third Party Claim with respect to such indemnified Party.
- (b) Right to Participate in Defense. Without limiting Section 8.3.2(a), any indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the indemnified Party's own expense unless (i) the employment thereof has been specifically authorized by the indemnifying Party in writing or (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 8.3.2(a) (in which case the Indemnified Party shall control the defense).
- (c) <u>Settlement</u>. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect

the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 8.3.2(a), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). The indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party.

- (d) <u>Cooperation</u>. Regardless of whether the indemnifying party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each other indemnified party to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnified parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.
- (e) Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

#### 8.4 Limitation of Liability

(a) SUBJECT TO SECTIONS 8.1 AND 8.2, AND EXCEPT IN CIRCUMSTANCES OF GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, NONE OF EMERGENT, HPA OR ANY OF THEIR RESPECTIVE AFFILIATES SHALL BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING FOR LOST PROFITS, MILESTONES OR ROYALTIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (A) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR (B) THE DEVELOPMENT, USE OR SALE OF ANY PRODUCT DEVELOPED HEREUNDER; PROVIDED, HOWEVER, THAT THE

FOREGOING LIMITATIONS SHALL NOT APPLY TO ANY LIABILITY OF HPA OR ITS AFFILIATES RESULTING FROM THE MANUFACTURE AND SUPPLY OF LICENSED PRODUCTS OR OTHERWISE RELATING TO SECTIONS 2.9 AND 9.3(f). NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS ATTEMPTING TO EXCLUDE OR LIMIT THE LIABILITY OF EITHER OF THE PARTIES OR THEIR RESPECTIVE AFFILIATES (A) FOR DEATH OR PERSONAL INJURY CAUSED BY THE NEGLIGENCE OF EITHER OF THE PARTIES, THEIR RESPECTIVE AFFILIATES, OR OF THE OFFICERS, EMPLOYEES OR AGENTS OF THE PARTIES OR THEIR RESPECTIVE AFFILIATES, (B) FOR FRAUD OR FRAUDULENT MISREPRESENTATION OR (C) FOR ANY MATTER IN RESPECT OF WHICH IT WOULD BE ILLEGAL FOR EITHER PARTY TO EXCLUDE OR ATTEMPT TO EXCLUDE ITS LIABILITY.

(b) SUBJECT TO THE PRECEDING SENTENCE, BUT NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, IN NO EVENT SHALL THE COMBINED AGGREGATE LIABILITY OF EITHER PARTY UNDER THIS AGREEMENT, TAKEN TOGETHER WITH SUCH PARTY'S AGGREGATE LIABILITY UNDER THE BT LICENSE AGREEMENT, THE 1BOT LICENSE AGREEMENT, THE 1BOT DEVELOPMENT AGREEMENT AND THE DISTRIBUTION AGREEMENT, EXCEED THE COMBINED AGGREGATE AMOUNTS PAID BY EMERGENT TO HPA, WHETHER AS LUMP SUMS OR PERIODIC PAYMENTS OF ROYALTIES OR SUBLICENSE INCOME, UNDER THIS AGREEMENT, THE BT LICENSE AGREEMENT, THE 1BOT LICENSE AGREEMENT, THE 1BOT DEVELOPMENT AGREEMENT AND THE DISTRIBUTION AGREEMENT (THE "AGGREGATE AMOUNT"); PROVIDED, HOWEVER, THAT IN THE EVENT THAT EITHER PARTY (THE "LIABLE PARTY") SHALL BECOME LIABLE TO THE OTHER PARTY HEREUNDER FOR AN AMOUNT (THE "TOTAL LIABILITY") LARGER THAN THE AGGREGATE AMOUNT CALCULATED AS OF THE DATE THAT THE TOTAL LIABILITY BECAME DUE AND PAYABLE, THE LIABLE PARTY SHALL PROMPTLY PAY SUCH OTHER PARTY A LUMP SUM EQUAL TO THE AGGREGATE AMOUNT AS SO CALCULATED; AND PROVIDED, FURTHER, THAT IF HPA IS THE LIABLE PARTY, EMERGENT SHALL THEREAFTER HAVE A RIGHT OF OFFSET WITH RESPECT TO ANY PAYMENT OBLIGATIONS OF EMERGENT TO HPA HEREUNDER AND THEREUNDER THAT BECOME DUE AND PAYABLE AFTER SUCH DATE, UNTIL SUCH TIME AS THE TOTAL AMOUNTS OFFSET BY EMERGENT EQUAL THE DIFFERENCE BETWEEN THAT IDECOME DUE AND PAYABLE AFTER SUCH DATE, UNTIL SUCH TIME AS THE TOTAL AMOUNTS OFFSET BY EMERGENT EQUAL THE DIFFERENCE BETWEEN THE TOTAL LIABILITY AND SUCH LUMP SUM PAYMENT BY HPA; AND PROVIDED, FURTHER, THAT IF EMERGENT IS THE LIABLE PARTY, THEN THEREAFTER, AT SUCH TIMES AS EMERGENT SHALL MAKE PAYMENTS TO HPA THAT ARE OTHERWISE DUE AND PAYABLE HEREUNDER OR THEREUNDER, EMERGENT SHALL PAY TO HPA AN EQUAL AMOUNT AS ADDITIONAL DAMAGES, UNTIL SUCH TIME AS THE TOTAL AMOUNTS SO PAID TO HPA AS ADDITIONAL DAMAGES EQUAL THE DIFFERENCE BETWEEN THE TOTAL LIABILITY AND SUCH LUMP SUM PAYMENT BY EMERGENT.

**8.5 Insurance**. Emergent shall use commercially reasonable efforts to obtain and maintain, with an insurance company of internationally recognized standing, such type and amounts of liability insurance, and HPA shall maintain such program of self-insurance, in each case covering the development of the Licensed Product(s), as is normal and customary in the pharmaceutical industry generally for parties similarly situated, and Emergent shall upon request

provide HPA with a copy of such policies of insurance, along with any amendments and revisions thereto; <u>provided</u>, <u>however</u>, that Emergent shall promptly notify HPA in writing if, after using commercially reasonable efforts, Emergent is unable to obtain such insurance or if, after obtaining such insurance, Emergent is unable to maintain such insurance; and <u>provided</u>, <u>further</u>, that Emergent shall not be required to seek such insurance coverage to the extent that the relevant liabilities are covered by a government indemnity in favor of Emergent or precluded by applicable law.

# ARTICLE IX Representations and Warranties

- 9.1 Representations and Warranties. Each Party hereby represents, warrants and covenants to the other Party as of the Effective Date as follows:
- (a) Such Party (i) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (ii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.
- (b) Such Party is not aware of any pending or threatened litigation (and has not received any communication) that alleges that such Party's activities related to this Agreement have violated, or that by conducting the activities as contemplated herein such Party would violate, any of the intellectual property rights of any other Person.
- (c) All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.
- (d) The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable law or regulation or any provision of the articles of incorporation, bylaws, limited partnership agreement or any similar instrument of such Party, as applicable, in any material way, and (ii) do not conflict with, violate, or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.
- 9.2 Additional Representations, Warranties and Covenants of Emergent. Emergent represents, warrants and covenants to HPA that Emergent is a corporation duly organized and in good standing under the laws of the State of Delaware, and has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.

#### 9.3 Additional Representations, Warranties and Covenants of HPA. HPA represents, warrants and covenants to Emergent that:

- (a) HPA is a governmental entity duly organized, validly existing and in good standing under the laws of England, and has full governmental power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.
- (b) HPA has conducted any and all studies and other development work related to the Licensed Product(s), including any such work performed pursuant to the Master Services Agreement, in accordance with Applicable Law. HPA and its Affiliates have employed (and, with respect to the Development Activities, will employ) Persons with appropriate education, knowledge and experience to conduct and to oversee the conduct of such activities with respect to the Licensed Products. Neither HPA nor any of its Affiliates is aware of any fact or circumstance that could adversely affect the acceptance, or the subsequent approval, by any Regulatory Authority of any filing, application or request for Regulatory Approval.
- (c) Neither HPA nor any of its Affiliates or Key Personnel have been debarred or are subject to debarment and neither HPA nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement or that have previously provided pursuant to the Master Services Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA, or who is the subject of a conviction described in such section. HPA agrees to inform Emergent in writing immediately if it or any Person who is performing services hereunder or the Master Services Agreement is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of HPA's knowledge, is threatened, relating to the debarment or conviction of HPA or any Person performing services hereunder or under the Master Services Agreement.
- (d) HPA agrees not to, and agrees to cause its Affiliates not to, directly or indirectly, expressly or by implication, by action or omission or otherwise (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the Regulatory Documentation or Joint Technology, (ii) grant any license or other right, title or interest in or to the Regulatory Documentation or Joint Technology in any manner, or (iii) agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to the Regulatory Documentation or Joint Technology, in each case ((i), (ii), and (iii)) that is inconsistent with the grants, assignments and other rights reserved to Emergent and its Affiliates under this Agreement and the BT License Agreement.
- (e) HPA shall cause each of its Affiliates and any other Person conducting Development Activities on behalf of HPA hereunder to assign to HPA rights to any and all Information and Inventions that relate to the Licensed Product(s), such that Emergent shall, by virtue of this Agreement and the BT License Agreement, receive from HPA, without payment of additional consideration beyond that required by this Agreement and the BT License Agreement, the licenses and other rights granted to Emergent and its Affiliates hereunder and under the BT License Agreement.

(f) At the time of delivery of each Licensed Product to Emergent pursuant to Section 2.9.2: (i) such Licensed Product will have been Manufactured, held and shipped in accordance with any applicable Regulatory Approvals for such Licensed Product, any applicable Good Manufacturing Practices and all other Applicable Law; (ii) such Licensed Product will have been manufactured in accordance, and be in conformity with, the product specifications for such Licensed Product (as set forth in the Development Plan) and will conform with any certificate of analysis provided by HPA; and (iii) title to such Licensed Product will pass to Emergent free and clear of any security interest, lien or other encumbrance.

9.4 Disclaimer of Warranties. EXCEPT FOR THOSE WARRANTIES SET FORTH IN THIS ARTICLE IX, AND SUBJECT TO SECTION 8.4(a), EACH PARTY HEREBY DISCLAIMS ANY AND ALL WARRANTIES, CONDITIONS AND TERMS, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING (A) ANY WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, (B) ANY WARRANTY WITH RESPECT TO THE VALIDITY OR ENFORCEABILITY OF ANY PATENT OR OTHER INTELLECTUAL PROPERTY, AND (C) ANY WARRANTY THAT THE PERFORMANCE OF ITS RIGHTS OR OBLIGATIONS HEREUNDER WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF ANY PERSON. SUBJECT TO SECTION 8.4(a), NO PARTY MAKES ANY REPRESENTATIONS HEREUNDER OTHER THAN THOSE SET FORTH EXPRESSLY HEREIN.

# ARTICLE X Intellectual Property Provisions

### 10.1 Intellectual Property Ownership.

- 10.1.1 Ownership of Emergent Technology and Regulatory Documentation. Subject to the license grant to HPA under Section 5.2(a), as between the Parties, Emergent shall own and retain all right, title and interest in and to the Emergent Technology. Subject to Applicable Law, as between the Parties, Emergent shall own all right, title and interest in and to the Regulatory Documentation (other than any Regulatory Documentation that HPA may develop at its expense solely in connection with the exercise of the Retained Rights).
- 10.1.2 Ownership and Exploitation of Joint Inventions and Joint Technology. Subject to the license grants under Sections 5.1 and 5.2 and the BT License Agreement, Emergent and HPA shall each own an equal, undivided interest in the Joint Inventions and the Joint Technology. Each Party agrees to disclose to the other Party promptly in writing any and all Joint Inventions and Joint Technology that are conceived, discovered, developed, or otherwise made by or on behalf of such Party or its Affiliates or permitted subcontractors during the period beginning on the Effective Date and ending on the last day of the term of this Agreement, and to assign to such other Party (and to cause its Affiliates, employees and permitted subcontractors to assign to such other Party), without payment of additional consideration, an equal, undivided interest in such Joint Inventions or Joint Technology. The parties agree that (a) Emergent shall be free to Exploit any Joint Invention or Joint Technology in the Territory for any purpose, without an accounting to HPA, and (b) in addition to such rights as

HPA has under Section 5.3, HPA shall be free to Exploit any Joint Inventions or Joint Technology in the Territory outside the Field.

### 10.2 Prosecution of Patents.

- 10.2.1 Emergent Patents. Emergent shall have the sole right, at its sole cost and expense, to obtain, prosecute and maintain any Patents covering or claiming the Emergent Technology in the Territory.
- 10.2.2 Joint Patents. Emergent shall have the sole right to prepare, file, prosecute and maintain the Joint Patents in the Territory. HPA shall, and shall cause its Affiliates, to assist and cooperate with Emergent in filing, prosecuting and maintaining the Joint Patents, at Emergent's cost. Subject to the following sentence, Emergent shall bear the costs and expenses of the filing, prosecution and maintenance of the Joint Patents. If Emergent elects not (a) to pursue the filing, prosecution or maintenance of a Joint Patent in a country, or (b) to take any other action with respect to a Joint Patent in a country that is necessary or useful to establish or preserve rights thereto, then in each such case ((a) and (b)) Emergent shall so notify HPA promptly in writing and in good time to enable HPA to meet any deadlines by which an action must be taken to establish or preserve any such rights in such Joint Patent in such country. Upon receipt of each such notice from Emergent, HPA shall have the right, but not the obligation, to pursue the filing or registration, or support the continued prosecution or maintenance, of such Joint Patent, at its expense in such country. If HPA elects to pursue such filing or registration, as the case may be, or continue such support, then HPA shall notify Emergent of such election and Emergent shall, and shall cause its Affiliates to, reasonably cooperate with HPA in this regard.

#### 10.3 Enforcement and Defense of Patents.

- 10.3.1 Party Patents. Except as otherwise provided in this Article X or in the BT License Agreement, each Party shall have the sole right, at its own expense, but not the obligation to enforce its rights under any Patents against all infringers at its sole cost and expense, and shall be entitled to any amounts it may recover from the infringer, whether by settlement or judgment.
- 10.3.2 <u>Joint Patents</u>. If either Party determines that any Joint Patent is being infringed by a Third Party's activities and that such infringement could affect the exercise by Emergent of its rights and obligations under this Agreement, it shall notify the other Party in writing and provide it with any evidence of such infringement that is reasonably available. In the event that any Joint Patent is being infringed by a Third Party, Emergent shall have the sole and exclusive right, but not the obligation, to attempt to remove such infringement, including by filing an infringement suit or taking other similar action. HPA shall provide reasonable assistance to Emergent in the event that Emergent acts to enforce the Joint Patent with respect to such infringement, including by providing access to relevant documentation and other evidence, and joining the action to the extent necessary to allow Emergent to maintain the action. Emergent shall bear all costs and expenses with respect to any such enforcement, and shall be entitled to retain any amounts recovered, whether by settlement or judgment.

#### 10.4 Potential Infringement of Third Party Rights.

- 10.4.1 <u>Third Party Licenses</u>. Each Party shall be responsible, in its sole discretion, (a) for determining whether to obtain any licenses from Third Parties in order to avoid infringing such Third Parties' intellectual property rights in performing its obligations hereunder, (b) for obtaining such licenses, and (c) for bearing any costs incurred in connection with obtaining such licenses.
- 10.4.2 <u>Third Party Litigation</u>. In the event that a Third Party commences litigation against a Party, its Affiliates or its sublicensees for infringement of such Third Party's Patents or other intellectual property rights, such Party shall have the sole right to defend against such infringement suit. The other Party shall use all reasonable efforts to assist and cooperating with the defending Party in connection with the defense of such suit. Each Party shall bear its own costs and expenses with respect to the defense of any suit, including any judgments or settlement against it.

# ARTICLE XI Term and Termination

- 11.1 Term and Expiration. This Agreement shall become effective as of the Effective Date and unless terminated earlier pursuant to Section 11.2, 11.3, 11.4, 11.5 or 11.7, the term of this Agreement shall continue in effect until the Development Activities are completed.
- 11.2 Termination by Emergent without Cause. Notwithstanding anything contained herein to the contrary, Emergent shall have the right to terminate this Agreement at any time in its sole discretion by giving not less than two hundred and seventy (270) days' written notice to HPA.
- 11.3 Termination by HPA for Failure to Meet Minimum Commitment. In the event that Emergent fails to meet its Minimum Commitment obligation under Section 3.4, HPA shall have the right upon thirty (30) days' written notice to Emergent to terminate this Agreement.
- 11.4 Termination by Either Party for Material Breach. Material failure by HPA to comply with any of its material obligations contained herein, or material failure by Emergent to pay HPA amounts owed by Emergent to HPA hereunder, shall entitle the Party not in default to give to the Party in default notice specifying the nature of the default, requiring the defaulting Party to make good or otherwise cure such default, and stating its intention to terminate if such default is not cured. In the event that Emergent is the notifying Party, Emergent shall have the right, in addition to all other remedies available to it by law, in equity or pursuant to this Agreement, to suspend payment of any amounts that it would otherwise owe to HPA hereunder until such time as the material breach of HPA is cured (whereupon such suspended amounts shall be paid). If a noticed default is not cured within thirty (30) days (the "Cure Period") after the receipt of such notice (or, if such default cannot be cured within such thirty (30)-day period, if the Party in default does not commence actions to cure such default within the Cure Period and

thereafter diligently continue such actions), the Party not in default shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement in its entirety; <u>provided, however</u>, that any right to terminate under this Section 11.4 shall be stayed in the event that, during any Cure Period, the Party alleged to have been in default shall have initiated dispute resolution in accordance with Section 12.7 with respect to the alleged default, which stay shall last so long as the initiating Party diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings.

11.5 Termination of the BT License Agreement. In the event that the BT License Agreement is terminated in its entirety for any reason, this Agreement shall automatically terminate as of the same date.

### 11.6 Accrued Rights; Survival; Return of Information.

- 11.6.1 <u>Accrued Rights</u>. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.
- 11.6.2 <u>Survival</u>. Sections 2.7, 2.9.3, 3.2, 3.3, 8.1, 8.2, 8.3, 8.4, 11.8, 12.2, 12.3, 12.5, 12.6, 12.7, 12.8, 12.9, 12.14, 12.16, 12.17 and this Section 11.6, and Articles IV, VI, VII, and X shall survive the termination or expiration of this Agreement for any reason. Sections 5.1 and 5.4 shall survive (a) the expiration of this Agreement and (b) the termination of this Agreement pursuant to Section 11.5 (if such termination resulted from the termination of the BT License Agreement by Emergent for breach by HPA). Sections 5.1 and 5.4 shall not survive the termination of this Agreement for any other reason.
- 11.6.3 Return of Information. Within ninety (90) days after the termination or expiration of this Agreement, each Party shall deliver to the other Party any and all data, files, and records in its possession or under its control that constitute the Confidential Information of such other Party (or, in the case of HPA as the delivering Party, that constitute Emergent Information), to which such Party does not retain rights hereunder (except that such Party shall have the right to retain one copy of each of the foregoing solely for archival purposes).
- 11.7 Termination upon Insolvency. Either Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

11.8 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Emergent or HPA are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the United States Bankruptcy Code, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

## ARTICLE XII Miscellaneous

12.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, when such failure or delay is caused by or results from causes beyond the reasonable control of the non-performing Party, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority. The non-performing Party shall notify the other Party of such force majeure within ten (10) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for one-hundred and eighty (180) days after the date of the occurrence, the Parties shall meet and discuss in good faith how best to proceed.

12.2 Export Control Regulations. The rights and obligations of the Parties under this Agreement shall be subject in all respects to United States laws and regulations and the analogous laws and regulations of England, as shall from time to time govern the license and delivery of technology and products between the United States and the United Kingdom, including the United States Foreign Assets Control Regulations, Transaction Control Regulations and Expert Control Regulations, as amended, and any successor legislation issued by the Department of Commerce, International Trade Administration, Office of Export Licensing. Without in any way limiting the provisions of this Agreement, each Party agrees that, unless prior authorization is obtained from the Office of Export Licensing, it shall not export, re-export, or transship, directly or indirectly, to any country, any of the technical data disclosed to it by the

other party if such export would violate the laws of the United States or the regulations of any department or agency of the United States Government.

12.3 Assignment. Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate, charge, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder, nor purport to do any of the same; provided, however, that Emergent may, without such consent, assign the benefit of this Agreement and its rights hereunder to an Affiliate, to the purchaser of all or substantially all of its assets, or to any Third Party pursuant to or in connection with any agreement and plan of merger, acquisition, reorganization, or other similar corporate transaction; and provided, further, that HPA may, without such consent, assign the benefit of this Agreement and its rights hereunder to an Affiliate, or to a Third Party in connection with the permitted assignment to such Third Party of HPA's rights under the BT License Agreement. Any attempted assignment in violation of the preceding sentence shall be void and of no effect. All validly assigned rights of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by the permitted assigns of Emergent or HPA, as the case may be. No assignment validly made pursuant to this Section 12.3 shall relieve the assigning Party of any of its obligations under this Agreement, unless the other Party has given its prior consent thereto.

12.4 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) the Parties agree to attempt to substitute for any such illegal, invalid or unenforceable provision a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof prohibited or unenforceable in any respect.

12.5 Notices. All notices or other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (promptly confirmed by personal delivery or courier as provided herein) or sent by internationally-recognized overnight courier, addressed as follows:

if to HPA, to: Health Protection Agency

Porton Down

Salisbury, Wiltshire SP4 0JG England Attention: Dr. David Rhodes Facsimile No.: +44-1980-61-22-41

with a copy to: Legal Department

Health Protection Agency

Porton Down

Salisbury, Wiltshire SP4 0JG England Facsimile No.: +44-1980-61-22-41

if to Emergent, to: Emergent BioSolutions, Inc.

300 Professional Drive

Gaithersburg, Maryland 20879 USA Attention: General Counsel Facsimile No.: +1-301-590-1252

with a copy to: Covington & Burling

One Front Street, 35th Floor

San Francisco, California 94111 USA Attention: James C. Snipes, Esq. Facsimile No.: +1-415-591-6091

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication shall be deemed to have been given when delivered if personally delivered on a Business Day, when transmitted if sent by facsimile (in accordance with this Section 12.5) on a Business Day, and on the third (3rd) Business Day after dispatch if sent by internationally-recognized courier. It is understood and agreed that this Section 12.5 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

12.6 Governing Law. This Agreement shall be governed by and construed in accordance with English law (without reference to the rules of conflict of laws thereof). Subject to Section 12.7, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of (i) the courts of the State of New York and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) initiated by HPA and arising out of or relating to this Agreement, and (ii) the English courts located in London for any action, suit or proceeding (other than appeals therefrom) initiated by Emergent and arising out of or relating to this Agreement. The Parties agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts, respectively. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or the United States District Court for the Southern District of New York or the English courts located in London, as the case may be, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Each Party hereto further agrees that service of any process, summons, notice or document by internationally recognized courier to its address set forth above shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

### 12.7 Dispute Resolution.

12.7.1 Negotiation. The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement (or

any document or instrument delivered in connection herewith) (each, a "Dispute"). In the event that the Parties are unable to, within ten (10) days, to reach a resolution, such Dispute shall be referred to the chief executive officers of Emergent and HPA, or their respective successors, who shall attempt in good faith to reach a resolution of the Dispute. If the foregoing procedures fail to achieve a mutually satisfactory resolution within ten (10) days, then either Party may, by written notice to the other Party, elect to have the matter settled by binding arbitration pursuant to Section 12.7.2.

12.7.2 Arbitration. Any arbitration under this Agreement shall take place at a location to be agreed by the Parties; provided, however, that in the event that the Parties are unable to agree on a location for an arbitration under this Agreement within five (5) days of the demand therefor, such arbitration shall be held in New York, New York if HPA is the Party that first demanded such arbitration or in London, England if Emergent is the Party that first demanded such arbitration under this Agreement shall be administered by the American Arbitration Association under its Commercial Arbitration Rules then in effect (the "AAA Rules"). The Parties shall appoint an arbitrator by mutual agreement. If the Parties cannot agree on the appointment of an arbitrator within thirty (30) days of the demand for arbitration, an arbitrator shall be appointed in accordance with AAA Rules. The arbitrator shall have the authority to grant any equitable and legal remedies that would be available in any judicial proceeding instituted to resolve the Dispute submitted to such arbitration in accordance with this Agreement; provided, however, that the arbitrator shall not have the power to alter, amend or otherwise affect the terms or the provisions of this Agreement. Judgment upon any award rendered pursuant to this Section may be entered by any court having jurisdiction over the Parties other assets. The arbitrator shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrator's fees and any administrative fees of arbitration, unless the arbitrator shall otherwise allocate such costs, expenses and fees between the Parties. The Parties agree that all arbitration awards shall be final and binding on the Parties and their Affiliates. The Parties hereby waive the right to contest the award in any court or other forum. Except to the extent necessary to confirm an award or as may be

12.7.3 <u>Interim Relief.</u> Notwithstanding anything herein to the contrary, nothing in this Section 12.7 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, either prior to or during any arbitration hereunder, if necessary to protect the interests of such Party. This Section 12.7.3 shall be specifically enforceable.

12.8 Equitable Relief. HPA acknowledges and agrees that the restrictions set forth in Article VI of this Agreement are reasonable and necessary to protect the legitimate interests of Emergent and that Emergent would not have entered into this Agreement in the absence of such restrictions, and that any violation or threatened violation of any provision of Article VI will result in irreparable injury to Emergent. HPA also acknowledges and agrees that in the event of

a violation or threatened violation of any provision of Article VI, Emergent shall be entitled to preliminary and permanent injunctive relief, without the necessity of proving irreparable injury or actual damages and without the necessity of having to post a bond, as well as to an equitable accounting of all earnings, profits and other benefits arising from any such violation. The rights provided in the immediately preceding sentence shall be cumulative and in addition to any other rights or remedies that may be available to Emergent. Nothing in this Section 12.8 is intended, or should be construed, to limit Emergent's right to preliminary and permanent injunctive relief or any other remedy for a breach of any other provision of this Agreement.

- 12.9 No Benefit to Third Parties. Article II confers a benefit on those Persons referred to in Section 2.11 (the "Emergent Beneficiaries") and, subject to the remaining provisions of this Section 12.9, is intended to be enforceable by the Emergent Beneficiaries by virtue of the Contracts (Rights of Third Parties) Act 1999 (the "Act"). The Parties do not intend that any provisions of this Agreement, apart from those of Article II, should be enforceable by virtue of the Act by any person who is not a party to this Agreement. Notwithstanding the provisions of this Section 12.9, this Agreement may be rescinded or amended in any way and at any time by the Parties in accordance with its terms, without the consent of any of the Emergent Beneficiaries.
- 12.10 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm the rights and remedies of the other Party under this Agreement.
- 12.11 English Language. This Agreement shall be written and executed in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control. All notices and other disclosure required of the parties hereunder shall be in English.
- 12.12 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section, Schedule or Exhibit shall mean references to such Article, Section, Schedule or Exhibit of this Agreement, (b) references in any section to any clause are references to such clause of such section, and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, as so varied, replaced or supplemented and in effect at the relevant time of reference thereto.
- 12.13 Independent Contractors. It is expressly agreed that HPA and Emergent shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither HPA nor Emergent shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other Party. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and

obligations incurred by reason of any such employment shall be for the account and expense of such Party.

- 12.14 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder, or the failure to exercise, or delay in exercising a right or remedy provided by this Agreement or by law, or the waiver of a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.
- 12.15 Counterparts. The Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument
- 12.16 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties, and no rule of strict construction shall be applied against either Party.
- 12.17 Entire Agreement; Modifications. This Agreement, together with the BT License Agreement, the rBOT Development Agreement, the rBOT License Agreement, and the Distribution Agreement, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understanding, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment, modification, release or discharge hereof shall be binding upon the parties unless in writing and duly executed by authorized representatives of both Parties.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first set forth above.

Emergent BioSolutions, Inc.	Health Protection Agency
By: /s/ Fuad El-Hibri	By: /s/ Pat Troop
Fuad El-Hibri	Pat Troop
Citle: Chairman and CEO	Title: CEO
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### Schedule 1.19

## **Development Plan**

A framework for the proposed development plan to produce a botulinum tetravalent (A,B, C & E) vaccine is given below. The framework consists of a number of work packages the scope of which are provided as outlines. It is intended that each work programme will be presented as a detailed, fully-costed proposal for written approval by Emergent BioSolutions prior to commencement. Whilst an attempt has been made to cover all work packages currently envisaged, further work may arise during the development programme and may be agreed between HPA and Emergent at a later date.

Process/Analytical Development

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Process Confirmation

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GMP Manufacture

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### Schedule 2.3

## **Key Personnel**

HPA operates a project management system and will nominate a project management team for this project. The lead will be taken by a General Project Manager who will provide the chief contact between HPA and Emergent BioSolutions. The following HPA staff have previous experience in the manufacture and testing of botulinum toxins and as such will provide form part of the project team or provide input into this project.

Confirmation of such key staff and their time allocation tot he various work packages will be provided as part of the detailed HPA proposals for agreement by Emergent prior to commencing work.

Process Development

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GMP Manufacture

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Project Management

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## Schedule 3.1

## **Development Budget**

The following budget figures are provided for indicative purposes only and should not be regarded as firm or complete. Firm prices will be prepared for each work package requested under the development programme.

**Process/Analytical Development** 

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**Process confirmation** 

\$[\*\*]

GMP Manufacture/Stability Studies

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Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

### **rBOT VACCINE LICENSE AGREEMENT**

THIS rBOT VACCINE LICENSE AGREEMENT (this "Agreement"), effective as of November 23, 2004, (the "Effective Date"), by and between Emergent BioSolutions, Inc., a corporation organized and existing under the laws of the State of Delaware ("Emergent"), and the Health Protection Agency, a governmental agency organized and existing under the laws of England ("HPA") (each of Emergent and HPA, a "Party").

#### WITNESSETH ·

WHEREAS, Emergent, which is the parent company of BioPort Corporation, desires to develop and commercialize one or more pharmaceutical products comprising Clostridium botulinum toxin fragments produced using recombinant technology which products are designed for the prevention or treatment of illness caused by C. botulinum toxin;

WHEREAS, HPA is the owner or licensee of certain information and inventions necessary or useful for the commercialization of such pharmaceutical products;

WHEREAS, Emergent desires to receive from HPA, and HPA desires to grant to Emergent, licenses in and to such information and inventions owned or controlled by HPA, all on the terms and conditions set forth herein;

WHEREAS, HPA desires to reserve the right to make and sell such pharmaceutical products within certain limitations, as set forth herein;

WHEREAS, Emergent is the owner or licensee of certain information and inventions necessary or useful for the commercialization of such pharmaceutical products;

WHEREAS, HPA desires to receive from Emergent, and Emergent desires to grant to HPA, licenses in and to such information and inventions owned or controlled by Emergent, all on the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

### ARTICLE I Definitions

Unless specifically set forth to the contrary herein, the following terms shall have the respective meanings set forth below:

1.1 "AAA Rules" shall have the meaning set forth in Section 11.7.2.

1.2 "Act" shall have the meaning set forth in Section 11.9.

- 1.3 "Affiliate" shall mean, (a) with respect to Emergent, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with Emergent, and (b) with respect to HPA, any Person that, directly or indirectly, through one or more intermediaries, is controlled by HPA. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, by application of applicable law, or otherwise, or (b) the ownership indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity); provided that, if local law restricts foreign ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests.
  - 1.4 "After-Acquired HPA Know-How" shall have the meaning set forth in Section 1.34.
  - 1.5 "Agreement" shall have the meaning set forth in the preamble hereto.
- 1.6 "Applicable Law" shall mean all laws, rules, regulations applicable to the Exploitation of the Licensed Products, including any such rules, regulations, guidelines, or other requirements of the Regulatory Authorities, that may be in effect from time to time in the Territory.
- 1.7 "BT Development Agreement" shall mean that certain BT Vaccine Development Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
- 1.8 "BT License Agreement" shall mean that certain BT Vaccine License Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
  - 1.9 "Business Day" shall mean any day other than a Saturday, Sunday, any public holiday and any bank holiday in either the United States or England.
  - 1.10 "Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
  - 1.11 "Calendar Year" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.
- 1.12 "Clinical Trials" shall mean, with respect to a Licensed Product, all tests and studies in patients that are required by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise, for Regulatory Approval of such product.
- 1.13 "Combination Product" shall mean any form or dosage of pharmaceutical composition or preparation for use in humans which contains, in co-formulated combination with a Licensed Product, therapeutic or antigenic levels of one or more other active ingredients (i) that

do not comprise *C. botulinum* toxin fragments that are produced using recombinant technology, act to stimulate an immune response and are designed or intended for use in the Field and (ii) the Manufacture of which does not use, and which active ingredients do not incorporate, any rBOT Licensed Technology. A Combination Product shall be deemed to be a Licensed Product.

- 1.14 "Commercially Reasonable Efforts" shall mean, with respect to the development, Manufacture or commercialization of a Licensed Product, the level of efforts and resources customarily applied in the research-based pharmaceutical industry to a product of similar commercial potential at a similar stage in its lifecycle, taking into consideration its safety and efficacy, its cost to develop, the competitiveness of alternative products, its proprietary position, the likelihood of regulatory approval, its profitability, and all other relevant factors. Commercially Reasonable Efforts shall be determined on a country-by-country basis for each Licensed Product.
  - 1.15 "Confidential Information" shall have the meaning set forth in Section 4.3.1.
- 1.16 "Control" shall mean, with respect to any item of Information and Invention, Patent, Trademark or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such Information and Invention, Patent, Trademark or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.
  - 1.17 "Dispute" shall have the meaning set forth in Section 11.7.1.
- 1.18 "Distribution Agreement" shall mean that certain Exclusive Distribution Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
  - 1.19 "Drug Master File" shall have the meaning set forth in the rBOT Development Agreement.
  - 1.20 "Effective Date" shall mean the date of this Agreement as set forth in the preamble hereto.
  - 1.21 "Emergent" shall have the meaning set forth in the preamble hereto.
  - 1.22 "Emergent Beneficiaries" shall have the meaning set forth in Section 11.9.
  - 1.23 "Emergent Information" shall have the meaning set forth in Section 4.1.2.
  - 1.24 "Europe" shall mean the European Union, as it may be constituted from time to time.
- 1.25 "Exploit" shall mean to make, have made, import, use, sell, or offer for sale, including to research, develop, register, modify, enhance, improve, Manufacture, have Manufactured, store, formulate, have used, export, transport, distribute, promote, market or have sold or otherwise dispose of.

- 1.26 "Exploitation" shall mean the making, having made, importation, use, sale, offering for sale or disposition of a product or process, including the research, development, registration, modification, enhancement, improvement, Manufacture, storage, formulation, optimization, import, export, transport, distribution, promotion or marketing of a product or process.
  - 1.27 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.
  - 1.28 "FFDCA" shall mean the United States Federal Food Drug and Cosmetic Act, as amended from time to time.
  - **1.29** "Field" shall mean the prevention or treatment of illness in humans caused by *C. botulinum* toxin.
- 1.30 "First Sale" shall mean, with respect to any Licensed Product, the first commercial sale of such Licensed Product in a country where use of such Licensed Product is authorized by the relevant Regulatory Authorities (even though Regulatory Approval for such Licensed Product may not have been granted in such country). Any sale of a Licensed Product to a governmental entity for stockpiling or other health-related purposes shall qualify, for purposes of this definition, as such a commercial sale.
  - 1.31 "FTE Rate" shall have the meaning set forth in the rBOT Development Agreement.
  - 1.32 "GAAP" shall mean United States generally accepted accounting principles, consistently applied.
  - 1.33 "HPA" shall have the meaning set forth in the preamble hereto.
- 1.34 "HPA Know-How" shall mean all Information and Inventions, to the extent not generally known, (a) that are listed on Schedule 1.34 to this Agreement, (b) that are developed by or on behalf of, or come into the possession or under the Control of, HPA or its Affiliates after the Effective Date during the term of this Agreement and are reasonably necessary for the research, development, manufacturing, use or sale of Licensed Products or any Improvements to the Licensed Products (the "After-Acquired HPA Know-How"), or (c) that are Improvements to any item in (a) or (b) above, but excluding in each case (x) any Information and Inventions to the extent claimed or covered by the HPA Patents or Joint Patents, and (y) any Joint Know-How. For the avoidance of doubt, HPA Know-How shall include all such (i) biological, chemical, pharmacological, pharmaceutical, physical and analytical, clinical, safety, manufacturing and quality control data and information related to the Licensed Products, and (ii) assays and biological methodology necessary or useful for the Exploitation of the Licensed Products.
- 1.35 "HPA Patents" shall mean all of the Patents that HPA and its Affiliates own, have under license, have a right to acquire (by option or otherwise) or otherwise Control, as of the Effective Date and at any time during the term of this Agreement, that (a) are reasonably necessary for the research, development, manufacturing, use or sale of the Licensed Products or

any Improvements thereto, (b) claim or cover any Licensed Products, or (c) are Improvements to any item in (a) or (b) above, but excluding the Joint Patents. Without limitation of the foregoing, HPA Patents shall include those Patents listed on Schedule 1.35 to this Agreement, and any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates, and any international or foreign equivalent of any Patent listed in Schedule 1.35.

- 1.36 "HPA Products" shall have the meaning set forth in Section 3.3(c)(i).
- 1.37 "HPA Technology" shall mean, collectively, the HPA Patents and the HPA Know-How.
- 1.38 "Improvement" shall mean any modification, variation or revision to a compound, product or technology or any discovery, technology, device, process or formulation related to such compound, product or technology, whether or not patented or patentable, including any enhancement in the efficiency, operation, Manufacture (including any manufacturing process), ingredients, preparation, presentation, formulation, means of delivery, packaging or dosage of such compound, product or technology, any discovery or development of any new or expanded indications for such compound, product or technology, or any discovery or development that improves the stability, safety or efficacy of such compound, product or technology.
- 1.39 "IND" shall mean an investigational new drug application filed with the FDA for authorization to commence human clinical trials, and its equivalent in other countries or regulatory jurisdictions in the Territory.
  - **1.40** "Indemnification Claim Notice" shall have the meaning set forth in Section 7.3.1.
  - 1.41 "Indemnified Party" shall have the meaning set forth in Section 7.3.1.
- 1.42 "Information and Inventions" shall mean all technical, scientific and other know-how, show-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer software, apparatuses, specifications, data, cell lines, seed stock and other biological materials, pre-clinical and clinical trial results, Manufacturing procedures, test procedures and purification and isolation techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed, and all Improvements, whether to the foregoing or otherwise, and other discoveries, developments, inventions, and other intellectual property (whether or not confidential, proprietary, patented or patentable), but excluding the Regulatory Documentation.
  - 1.43 "Infringement Suit" shall have the meaning set forth in Section 9.4.1.
  - 1.44 "In-License Agreements" shall have the meaning set forth in Section 8.3(b).
  - 1.45 "Joint Know-How" shall have the meaning set forth in the rBOT Development Agreement.

- 1.46 "Joint Patents" shall have the meaning set forth in the rBOT Development Agreement.
- 1.47 "Joint Technology" shall mean, collectively, the Joint Patents and the Joint Know-How.
- 1.48 "Jurisdiction" shall mean the countries constituting Europe collectively and each other country in the Territory.
- 1.49 "Licensed HPA Patents" shall have the meaning set forth in Section 8.3(b).
- **1.50** "Licensed Product" shall mean a recombinant product that (a) comprises one or more *C. botulinum* toxin fragments that acts to stimulate an immune response, (b) is designed for use in the Field, (c) comprises, is comprised of (in whole or in part), or is Exploited using, HPA Technology or Joint Technology, and (d) is Manufactured by or on behalf of Emergent (or, in relation to a Sublicensee, Manufactured by or on behalf of such Sublicensee).
  - 1.51 "Losses" shall have the meaning set forth in Section 7.1.
  - 1.52 "Major Market" shall mean each of the United Kingdom, the United States, France, Germany, Italy, and Japan.
- 1.53 "Manufacture" and "Manufacturing" shall mean, with respect to a product or compound, the manufacturing, processing, formulating, packaging, labeling, holding and quality control testing of such product or compound.
- 1.54 "Marketing Authorization" shall mean a New Drug Application or Biologics License Application, each as defined in the FFDCA, and the regulations promulgated thereunder, and any corresponding foreign application, registration or certification, necessary or reasonably useful to market a Licensed Product in the Territory, but not including pricing and reimbursement approvals.
  - 1.55 "Minor Market" shall have the meaning set forth in Section 5.2.
- 1.56 "Net Sales" shall mean, for any period, the gross amount invoiced by Emergent, its Affiliates or its Sublicensees, as the case may be, for arm's-length sales of Licensed Products to Third Parties, after deducting (to the extent not already deducted from the amount invoiced or received): (a) normal and customary trade, quantity and cash discounts and sales returns and allowances, including (i) those granted on account of price adjustments, billing errors, rejected goods, damaged goods, returns and rebates, (ii) administrative and other fees and reimbursements and similar payments to wholesalers and other distributors, buying groups, pharmacy benefit management organizations, health care insurance carriers and other institutions, (iii) allowances, rebates and fees paid to distributors and (iv) chargebacks; (b) freight, postage, shipping and insurance expenses to the extent that such items are included in the gross amount invoiced; (c) customs and excise duties and other duties related to the sales to the extent that such items are included in the gross amount invoiced; (d) rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state

Medicaid, Medicare or similar state program or equivalent foreign governmental program; (e) sales and other taxes and duties directly related to the sale or delivery of Licensed Products (but not including taxes assessed against the income derived from such sale); (f) distribution expenses to the extent that such items are included in the gross amount invoiced; (g) any other similar and customary deductions that are consistent with GAAP, or in the case of non-United States sales, other applicable accounting standards (consistently applied); (h) any such invoiced amounts that are not collected by Emergent, its Affiliates or its Sublicensees, as the case may be; and (i) an amount equal to all royalties paid by Emergent, its Affiliates or its Sublicensees, as the case may be, to Third Parties in connection with the Exploitation of Licensed Products. Any of the deductions listed above that involves a payment by Emergent, its Affiliates or its Sublicensees, as the case may be, shall be taken as a deduction in the Calendar Quarter in which the payment is accrued by such entity. Deductions pursuant to clause (h) above shall be taken in the Calendar Quarter in which such sales are no longer recorded as a receivable. For purposes of determining Net Sales, the Product(s) shall be deemed to be sold when invoiced and a "sale" shall not include transfers or dispositions for charitable or promotional purposes.

For purposes of calculating Net Sales, sales between or among Emergent, its Affiliates, and its Sublicensees shall be excluded from the computation of Net Sales, but sales by Emergent, its Affiliates or its Sublicensees to Third Parties (other than its Sublicensees) shall be included in the computation of Net Sales.

In the event that a Licensed Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the first paragraph of this Section by the fraction A/(A+B), where A is the average invoice price in such country of the Licensed Product containing as its sole active ingredient C. botulinum toxin fragments produced using recombinant technology that act to stimulate an immune response and are intended for use in the Field, if sold separately in such country, and B is the average invoice price in such country of the other therapeutically or antigenically active ingredients in the Combination Product, if sold separately in such country. If, in a specific country, such other therapeutically or antigenically active ingredients in the Combination Product are not sold separately, Net Sales shall be adjusted by multiplying actual Net Sales of such Combination Product calculated pursuant to the first paragraph of this Section by the fraction A/C, where A is the average invoice price in such country of the Licensed Product containing as its sole active ingredient C. botulinum toxin fragments produced using recombinant technology that act to stimulate an immune response and are intended for use in the Field, and C is the invoice price in such country of such Combination Product. If, in a specific country, the Licensed Product containing as its sole active ingredient C. botulinum toxin fragments produced using recombinant technology that act to stimulate an immune response and are intended for use in the Field is not sold separately, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product calculated pursuant to the first paragraph of this Section by the fraction (C-B)/C, where B is the average invoice price in such country of the other therapeutically or antigenically active ingredients in the Combination Product and C is the invoice price

in such Combination Product and of the same class, purity and potency. If, in a specific country, neither a Licensed Product containing as its sole active ingredient *C. botulinum* toxin fragments produced using recombinant technology that act to stimulate an immune response and are intended for use in the Field nor the other therapeutically or antigenically active ingredients in such Combination Product is sold separately, a market price for such Licensed Product and such other therapeutically or antigenically active ingredients shall be negotiated by the Parties in good faith based upon the manufacturing costs, overhead and profit for such Combination Product and all similar substances then being made and marketed and having an ascertainable market price.

- 1.57 "Owned HPA Patents" shall have the meaning set forth in Section 8.3(b).
- 1.58 "Patents" shall mean (a) all patents and patent applications, (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patents or patent application, and (c) any foreign or international equivalent of any of the foregoing.
  - 1.59 "PCT" shall mean the Patent Cooperation Treaty, opened for signature June 19, 1970, 28 U.S.T. 7645.
- 1.60 "Person" shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government (whether or not having a separate legal personality).
  - **1.61** "Prosecution Jurisdictions" shall have the meaning set forth in Section 9.2.1.
- 1.62 "rBOT Development Agreement" shall mean that certain rBOT Vaccine Development Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms
  - 1.63 "rBOT Licensed Technology" shall mean, collectively, the rBOT Licensed Patents and the rBOT Licensed Know-How.
  - 1.64 "rBOT Licensed Know-How" shall mean, collectively, the HPA Know-How and Joint Know-How.
  - 1.65 "rBOT Licensed Patents" shall mean, collectively, the HPA Patents and the Joint Patents.
- 1.66 "Regulatory Approval" shall mean any and all approvals (including pricing and reimbursement approvals), governmental licenses, registrations or authorizations of any Regulatory Authority, necessary for the Exploitation of the Licensed Products in a country in the Territory, including any (a) approval of any Licensed Product (including any INDs, Marketing Authorizations and supplements and amendments thereto); (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); (c) labeling approval; and (d) technical, medical and scientific licenses.

- 1.67 "Regulatory Authority" shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of the Licensed Products in the Territory, but excluding HPA acting in its capacity as a Party.
- 1.68 "Regulatory Documentation" shall mean all applications, registrations, governmental licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests, relating to any Licensed Product, and all data contained in any of the foregoing, including all INDs, Marketing Authorizations, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files and Manufacturing records (including Manufacturing records maintained pursuant to Section 2.9.3 of the rBOT Development Agreement and any Drug Master Files prepared and filed by HPA).
  - 1.69 "Retained Rights" shall have the meaning set forth in Section 3.3(a).
  - 1.70 "Subject Product" shall have the meaning set forth in Section 5.5.
- 1.71 "Sublicense Income" shall mean consideration of any kind, including any fees, royalties, milestones or other payments (whether cash or non-cash), received by Emergent or any of its Affiliates from one or more Sublicensees in consideration of a grant of rights by Emergent to Sublicensee to Exploit any Licensed Product for use in the Field in a Minor Market, but excluding (a) amounts received at or below fair market value for equity in Emergent or any of its Affiliates, (b) equity received from a Sublicensee in exchange for monetary consideration at or above fair market value, or (c) amounts received in the form of a loan to Emergent or a repayment of a loan from Emergent.
- 1.72 "Sublicensee" shall mean a Third Party to which Emergent or any of its Affiliates grants a license or sublicense to Manufacture, and sell or otherwise Exploit any Licensed Product for use in the Field in one or more countries in the Territory. For the avoidance of doubt, a distributor, sales agent, marketing representative or other Person whose role is to import, promote and sell Licensed Products, but not to Manufacture, develop and/or secure Regulatory Approvals of such Licensed Products, shall not be deemed to be a Sublicensee.
  - 1.73 "Territory" shall mean all of the countries in the world.
  - 1.74 "Third Party" shall mean any Person other than Emergent, HPA and their respective Affiliates.
  - 1.75 "Third Party Claim" shall have the meaning set forth in Section 7.3.2.
- 1.76 "Trademark" shall include any word, name, symbol, color, designation or device or any combination thereof, including any trademark, trade dress, brand mark, trade name, brand name, logo or business symbol.

1.77 "U.K. Public Entity" shall mean any national, local, regional or provincial governmental agency of the United Kingdom, including any components of the National Health Service.

1.78 "Valid Claim" shall mean, with respect to a particular country, a claim of an issued and unexpired Patent in such country that (a) has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken or has been taken within the time allowed for appeal; (b) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise in such country; and (c) provides exclusive and enforceable rights with respect to the sale of the Licensed Product in such country.

### ARTICLE II Commercialization

- 2.1 Commercialization Activities. Emergent shall have the exclusive right to commercialize any and all Licensed Products in the Territory. HPA may commercialize any and all HPA Products only to the extent of its Retained Rights as more completely described in Section 3.3. Except as otherwise expressly provided herein Emergent shall be solely responsible for any costs and expenses it incurs in connection with its Exploitation of Licensed Products. HPA shall be solely responsible for any costs and expenses it incurs in connection with the exercise of the Retained Rights.
- 2.2 Communications with Regulatory Authorities. Emergent shall have the sole right to conduct all communications with regard to the Exploitation of the Licensed Products, with the Regulatory Authorities in countries in the Territory. Nothing in this Section 2.2 shall limit HPA's rights to communicate with Regulatory Authorities in the United Kingdom, or if necessary agencies of the European Commission, in connection with the Exploitation of HPA Products pursuant to its Retained Rights as more completely described in Section 3.3.
- 2.3 Regulatory Approvals. Emergent shall have the sole right to develop and implement the strategy for obtaining and maintaining Regulatory Approvals for Licensed Product throughout the Territory. In connection with the foregoing, Emergent shall be entitled to prepare and submit INDs, Marketing Authorizations and other filings, applications or requests made pursuant to or in connection with the Regulatory Approvals in its name or in the name of its designee, unless Applicable Law requires that a Regulatory Approval be granted solely or jointly in the name of HPA or its Affiliates, in which case HPA shall, or shall cause its Affiliates to, as applicable, take actions to effect the assignment of such Regulatory Approval to Emergent pursuant to Section 3.2, to the extent permitted by Applicable Law. Emergent shall further be entitled to prepare, file, maintain and hold all regulatory filings for Licensed Products and shall keep HPA informed of the initial filing, and final approval of, any application for Regulatory Approval of such Licensed Product(s) in the Territory. Upon the request of Emergent, HPA shall, and shall cause its Affiliates to, provide to Emergent or its designee all information in HPA's or its Affiliates' possession that is reasonably necessary to support any and all applications for Regulatory Approval of the Licensed Product(s) in the Territory, at Emergent's expense (charged at rates no less favorable than those charged by HPA to its largest non-governmental customers). Nothing in this Section 2.3 shall limit HPA's rights to develop and

implement the strategy for obtaining and maintaining Regulatory Approval for HPA Products pursuant to its Retained Rights as more completely described in Section 3.3.

- 2.4 Development and Use of Trademarks. Emergent shall have the sole right to determine the Trademarks to be used with respect to the Exploitation of Licensed Products and any and all Improvements thereto. Without the prior express written permission of HPA, Emergent shall not use, and shall not permit its Affiliates to use, the name of HPA or any of its Affiliates, or any Trademarks that is confusingly similar to, misleading or deceptive with respect to, or that dilutes any of the Trademarks owned, controlled or used by HPA or its Affiliates. Without the prior express written permission of Emergent, HPA shall not, and shall not permit its Affiliates to use the name of Emergent or any of its Affiliates, or any Trademark that is confusingly similar to, misleading or deceptive with respect to, or that dilutes any of the Trademarks owned, controlled or used by Emergent or any of its Affiliates.
- 2.5 Discretion. Subject to the terms of this Agreement, including Section 2.6, and the terms of the Distribution Agreement, the Parties acknowledge and agree that all decisions relating to Emergent's Exploitation and pricing of Licensed Products and any and all Improvements thereto, shall be within the sole discretion of Emergent. HPA acknowledges that Emergent is in the business of researching, developing, manufacturing, marketing and selling pharmaceutical products and nothing in this Agreement shall be construed as restricting such business or imposing on Emergent the duty to Exploit or otherwise commercialize any Licensed Product for which royalties are payable hereunder to the exclusion of, or in preference to, any other product, or in any manner other than in accordance with its normal commercial practices.
- 2.6 Diligence. The Parties acknowledge and agree that Emergent's development of the Licensed Products is subject to, and dependent upon, the availability of government funding for such product and clinical development activities; that the availability of such funding in general, and for Emergent specifically, is uncertain as of the Effective Date; that the timing and continuity of any such funding is also uncertain; and that any and all of these factors could result in significant delays in Emergent's Exploitation of the Licensed Products. Emergent agrees to use Commercially Reasonable Efforts (a) to respond to any solicitations and procurement proposals of government agencies in each Major Market (including, in the case of the United States, federal, state and local agencies), of which HPA gives notice to Emergent or of which Emergent is otherwise aware, that are directly applicable to one or more Licensed Products and (b) to enter into procurement contracts and development contracts with such government agencies with respect to the Licensed Products; provided, however, that Emergent shall not be required to do so with respect to any Licensed Product if a Third Party has instituted, or in the good faith judgment of Emergent is reasonably likely to institute, an Infringement Suit with respect to the Exploitation of such Licensed Product in such Major Market. Emergent shall be deemed to have satisfied its obligations under this Section 2.6 if it files an IND with respect to one or more Licensed Products by the fifth anniversary of the Effective Date. In the event that Emergent fails to file an IND with respect to at least one Licensed Product by such date (the "Penalty Date,"), then it shall pay HPA [\*\*] Dollars (US S[\*\*]) within ten days after the Penalty Date, and an equal sum thereafter on an annual basis, within ten days after each anniversary of the Penalty Date, until such time as Emergent has filed an IND with respect to at least one Licensed Product; provided, however, that if Emergent files such an IND

Emergent shall pay HPA a lump sum equal to the difference between [\*\*] Dollars (US \$[\*\*]) and the aggregate amount previously paid by Emergent to HPA pursuant to this sentence; and provided, further, that Emergent shall not be required to make any payment in the event that Emergent's failure to file such IND by such date results directly from the failure by HPA to perform any of its obligations hereunder in a timely manner. Such payment shall be the sole remedy of HPA for any breach of this Section 2.6, and any breach of this Section 2.6 (other than a breach of such payment obligation) shall not be deemed a material breach of this Agreement for purposes of Section 10.5.

- 2.7 Records and Audits. HPA shall prepare and maintain complete and accurate records regarding its marketing and sales of HPA Products in the Field. Upon the written request of Emergent and not more than once in each Calendar Year, HPA shall permit an independent firm of internationally recognized standing that is expert in the field of vaccine or pharmaceutical products, selected by Emergent, and reasonably acceptable to HPA, to have access during normal business hours, and upon reasonable prior written notice, to such of the records of HPA as may be reasonably necessary to verify that HPA's sales of HPA Products in the Field are within the scope of the Retained Rights. The firm that conducts such audit shall disclose to Emergent and HPA only the details of any sales made by HPA beyond the scope of the Retained Rights. Emergent shall bear the cost of such audit unless HPA is determined to have made sales beyond the scope of the Retained Rights, in which case HPA shall bear such cost.
- 2.8 Cooperation of HPA. HPA shall cooperate with any and all reasonable requests for assistance from Emergent with respect to the commercialization of the Licensed Products, including by making its employees, consultants and other scientific staff available upon reasonable notice during normal business hours at their respective places of employment to consult with Emergent on issues arising during such commercialization. In addition, HPA shall promptly disclose to Emergent any and all After-Acquired HPA Know-How, subject to the rights of any Third Parties therein. Emergent shall reimburse HPA for any and all reasonable and verifiable direct out-of-pocket costs and expenses incurred by HPA in providing such assistance, provided that the rate charged for any employee costs shall not exceed the most favorable rates charged by HPA to its largest non-governmental customers.
- 2.9 Rights and Obligations. Any and all rights of Emergent under this Article II are intended, and shall be construed, to benefit such of its Affiliates and Sublicensees as and to the extent Emergent may, from time to time, designate. Further, Emergent shall have the right to satisfy any or all of its obligations under this Article II through one or more of its Affiliates or Sublicensees; provided, however, that Emergent shall remain liable to HPA for the performance of such obligations.

## ARTICLE III

### License Grants and Assignments

- 3.1 Grants to Emergent. HPA hereby grants to Emergent and its Affiliates, and shall cause HPA's Affiliates to grant to Emergent and its Affiliates:
  - (a) an exclusive (even with regard to HPA and its Affiliates), perpetual and irrevocable (in each case subject to the provisions of Article X), royalty-bearing license, with the

right to grant sublicenses (through multiple tiers of sublicensees), under HPA's and its Affiliates' rights, title, and interest in and to the rBOT Licensed Technology, to Exploit Licensed Products and any and all Improvements thereto in the Field in the Territory (other than to make, have made, and use Licensed Products and any and all Improvements thereto in the Field in the United Kingdom and to sell or otherwise distribute Licensed Products and any and all Improvements thereto in the Field in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service)), which license shall be subject, in the case of the After-Acquired HPA Know-How, to any rights in such After-Acquired HPA Know-How granted by HPA to Third Parties prior to the creation of such After-Acquired HPA Know-How;

(b) a non-exclusive, perpetual and irrevocable (in each case subject to the provisions of Article X), royalty-bearing license, with right to grant sublicenses (through multiple tiers of sublicenses), under HPA's and its Affiliates' rights, title, and interest in and to the HPA Technology, to make, have made, and use Licensed Products and any and all Improvements thereto in the Field in the United Kingdom and to sell or otherwise distribute Licensed Products and any and all Improvements thereto in the Field in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service), which license shall be subject, in the case of the After-Acquired HPA Know-How, to any rights in such After-Acquired HPA Know-How granted by HPA to Third Parties prior to the creation of such After-Acquired HPA Know-How;

(c) an exclusive (even with regard to HPA and its Affiliates), perpetual and irrevocable (in each case subject to the provisions of Article X), royalty-bearing license and right of reference, with the right to grant sublicenses (through multiple tiers of sublicensees), under HPA's and its Affiliates' rights, title and interest in and to the Regulatory Documentation, to the extent not assigned to Emergent and its Affiliates pursuant to Section 3.2 or the rBOT Development Agreement, to Exploit Licensed Products and any and all Improvements thereto in the Territory (other than to make, have made, and use Licensed Products and any and all Improvements thereto in the Field in the United Kingdom and to sell or otherwise distribute Licensed Products and any and all Improvements thereto in the Field in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service)); and

(d) a non-exclusive, perpetual and irrevocable (in each case subject to the provisions of Article X), royalty-bearing license and right of reference, with the right to grant sublicenses (through multiple tiers of sublicensees), under HPA's and its Affiliates' rights, title and interest in and to the Regulatory Documentation, to the extent not assigned to Emergent and its Affiliates pursuant to Section 3.2 or the rBOT Development Agreement, to make, have made, and use Licensed Products and any and all Improvements thereto in the Field in the United Kingdom and to sell or otherwise distribute Licensed Products and any and all Improvements thereto in the Field in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase

Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service).

3.2 Assignment of Regulatory Documentation. HPA hereby assigns to Emergent, and shall cause its Affiliates to assign to Emergent, all of HPA's and its Affiliates' rights, title and interest in and to all Regulatory Documentation, including, to the extent permitted by Applicable Law, all Regulatory Approvals, Controlled by HPA or its Affiliates as of the Effective Date and from time to time during the term of this Agreement; provided, however, that HPA shall not be required to assign any Regulatory Documentation that it may develop, at its expense, solely in connection with the exercise of the Retained Rights under Section 3.3. HPA shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such agreements, documents and instruments, as may be necessary under, or as Emergent may reasonably request in connection with, or to carry out more effectively, the purposes of this Section 3.2.

### 3.3 HPA's Retained Rights and Licenses.

- (a) Subject to the provisions of Article X, HPA hereby retains the right under all of HPA's and its Affiliates' rights, title and interest in and to the rBOT Licensed Technology and the Regulatory Approvals, to the extent not assigned to Emergent and its Affiliates pursuant to Section 3.2 or the rBOT Development Agreement, to make, have made, and use HPA Products in the Field in the United Kingdom and to sell or otherwise distribute HPA Products in the Field in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase HPA Products for the purpose of supplying such HPA Products to or for the National Health Service) (collectively, the "Retained Rights").
- (b) HPA shall not, and shall cause its Affiliates not to, assign, sell or otherwise transfer, or grant any license or right of reference under, any of the Retained Rights to any Affiliate of HPA or any Third Party.
  - (c) Emergent hereby grants to HPA and its Affiliates, solely for use in connection with HPA's (or its Affiliates') exploitation of the Retained Rights:
- (i) a non-exclusive, perpetual and irrevocable (in each case subject to the provisions of Article X), royalty-free license (without the right to grant sublicenses), under Emergent's and its Affiliates' rights, title, and interest in and to (A) the patents, patent applications and know-how identified on Schedule 3.3(c), and (B) any Information and Inventions owned by Emergent during the term of this Agreement, or Controlled by Emergent during the term of this Agreement and as to which Emergent does not have royalty obligations to a Third Party, that are incorporated into the Licensed Products, to make, have made, and use a recombinant product that (w) comprises one or more *C. botulinum* toxin fragments that acts to stimulate an immune response, (x) is designed for use in the Field, (y) comprises, is comprised of (in whole or in part), or is Exploited using, HPA Technology or Joint Technology, and is (z) Manufactured by or on behalf of HPA (hereinafter "HPA Products") and any and all Improvements thereto in the Field in the United Kingdom to meet the

requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase HPA Products for the purpose of supplying such HPA Products to or for the National Health Service); and

- (ii) a non-exclusive, perpetual and irrevocable (in each case subject to the provisions of Article X), royalty-free license and right of reference (without the right to sublicense), under Emergent's and its Affiliates' rights, title and interest in and to the Regulatory Documentation, to make, have made, and use HPA Products and any and all Improvements thereto in the Field in the United Kingdom and to sell or otherwise distribute HPA Products and any and all Improvements thereto in the Field in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase HPA Products for the purpose of supplying such HPA Products to or for the National Health Service).
- (d) Notwithstanding anything in this Agreement to the contrary, subject to the license grant to HPA in Section 3.3(c), as between the Parties, Emergent shall own and retain all right, title and interest in and to all Emergent intellectual property and technology described therein and licensed thereunder.

### 3.4 Negative Covenant.

- (a) HPA hereby covenants and irrevocably (subject to the provisions of Article X) agrees for itself and each of its Affiliates that it and each of them shall not directly or indirectly assert, authorize, pursue or induce any third party to assert or pursue, assist or cooperate with any third party in asserting or pursuing, or seek to obtain any recovery with respect to any legal or equitable cause of action, suit, claim, defense, offset, counterclaim, cross-claim or pleading or other proceeding of any sort whatsoever, participate in any proceeding or action, or make any allegations against Emergent or any Affiliate, sub-licensee, authorized manufacturer or authorized distributor asserting that the (i) manufacture, use, sale, offer for sale, importation, or exportation of any product, or (ii) act of authorizing others to manufacture, use, sell, offer for sale, import, or export any product, or (iii) provision of any service, or (iv) practice of any method, that is both
  - (A) conducted with respect to Licensed Products, and
- (B) covered by or includes, in whole or in part, directly or indirectly, or is performed or used in conjunction with any know-how, show-how, patent or patent application (including without limitation Information and Inventions) owned or Controlled prior to, on or following the Effective Date by HPA or any of its Affiliates,
- constitutes direct infringement, contributory infringement, inducement to infringe, or otherwise violates, misappropriates or infringes any legal right under any of such intellectual property of HPA or any of its Affiliates.
- (b) Emergent hereby covenants and irrevocably (subject to the provisions of Article X) agrees (for itself and each of its Affiliates) that it and each of them shall not directly or indirectly assert, authorize, pursue or induce any third party to assert or pursue, assist or

cooperate with any third party in asserting or pursuing, or seek to obtain any recovery with respect to any legal or equitable cause of action, suit, claim, defense, offset, counterclaim, cross-claim or pleading or other proceeding of any sort whatsoever, participate in any proceeding or action, or make any allegations against HPA or any Affiliate asserting that the (i) manufacture, use, sale, offer for sale, importation, or exportation of any product, or (ii) act of authorizing others to manufacture, use, sell, offer for sale, import, or export any product, or (iii) provision of any service, or (iv) practice of any method, that is both

- (A) conducted by HPA or its Affiliates solely in furtherance of the Exploitation of HPA Products under its Retained Rights under Section 3.3 and
- (B) covered by or includes, in whole or in part, directly or indirectly, or is performed or used in conjunction with any know-how, show-how, patent or patent application (including without limitation Information and Inventions) owned or controlled by Emergent or any of its Affiliates that have been incorporated into Licensed Products,

constitutes direct infringement, contributory infringement, inducement to infringe, or otherwise violates, misappropriates or infringes any legal right under any of such intellectual property of Emergent or any of its Affiliates.

(c) The Parties acknowledge that the restrictions contained in this Section 3.4 are reasonable, valid and necessary for the adequate protection of the Licensed Products and HPA Products businesses and that the Parties would not have entered into this Agreement without the protection afforded them by this Section 3.4.

## ARTICLE IV Confidentiality and Nondisclosure

### 4.1 Confidentiality Obligations.

- 4.1.1 <u>General Obligations</u>. Except as provided herein, the Parties agree that, during the term of this Agreement and for five (5) years after this Agreement's expiration or termination pursuant to Article X, each Party shall hold in strict confidence and shall not publish or otherwise disclose, directly or indirectly, to any Person (other than employees, Affiliates, legal counsel, consultants, auditors and advisors who, except in the case of legal counsel, are bound in writing by confidentiality and non-use obligations no less onerous than those set forth herein) any Confidential Information of the other Party. During such period, a Party (and its Affiliates) shall not use for any purpose, directly or indirectly, Confidential Information of the other Party or its Affiliates furnished or otherwise made known to it, except as permitted hereunder.
- 4.1.2 <u>Additional HPA Obligations</u>. HPA recognizes that by reason of Emergent's status as an exclusive licensee pursuant to this Agreement and the rBOT Development Agreement, Emergent has an interest in HPA's retention in confidence of certain information of HPA. Accordingly, HPA shall, and shall cause its Affiliates, officers, directors, employees and agents to, hold in strict confidence, and not publish or otherwise disclose, and not use directly or indirectly for any purpose, any information relating to the Licensed Product(s) or the Regulatory Documentation, including the Regulatory Approvals (collectively, the "Emergent"

Information"), except to the extent that (a) the Emergent Information is in the public domain through no fault of HPA, its Affiliates, or any of their respective officers, directors, employees or agents, or (b) such disclosure is reasonably necessary for the performance of HPA's obligations hereunder or the exercise of the Retained Rights, provided that any Third Party to which HPA proposes to disclose any Emergent Information is bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article IV. For clarification, the disclosure by HPA to Emergent or by Emergent to HPA of Emergent Information shall not cause such information to cease to be subject to the confidentiality provisions of this Section 4.1.2.

- 4.2 Permitted Disclosures. Each Party may disclose Confidential Information or Emergent Confidential Information to the extent that such disclosure is:
- (a) Made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the receiving Party shall first have given notice to the disclosing Party and, insofar as permitted by applicable law, given the disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order; shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;
- (b) Otherwise required by law, in the opinion of legal counsel to the receiving Party as expressed in an opinion letter in form and substance reasonably satisfactory to the disclosing Party, which shall be provided to the disclosing Party at least two (2) business days prior to the receiving Party's disclosure of the Confidential Information pursuant to this Section 4.2(b);
- (c) Made by the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; <u>provided</u>, <u>however</u>, that reasonable measures shall be taken to assure confidential treatment of such information;
- (d) Made by Emergent to existing or potential acquirers or merger candidates; existing or potential pharmaceutical collaborators; investment bankers; existing or potential investors, venture capital firms or other financial institutions for purposes of obtaining financing; each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article IV;
- (e) Made by HPA to potential investors in any spin-off entity to which HPA intends to transfer its business relating to the Development Program (as defined in the rBOT Development Agreement) and the Exploitation of Licensed Products and HPA Products, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article IV: or

(f) Made by Emergent or its Affiliates or Sublicensees to Third Parties as may be necessary or reasonably useful in connection with the Exploitation of any Licensed Product, including subcontracting and sublicensing transactions in connection therewith.

### 4.3 Confidential Information.

- 4.3.1 <u>Defined</u>. "Confidential Information" of a Party shall mean all information and know-how and any tangible embodiments thereof provided by or on behalf of such Party to the other Party either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement, including data; knowledge; practices; processes; ideas; research plans; engineering designs and drawings; research data; manufacturing processes and techniques; scientific, manufacturing, marketing and business plans; and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business. For the avoidance of doubt, Confidential Information shall be deemed to include any and all information provided by one Party to the other Party relating to Licensed Products or HPA Products, and the terms of this Agreement.
- 4.3.2 Exclusions. Notwithstanding the foregoing, information or know-how of a Party shall not be deemed Confidential Information with respect to the receiving Party for purposes of this Agreement if such information or know-how: (a) was already known to the receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, at the time of disclosure to, or, with respect to know-how, discovery or development by, such receiving Party; (b) was generally available or known, or was otherwise part of the public domain, after its disclosure to, or, with respect to know-how, discovery or development by, such receiving Party; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to know-how, discovery or development by, such receiving Party through no fault of the receiving Party; (d) was disclosed to such receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the Party that Controls such information and know-how not to disclose such information or know-how to others; or (e) was independently discovered or developed by such receiving Party or its Affiliates, as evidenced by their written records, without the use of Confidential Information belonging to the Party that Controls such information and know-how.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of a Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of such Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of a Party merely because individual elements of such Confidential Information are in the public domain or in the possession of such Party unless the combination and its principles are in the public domain or in the possession of such Party.

**4.4 Use of Name.** Neither Party shall mention or otherwise use the name, symbol, trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this

Section shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law.

- 4.5 Press Releases; Publication. Each Party shall have the right to issue press releases and to make other public disclosures, presentations or publications with respect to this Agreement; provided, however, that no such press release or other public disclosure, presentation or publication shall disclose any Confidential Information of the other Party without the prior written consent of such other Party; and, provided further, that neither HPA nor any of its Affiliates, officers, directors, employees or agents shall be permitted to issue any Press release or make any other public disclosure, presentation or publication regarding any information, data or results pertaining to or resulting from the Emergent Information, without the prior written consent of Emergent. HPA agrees to acknowledge Emergent in all such publications or other public disclosures by coauthorship or acknowledgement, as appropriate according to customary practice for such research publications and disclosures.
- **4.6 Equitable Relief.** Each Party acknowledges and agrees that breach of any of the terms of this Article IV would cause irreparable harm and damage to the other Party and that such damage may not be ascertainable in money damages and that as a result thereof the non-breaching Party would be entitled to seek from a court equitable or injunctive relief restraining any breach or future violation of the terms contained herein by the breaching Party without the necessity of proving actual damages. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of law or equity, including money damages, which other remedies are subject to Section 11.7.

# ARTICLE V Payments and Reports

- **5.1 Payments to HPA for Sales of Licensed Products in Major Markets.** Subject to Sections 5.4, 5.5, and 10.6.2(b), the right of offset of Emergent under Section 7.4(b), and the other terms and conditions of this Agreement, in partial consideration of the licenses and other rights granted herein, Emergent, on a Licensed Product-by-Licensed Product and Major Market-by-Major Market basis, shall pay to HPA royalties in an amount equal to:
  - (a) [\*\*] percent ([\*\*]%) of Net Sales of such Licensed Product by Emergent, its Affiliates, or its Sublicensees in such Major Market; and
- (b) until aggregate cumulative Net Sales of all Licensed Products by Emergent, its Affiliates, and its Sublicensees in all Major Markets and by Emergent and its Affiliates in all Minor Markets have reached [\*\*] Dollars (US \$[\*\*]), an additional [\*\*] percent ([\*\*]%) of Net Sales of such Licensed Product by Emergent, its Affiliates or its Sublicensees in such Major Market.
- **5.2 Payments to HPA for Sales of Licensed Products in Other Countries.** Subject to Sections 5.3, 5.4, 5.5, 10.6.2(b), the right of offset of Emergent under Section 7.4(b), and the other terms and conditions of this Agreement, in partial consideration of the licenses and other rights granted herein, Emergent, on a Licensed Product-by-Licensed Product and country-by-

country basis for countries other than the Major Markets (each, a "Minor Market"), shall pay to HPA the following:

- (a) royalties in an amount equal to [\*\*] percent ([\*\*]%) of Net Sales of such Licensed Product by Emergent or its Affiliates (but not its Sublicensees) in such Minor Market; and
- (b) an amount equal to [\*\*] percent ([\*\*]%) of the difference between (i) all Sublicense Income received by Emergent or any of its Affiliates from the Sublicensee(s) for such Minor Market in connection with the Exploitation of such Licensed Product in the Field in such Minor Market and (ii) all fully-loaded internal costs and out-of-pocket costs incurred by Emergent and its Affiliates in connection with the identification of, negotiation with, and training of such Sublicensee and its employees and agents, and all other project costs related to Emergent's and its Affiliates' support of such Sublicensee's efforts to Exploit such Licensed Product in the Field in such Minor Market, all of which costs shall be calculated in a manner consistent with Emergent's standard method of accounting.
- **5.3 Reduction in Royalties for Compulsory Licenses**. In the event that a court or a governmental agency of competent jurisdiction requires Emergent or one of its Affiliates to grant a compulsory license to a Third Party permitting such Third Party to make and sell a Licensed Product in a Minor Market, and the rate of royalty payable to Emergent or its Affiliate under such license is lower than the market rate of royalty for such license is or would be in such country, then all Net Sales of such Licensed Product by Emergent and its Affiliates in such country shall be excluded from the royalty calculations set forth in Section 5.2(a) and the rate of royalty to be paid by Emergent to HPA on such Net Sales shall be equal to [\*\*] percent ([\*\*]%) of the royalty rate under such compulsory license, during the time period when such compulsory license is in effect and being exercised.
- 5.4 Reduction in Royalties for Competition. In the event that HPA or its Affiliates shall knowingly and materially assist any Third Party to develop or otherwise Exploit a Vaccine Product (as defined in the rBOT Development Agreement) designed or intended for the prevention or treatment of illness in humans caused by *C. botulinum* toxin that competes with any Licensed Product and achieves a market share of at least [\*\*] percent ([\*\*]%) in a country, then the rate of royalty applicable to such Licensed Product in such country under Section 5.1 or 5.2(a), as the case may be, shall be reduced by [\*\*] percent ([\*\*]%). For purposes of this Section 5.4, the provision by HPA to a Third Party of standard commercially available services on a fee-for-service basis (e.g., sample testing using customer supplied assays or commercially available assays) that do not involve a research component (e.g., assay development) shall not, standing alone, be deemed "material assistance" to such Third Party.
- **5.5 Royalty Term**. Emergent's royalty obligations under Sections 5.1 and 5.2 shall terminate, on a country-by-country basis, with respect to each Licensed Product (for purposes of this Section 5.5, each a "Subject Product"):
- (a) in the case of any country in Europe, on the later to occur of (i) the seventh (7th) anniversary of the First Sale of the first Licensed Product in any country in Europe and (ii) the expiration date in such country of the last to expire of any issued HPA Patents and Joint

Patents that includes at least one Valid Claim covering the sale of such Subject Product in such country; or

(b) in the case of any country not in Europe, on the later to occur of (i) the seventh (7th) anniversary of the First Sale of the first Licensed Product in such country and (ii) the expiration date in such country of the last to expire of any issued HPA Patents and Joint Patents that includes at least one Valid Claim covering the sale of such Subject Product in such country.

Upon termination of the royalty obligations of Emergent under this Section 5.5 in a country, the license grants to Emergent in Section 3.1 shall become fully paid-up with respect to such country.

5.6 Reports; Payments. Following the First Sale of a Licensed Product, Emergent shall furnish to HPA a written report for each Calendar Quarter showing (a) invoiced sales and Net Sales by Emergent and its Affiliates in the Territory, and by Sublicensees in the Major Markets, (b) the number of units of each Licensed Product sold on a country-by-country basis during the applicable Calendar Quarter, and (c) the calculation of amounts owed to HPA pursuant to Section 5.1 and 5.2 in such Calendar Quarter. Reports shall be due and amounts owed to HPA shall be due and payable sixty (60) days following the close of each Calendar Quarter. Emergent shall keep complete and accurate records in sufficient detail to enable the amounts payable hereunder to be determined.

#### 5.7 Audits

(a) Upon the written request of HPA and not more than once in each Calendar Year, Emergent shall permit an independent certified public accounting firm of internationally recognized standing selected by HPA, and reasonably acceptable to Emergent, to have access during normal business hours, and upon reasonable prior written notice, to such of the records of Emergent as may be reasonably necessary to verify the accuracy of the reports provided in accordance with Section 5.6, for any Calendar Year ending not more than twenty-four (24) months prior to the date of such request. The accounting firm shall disclose to Emergent and HPA only whether the financial statements and any related invoices are correct or incorrect and the specific details concerning any discrepancies. If such accounting firm concludes that Emergent owed additional amounts to HPA during such period, Emergent shall pay HPA the difference between the amount actually owed, as determined by the accounting firm, and the amount actually paid by Emergent, with interest from the date originally due at the prime rate, as published in *The Wall Street Journal*, Eastern United States Edition, on the last business day preceding such date, within thirty (30) days after the date on which such accounting firm's written report is delivered to HPA. If such accounting firm concludes that Emergent has underpaid HPA during such period, Emergent shall pay such difference to HPA within thirty (30) days after the date of delivery of such report. If, and only if, the amount of the underpayment is greater than five percent (5%) of the total actual amount owed as determined by the accounting firm, Emergent shall bear all costs related to such audit. In all other cases, HPA shall bear the cost of such audit.

- (b) Emergent shall include in each sublicense granted by it in a Major Market pursuant to this Agreement a provision requiring the Sublicensee to make reports to Emergent, to keep and maintain records of sales made pursuant to such sublicense and to grant access to such records by HPA's independent accountant to the same extent required of Emergent under this Agreement. Upon the expiration of twenty-four (24) months following the end of any year, the calculation of amounts payable with respect to such year shall be binding and conclusive upon HPA, and Emergent and its Sublicensees shall be released from any liability or accountability with respect to amounts payable for such year.
- (c) HPA shall treat all information subject to review under this Article V in accordance with the confidentiality provisions of Article IV and shall cause its accounting firm to enter into a reasonably acceptable confidentiality agreement with Emergent obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.
- **5.8 Mode of Payment**. All payments to be made by a Party to the other Party under this Agreement shall be made in United States dollars and may be paid by check made to the order of the receiving Party or bank wire transfer in immediately available funds to such bank account designated in writing by the receiving Party from time to time. Payments shall be free and clear of any taxes (other than withholding and other taxes imposed on the receiving Party, which shall be for the account of such Party), fees or charges, to the extent applicable. With respect to payments in currencies other than United States dollars, payments shall be calculated based on currency exchange rates for the month in which the invoice is received. For each month and each currency, such exchange rate shall equal the arithmetic average of the daily exchange rates for such month listed in *The Wall Street Journal*, Eastern United States Edition, or, if not so available, as otherwise agreed by the Parties. Any delinquent payments shall accrue interest from the date on which payment was due, at the prime rate, as published in *The Wall Street Journal*, Eastern United States Edition, on the last Business Day preceding such date.

### ARTICLE VI

### Complaints, Adverse Event Reporting and Product Recall

- **6.1 Complaints**. Each Party shall maintain a record of any and all complaints it receives with respect to either the Licensed Products or the HPA Products. Each Party shall notify the other Party in reasonable detail of any such complaint received by it at the same time as such Party is required to first report such complaint to any Regulatory Authority, if such Party is required to report such complaint, and in any event in sufficient time to allow such other Party to comply with any and all regulatory and other requirements imposed upon it in any country in which the Licensed Products or the HPA Products, as the case may be, are being marketed or distributed.
- 6.2 Adverse Event Reporting. Each Party shall provide the other Party with all information necessary or desirable for such other Party to receive in order to comply with all Applicable Law relating to adverse event reporting with respect to the Licensed Products and the HPA Products. In furtherance hereof, Emergent and HPA shall each (a) develop appropriate adverse experience reporting procedures; (b) provide to the other Party any material information on the HPA Products or the Licensed Products, respectively, from pre-clinical or clinical

laboratory, animal toxicology and pharmacology studies, as well as serious or unexpected adverse experience reports from clinical trials and commercial experiences with the HPA Products or the Licensed Products, respectively; and (c) report and provide such information to the other Party in such a manner and time so as to enable such other Party to comply with all Applicable Law in countries in which such other Party has sought or will seek Regulatory Approval.

### 6.3 Product Recall

- 6.3.1 Notification and Recall. Emergent and HPA shall each have the sole right to decide, in its discretion, whether to conduct a recall of any Licensed Product or HPA Product, respectively (except in the case of a government-mandated recall), and the manner in which any such recall shall be conducted.
- 6.3.2 <u>Recall Expenses</u>. Emergent and HPA shall each bear the expenses of any recall of any Licensed Product or HPA Product, respectively; <u>provided</u>, <u>however</u>, that HPA shall bear the expense of a recall to the extent that such recall resulted from any defect in the Manufacturing of any Licensed Product or any intermediate thereof supplied to Emergent by or on behalf of HPA, HPA's breach of its obligations hereunder or HPA's gross negligence or willful misconduct. Such expenses of recall shall include expenses for notification, destruction or return of the recalled Licensed Product, any refund to consumers of amounts paid for the recalled Licensed Product, and any royalties paid by Emergent to HPA with respect to such recalled Licensed Product.

### ARTICLE VII Indemnity

- 7.1 Indemnification of Emergent. Subject to Sections 7.3 and 7.4(b), HPA shall indemnify Emergent, its Affiliates and its and their respective directors, officers, employees and agents, and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) in connection with any and all suits, investigations, claims or demands (collectively, "Losses") arising from or occurring as a result of (a) any material breach by HPA of this Agreement, (b) any gross negligence or willful misconduct of HPA, its Affiliates or its other permitted subcontractors in performing HPA's obligations under this Agreement, or (c) the Exploitation of HPA Licensed Products, except for those Losses for which Emergent has an obligation to indemnify HPA pursuant to Section 7.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the
- **7.2 Indemnification of HPA**. Subject to Sections 7.3 and 7.4(b), Emergent shall indemnify HPA, its Affiliates and their respective directors, officers, employees and agents, and defend and save each of them harmless, from and against any and all Losses arising from or occurring as a result of (a) any material breach by Emergent of this Agreement, (b) the gross negligence or willful misconduct of Emergent, its Affiliates or its other subcontractors in performing Emergent's obligations under this Agreement, or (c) the Exploitation of Licensed Products by Emergent or any of its Affiliates, except for those Losses for which HPA has an

obligation to indemnify Emergent and its Affiliates pursuant to Section 7.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

### 7.3 Indemnification Procedure

- 7.3.1 Notice of Claim. The indemnified Party shall give the indemnifying Party prompt written notice (an "Indemnification Claim Notice") of any Losses or discovery of fact upon which such indemnified Party intends to base a request for indemnification under Section 7.1 or Section 7.2. In no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses. All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "Indemnified Party").
- 7.3.2 Third Party Claims. The obligations of an indemnifying Party under this Article VII with respect to Losses arising from claims of any Third Party that are subject to indemnification as provided for in Sections 7.1 or 7.2 (a "Third Party Claim") shall be governed by and be contingent upon the following additional terms and conditions:
- (a) Control of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify any Person seeking indemnification in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against any such claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by any indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, the indemnifying Party shall not be liable to the Indemnified Party or any other indemnified Party for any legal expenses subsequently incurred by such indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in its defense of the Third Party Claim with respect to such indemnified Party.
- (b) Right to Participate in Defense. Without limiting Section 7.3.2(a), any indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to retain counsel of its choice for such purpose; provided, however, that such

retention shall be at the indemnified Party's own expense unless (i) the employment thereof has been specifically authorized by the indemnifying Party in writing or (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 7.3.2(a) (in which case the Indemnified Party shall control the defense).

- (c) <u>Settlement</u>. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 7.3.2(a), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). The indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim in a manner that has a materially adverse effect on the indemnifying Party without the prior written consent of the indemnifying Party.
- (d) <u>Cooperation</u>. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each other indemnified Party to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.
- (e) Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

#### 7.4 LIMITATION OF LIABILITY.

(a) SUBJECT TO SECTIONS 7.1 AND 7.2, AND EXCEPT IN CIRCUMSTANCES OF GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, NONE OF EMERGENT, HPA OR ANY OF THEIR RESPECTIVE AFFILIATES SHALL BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING FOR LOST PROFITS, MILESTONES OR ROYALTIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (A) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT, OR (B) THE DEVELOPMENT, MANUFACTURE, USE OR SALE OF ANY PRODUCT DEVELOPED, MANUFACTURED OR MARKETED HEREUNDER. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS ATTEMPTING TO EXCLUDE OR LIMIT THE LIABILITY OF EITHER OF THE PARTIES OR THEIR RESPECTIVE AFFILIATES (A) FOR DEATH OR PERSONAL INJURY CAUSED BY THE NEGLIGENCE OF EITHER OF THE PARTIES, THEIR RESPECTIVE AFFILIATES, OR OF THE OFFICERS, EMPLOYEES OR AGENTS OF THE PARTIES OR THEIR RESPECTIVE AFFILIATES, (B) FOR FRAUD OR FRAUDULENT MISREPRESENTATION OR (C) FOR ANY MATTER IN RESPECT OF WHICH IT WOULD BE ILLEGAL FOR EITHER PARTY TO EXCLUDE OR ATTEMPT TO EXCLUDE ITS LIABILITY

(b) SUBJECT TO THE PRECEDING SENTENCE, BUT NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, IN NO EVENT SHALL THE COMBINED AGGREGATE LIABILITY OF EITHER PARTY UNDER THIS AGREEMENT, TAKEN TOGETHER WITH SUCH PARTY'S AGGREGATE LIABILITY UNDER THE 1BOT DEVELOPMENT AGREEMENT, THE BT LICENSE AGREEMENT, THE BT DEVELOPMENT AGREEMENT AND THE DISTRIBUTION AGREEMENT, EXCEED THE COMBINED AGGREGATE AMOUNTS PAID BY EMERGENT TO HPA, WHETHER AS LUMP SUMS OR PERIODIC PAYMENTS OF ROYALTIES OR SUBLICENSE INCOME, UNDER THIS AGREEMENT, THE BOT DEVELOPMENT AGREEMENT, THE BT DEVELOPMENT AGREEMENT AND THE DISTRIBUTION AGREEMENT (THE "AGGREGATE AMOUNT"); PROVIDED, HOWEVER, THAT IN THE EVENT THAT EITHER PARTY (THE "LIABLE PARTY") SHALL BECOME LIABLE TO THE OTHER PARTY HEREUNDER OR THEREUNDER FOR AN AMOUNT (THE "TOTAL LIABILITY") LARGER THAN THE AGGREGATE AMOUNT CALCULATED AS OF THE DATE THAT THE TOTAL LIABILITY BECAME DUE AND PAYABLE, THE LIABLE PARTY SHALL PROMPTLY PAY SUCH OTHER PARTY A LUMP SUM EQUAL TO THE AGGREGATE AMOUNT AS SO CALCULATED; AND PROVIDED, FURTHER, THAT IF HPA IS THE LIABLE PARTY, EMERGENT SHALL THEREAFTER HAVE A RIGHT OF OFFSET WITH RESPECT TO ANY PAYMENT OBLIGATIONS OF EMERGENT TO HPA HEREUNDER AND THEREUNDER THAT BECOME DUE AND PAYABLE AFTER SUCH DATE, UNTIL SUCH TIME AS THE TOTAL AMOUNTS OFFSET BY EMERGENT EQUAL THE DIFFERENCE BETWEEN THE TOTAL LIABILITY AND SUCH LUMP SUM PAYMENT BY HPA; AND PROVIDED, FURTHER, THAT IF EMERGENT IS THE LIABLE PARTY, THEN THEREAFTER, AT SUCH TIMES AS EMERGENT SHALL MAKE PAYMENTS TO HPA THAT ARE OTHERWISE DUE AND PAYABLE HEREUNDER OR THEREUNDER, EMERGENT

SHALL PAY TO HPA AN EQUAL AMOUNT AS ADDITIONAL DAMAGES, UNTIL SUCH TIME AS THE TOTAL AMOUNTS SO PAID TO HPA AS ADDITIONAL DAMAGES EQUAL THE DIFFERENCE BETWEEN THE TOTAL LIABILITY AND SUCH LUMP SUM PAYMENT BY EMERGENT..

7.5 Insurance. Emergent shall use commercially reasonable efforts to obtain and maintain, with an insurance company of internationally recognized standing, such type and amounts of liability insurance covering the Exploitation of the Licensed Products, and HPA shall maintain such program of self-insurance covering the Exploitation of the HPA Products, as is normal and customary in the pharmaceutical industry generally for Parties similarly situated, and Emergent shall upon request provide HPA with a copy of such policies of insurance, along with any amendments and revisions thereto; provided, however, that Emergent shall promptly notify HPA in writing if, after using commercially reasonable efforts, Emergent is unable to obtain such insurance or if, after obtaining such insurance, Emergent is unable to maintain such insurance; and provided, further, that Emergent shall not be required to seek such insurance coverage to the extent that the relevant liabilities are covered by a government indemnity in favor of Emergent or precluded by applicable law.

## ARTICLE VIII Representations and Warranties

- 8.1 Representations and Warranties. Each Party hereby represents, warrants and covenants to the other Party as of the Effective Date as follows:
- (a) Such Party (i) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (ii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.
- (b) Such Party is not aware of any pending or threatened litigation (and has not received any communication) that alleges that such Party's activities related to this Agreement have violated, or that by conducting the activities as contemplated herein such Party would violate, any of the intellectual property rights of any other Person.
- (c) All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.
- (d) The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable law or regulation or any provision of the articles of incorporation, bylaws, limited partnership

agreement or any similar instrument of such Party, as applicable, in any material way, and (ii) do not conflict with, violate, or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

- **8.2** Additional Representations, Warranties and Covenants of Emergent. Emergent represents, warrants and covenants to HPA as of the Effective Date that Emergent is a corporation duly organized and in good standing under the laws of the State of Delaware, and has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.
  - 8.3 Additional Representations, Warranties and Covenants of HPA. HPA represents, warrants and covenants to Emergent as of the Effective Date that:
- (a) HPA is a governmental entity duly organized, validly existing and in good standing under the laws of England, and has full governmental power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.
- (b) HPA is the sole and exclusive owner of all right, title and interest in and to the Patents listed in Part A of Schedule 1.35 (the "Owned HPA Patents") and, except as provided in Schedule 1.35, such rights are not subject to any encumbrance, lien or claim of ownership by any Third Party. HPA is the exclusive licensee of and Controls all right, title and interest in and to the Patents listed in Part B of Schedule 1.35 (the "Licensed HPA Patents") and, except as provided in Schedule 1.35, such rights are not subject to any encumbrance, lien or claim of ownership by any Third Party. The Parties acknowledge that Emergent has received an opinion from counsel to HPA, Mathys & Squire, that the grant by HPA to Emergent of the licenses in Section 3.1 does not conflict with, violate, breach or constitute a default under, or require any consent under that certain Agreement dated as of February 1, 2000, by and between Microbiological Research Authority and Allergan, Inc. or under that certain Agreement dated as of November 10, 1998, by and between Microbiological Research Authority and The Speywood Laboratory (such agreements, collectively, the "In-License Agreements"), with respect to any of the Owned HPA Patents or the Licensed HPA Patents. The Owned HPA Patents and the Licensed HPA Patents constitute all of the HPA Patents as of the Effective Date. During the term of this Agreement, HPA shall not encumber or diminish the rights granted to Emergent hereunder with respect to the HPA Patents, including by not (i) committing any acts or permitting the occurrence of any omissions that would cause the breach or termination of any In-License Agreement, or (ii) amending or otherwise modifying, or permitting to be amended or modified, any In-License Agreement. HPA shall promptly provide Emergent with notice of any alleged, threatened, or actual breach of any In-License Agreement. As of the date hereof, none of HPA, its Affiliates and, to the best of their knowledge, no Third Party is in breach of any In-License Agreement.
- (c) To the best knowledge of HPA, the HPA Patents existing as of the Effective Date are subsisting and are not invalid or unenforceable, in whole or in part, and the conception, development and reduction to practice of the Regulatory Documentation, the HPA Patents and HPA Know-How existing as of the Effective Date have not constituted or involved the

misappropriation of trade secrets or other rights or property of any Third Party. There are no claims, judgments or settlements against or amounts with respect thereto owed by HPA or any of its Affiliates relating to the Regulatory Documentation, the HPA Patents, or the HPA Know-How. No claim or litigation has been brought or threatened by any Person alleging, and HPA is not aware of any possible claim, whether or not asserted, that (i) the HPA Patents are invalid or unenforceable or (ii) the Regulatory Documentation, the HPA Patents, or the HPA Know-How or the disclosing, copying, making, assigning, licensing or Exploitation of the Regulatory Documentation, the HPA Patents, or the HPA Know-How, including the Exploitation of any Licensed Product, violates, infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Third Party. To the best knowledge of HPA, Emergent's worldwide Exploitation of any Licensed Product pursuant to the exercise of the licenses granted by HPA to Emergent in this Agreement will not infringe any Patents Controlled by any Third Party.

- (d) Except for the license grants and assignment in Sections 3.1 and 3.2, neither HPA nor any of its Affiliates has, directly or indirectly, expressly or by implication, by action or omission or otherwise (i) assigned, transferred, conveyed or otherwise encumbered any right, title or interest in or to the Regulatory Documentation or the HPA Technology in the Field; (ii) granted any license or other right, title or interest in or to the Regulatory Documentation or the HPA Technology in the Field; or (iii) agreed to or is otherwise bound by any covenant not to sue for any infringement, misuse or otherwise with respect to the Regulatory Documentation or the HPA Technology in the Field.
- (e) HPA agrees not to, and agrees to cause its Affiliates not to, directly or indirectly, expressly or by implication, by action or omission or otherwise (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the HPA Technology or Joint Technology, (ii) grant any license or other right, title or interest in or to the HPA Technology or the Joint Technology in any manner, or (iii) agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to the HPA Technology or the Joint Technology, in each case ((i), (ii), and (iii)) that is inconsistent with the grants, assignments and other rights reserved to Emergent and its Affiliates under this Agreement and the rBOT Development Agreement.
- (f) HPA shall cause each of its Affiliates and any other Person conducting Development Activities on behalf of HPA hereunder to assign to HPA rights to any and all Information and Inventions that relate to the Licensed Product(s), such that Emergent shall, by virtue of this Agreement and the rBOT License Agreement, receive from HPA, without payment of additional consideration beyond that required by this Agreement and the rBOT Development Agreement, the licenses and other rights granted to Emergent and its Affiliates hereunder and under the rBOT Development Agreement.
  - (g) To the best of HPA's and its Affiliate's knowledge, there is no actual or threatened infringement by a Third Party of the Regulatory Documentation or the rBOT Licensed Technology.

8.4 Disclaimer of Warranties. EXCEPT FOR THOSE WARRANTIES SET FORTH IN THIS ARTICLE VIII, AND SUBJECT TO SECTION 7.4(a), EACH PARTY HEREBY DISCLAIMS ANY AND ALL WARRANTIES, CONDITIONS AND TERMS, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING (A) ANY WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, (B) ANY WARRANTY WITH RESPECT TO THE VALIDITY OR ENFORCEABILITY OF ANY PATENT OR OTHER INTELLECTUAL PROPERTY, AND (C) ANY WARRANTY THAT THE PERFORMANCE OF ITS RIGHTS OR OBLIGATIONS HEREUNDER WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF ANY PERSON. SUBJECT TO SECTION 7.4(a), NO PARTY MAKES ANY REPRESENTATIONS HEREUNDER OTHER THAN THOSE SET FORTH EXPRESSLY HEREIN.

# ARTICLE IX Intellectual Property Provisions

**9.1 Ownership of HPA Technology and Emergent Technology.** Subject to the license grants to Emergent and its Affiliates in Sections 3.1(a) and 3.1(b), as between the Parties, HPA shall own and retain all right, title and interest in and to all HPA Technology.

#### 9.2 Prosecution of HPA Patents

- 9.2.1 HPA Patents. Subject to Sections 9.2.3 and 9.2.4, HPA shall be responsible, at the shared expense of Emergent and such other Persons as may be granted licenses thereunder by HPA consistent with the limitations of this Agreement, for obtaining, prosecuting and maintaining the HPA Patents in the United States, Canada, the European Union, Australia and Japan (the "Prosecution Jurisdictions") and such other countries in the Territory as Emergent, in its sole discretion, may elect. HPA shall file, prosecute and maintain Patent applications to secure Patent rights for the patentable HPA Technology (except to the extent that a Third Party licensor has retained the right to do so, in which case HPA shall use its commercially reasonable efforts to cause such Third Party licensor to do so), in the Prosecution Jurisdictions and in such other countries as Emergent may from time to time designate in writing.
  - 9.2.2 Interference, Opposition, Reexamination and Reissue of HPA Patents. In addition to the other obligations imposed on HPA pursuant to this Section 9.2:
- (a) HPA shall promptly, and in any event within fifteen (15) days of such event, inform Emergent of any request for, or filing or declaration, any interference, opposition, or reexamination relating to any HPA Patents. Emergent and HPA shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Emergent shall have the right to review and approve any submission to be made in connection with such proceeding.
  - (b) HPA shall not institute any reexamination, or reissue proceeding relating to HPA Patents without the prior written consent of Emergent, which consent shall not be unreasonably withheld.

(c) In connection with any interference, opposition, reissue, or reexamination proceeding relating to HPA Patents, Emergent and HPA shall cooperate fully and shall provide each other with any information or assistance that either may reasonably request. HPA shall keep Emergent informed of developments in any such action or proceeding, including, to the extent permissible, the status of any settlement negotiations and the terms of any offer related thereto.

#### 9.2.3 Cooperation.

- (a) In General. HPA shall regularly provide Emergent with copies of all Patent applications filed under this Section 9.2 and other material submissions and correspondence with any patent authorities, as applicable, in sufficient time to allow for review and comment by Emergent. In addition, HPA shall provide Emergent and its counsel with an opportunity to consult with HPA and its counsel regarding the filing and contents of any application, amendment, registration, submission, response or correspondence with any patent authorities, and HPA shall accede to reasonable requests of Emergent regarding the filing and prosecution of the HPA Patents. HPA agrees to retain counsel designated by Emergent for the purpose of filing, prosecuting and maintaining Patents with respect to any HPA Technology for which Patent protection is first sought after the Effective Date, at the shared expense of Emergent and such other Persons as may be granted licenses thereunder by HPA consistent with the limitations of this Agreement.
- (b) <u>Patent Term Restoration</u>. The Parties hereto shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable HPA Patents have issued. In the event that elections with respect to obtaining such patent term restoration are to be made, Emergent shall have the right to make the election and HPA agrees to abide by such election.
- 9.2.4 Election not to Prosecute. If HPA elects not (a) to pursue the filing, prosecution or maintenance of a HPA Patent in a Jurisdiction, or (b) to take any other action with respect to a HPA Patent in a Jurisdiction that is necessary or useful to establish or preserve rights thereto, then in each such case ((a) and (b)) HPA shall so notify Emergent promptly in writing and in good time to enable Emergent to meet any deadlines by which an action must be taken to establish or preserve any such rights in such HPA Patent in such Jurisdiction. Upon receipt of each such notice from HPA or if, at any time, HPA fails to initiate any such action within thirty (30) days after a request by Emergent that it do so (or within such shorter time as may be required to prevent the forfeiture of rights), and thereafter diligently pursue such action, Emergent shall have the right, but not the obligation, to pursue the filing or registration, or support the continued prosecution or maintenance, of such HPA Patent, at its expense in such Jurisdiction. If Emergent elects to pursue such filing or registration, as the case may be, or continue such support, then Emergent shall notify HPA of such election and HPA shall, and shall cause its Affiliates to, (i) reasonably cooperate with Emergent in this regard, and (ii) promptly release or assign to Emergent, without consideration, all right, title and interest in and to such HPA Patent in such Jurisdiction.

#### 9.3 Enforcement of rBOT Licensed Patents

- 9.3.1 Rights and Procedures. If either Party determines that any HPA Patent is being infringed by a Third Party's activities and that such infringement could affect the exercise by Emergent of its rights and obligations under this Agreement, it shall notify the other Party in writing and provide it with any evidence of such infringement that is reasonably available. Emergent shall have the first right, but not the obligation, to attempt to remove such infringement by commercially appropriate steps, including filing an infringement suit or taking other similar action, at its own expense. If required by law in order for Emergent to prosecute such suit, HPA shall join such suit as a Party, at Emergent's expense. HPA shall use its best efforts to obtain any consents required by Third Parties owning Licensed HPA Patents in order to authorize Emergent to take legal action to remove such infringement. In the event Emergent fails within one hundred and twenty (120) days following notice of such infringement, or earlier notifies HPA in writing of its intent not to take commercially appropriate steps to remove any infringement of any such HPA Patent, HPA may do so at its own expense; provided, however, that if HPA fails to bring such suit or otherwise terminate such infringement within one hundred and twenty (120) days of its first having the right to do so, Emergent shall be permanently relieved of its royalty obligations under this Agreement until the earlier of (a) the date such suit is commenced, provided that Emergent shall be relieved of such obligations during any period that HPA is not diligently prosecuting such suit, and (b) the date that such infringement is otherwise terminated. The Party not enforcing the applicable HPA Patent shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence, making its employees available at reasonable business hours, and joining the action to the extent necessary to allow the enforcing Party to maintain the action.
- 9.3.2 <u>Costs and Expenses</u>. Any amounts recovered by either Party pursuant to Section 9.3.1, whether by settlement or judgment, shall be used to reimburse the Parties for their reasonable costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses), with any remainder being retained by or paid to Emergent and being deemed "Net Sales" for which Emergent shall pay HPA a royalty under Section 5.1 or 5.2(a), as the case may be.
- 9.3.3 <u>Certification Under FFDCA</u>. HPA shall inform Emergent of any certification regarding any HPA Patents it has received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vii) (IV) or such similar laws as may exist in jurisdictions other than the United States and shall provide Emergent with a copy of such certification within five (5) days of receipt. HPA's and Emergent's rights with respect to the initiation and prosecution of any legal action as a result of such certification or any recovery obtained as a result of such legal action shall be as defined in Sections 9.3.1 and 9.3.2.
- 9.3.4 <u>Certification Under Drug Price Competition and Patent Restoration Act</u>. HPA and Emergent each shall immediately give notice to the other of any certification of which they become aware filed by a Third Party under the United States Drug Price Competition and Patent Term Restoration Act of 1984 claiming that HPA Patents covering Licensed Products are invalid or that infringement will not arise from the manufacture, use or sale of Licensed Products by such Third Party. If HPA or Emergent (depending on which Party is defending the HPA Patents in accordance with Section 9.3.1) decides not to bring infringement proceedings against

the entity making such a certification, such Party shall give notice to the other Party of its decision not to bring suit within twenty-one (21) days after receipt of notice of such certification. The Party receiving such notice may then, but is not required to, bring suit against the Party that filed the certification. Any suit by Emergent or HPA shall either be in the name of Emergent or in the name of HPA, or jointly by Emergent and HPA. For this purpose, the Party not bringing suit shall execute such legal papers necessary for the prosecution of such suit as may be reasonably requested by the Party bringing suit.

#### 9.4 Infringement of Third Party Rights.

- 9.4.1 Third Party Litigation. In the event that a Third Party institutes a patent, trade secret, trademark or other infringement suit against Emergent or its Affiliates or sublicensees during the term of this Agreement, alleging that the practice by Emergent of the HPA Technology in the exercise of its rights as licensee under this Agreement infringes one or more patent, trademark, trade secret or other intellectual property rights held by such Third Party (an "Infringement Suit"), then (i) as between the Parties, Emergent shall assume direction and control of the defense of claims arising therefrom (including the right to settle such claims at its sole discretion), and (ii) Emergent may withhold and deposit into an interest-bearing escrow account [\*\*] percent ([\*\*]%) of all amounts that Emergent would otherwise be obligated to pay to HPA pursuant to Article V (the "Escrowed Amount"), and Emergent's payment obligations to HPA under Article V shall be reduced accordingly, until such time as a final, non-appealable judgment is rendered with respect to such Infringement Suit by a court of competent jurisdiction, or the time permitted for appeal of a final, appealable judgment has lapsed (the "Final Judgment"). If Final Judgment is rendered in favor of Emergent (or its Affiliates or sublicensees, as the case may be), then Emergent shall pay to HPA, within ten days after the entry of such judgment, the full amount of the Escrowed Amount. If the Final Judgment is rendered partially or entirely in favor of such Third Party, then Emergent may apply the Escrowed Amount to the payment of its defense costs in connection with such Infringement Suit and to the payment of any award it is required to pay pursuant to such Final Judgment. If the Escrowed Amount exceeds such defense costs and award then Emergent, within ten (10) days following the date of the Final Judgment, shall remit to HPA the amount of such defense costs and award, then from and after the date of the Final Judgment, Emergent shall be entitled to withhold [\*
- 9.4.2 Cooperation. In the event that a Third Party institutes a Patent, Trademark, trade secret or other infringement suit against Emergent or its Affiliates or Sublicensees during the term of this Agreement, HPA shall use, and shall cause its Affiliates and any Third Parties owning relevant HPA Patents to use commercially reasonable efforts to assist and cooperate with Emergent in connection with the defense of such suit.
- 9.4.3 Retained Rights. Nothing in this Section 9.4 shall prevent either Party, at its own expense, from obtaining any license or other rights from Third Parties it deems appropriate in order to permit the full and unhindered exercise of its rights under this Agreement.

# ARTICLE X Term and Termination

- 10.1 Term and Expiration. This Agreement shall become effective as of the Effective Date and unless terminated earlier pursuant to Section 10.2, 10.3, 10.4, 10.5 or 10.9, the term of this Agreement shall continue in effect until expiration of all royalty obligations hereunder. Upon expiration of this Agreement, Emergent's licenses under Section 3.1 and HPA's licenses under Section 3.3 shall become fully paid-up, perpetual licenses, and the covenants in Section 3.4(a) and 3.4(b) shall survive with respect to such intellectual property of HPA and Emergent, respectively, as has been incorporated into the Licensed Products or HPA Products, as the case may be, as of the date of expiration of this Agreement.
- 10.2 Termination by Emergent without Cause. Notwithstanding anything contained herein to the contrary, Emergent shall have the right to terminate this Agreement in its entirety or with respect to one or more countries at any time in its sole discretion by giving one hundred and eighty (180) days' written notice to HPA.
- 10.3 Termination by HPA in Certain Events. In the event that (a) Emergent terminates the rBOT Development Agreement without cause prior to performing its obligations under Section 3.4 thereof, (b) HPA terminates the rBOT Development Agreement pursuant to Section 11.3 thereof, or (c) Emergent challenges the validity of the HPA Patents, or knowingly and voluntarily assists a Third Party to do so, HPA shall have the right upon written notice to Emergent to terminate this Agreement.
- 10.4 Termination by Emergent for Material Breach by HPA under the rBOT Development Agreement. In the event that Emergent terminates the rBOT Development Agreement pursuant to Section 11.4 thereof, Emergent shall have the right upon written notice to HPA to terminate this Agreement.
- 10.5 Termination of this Agreement by Either Party for Material Breach. Material failure by HPA to comply with any of its material obligations contained herein, or material failure by Emergent to make payments owed to HPA pursuant to this Agreement, shall entitle the Party not in default to give to the Party in default notice specifying the nature of the default, requiring the defaulting Party to make good or otherwise cure such default, and stating its intention to terminate if such default is not cured. In the event that Emergent is the notifying Party, Emergent shall have the right, in addition to all other remedies available to it by law, in equity or pursuant to this Agreement, to suspend payment of any amounts that it would otherwise owe to HPA hereunder until such time as the material breach of HPA is cured (whereupon such suspended amounts shall be paid). If a noticed default is not cured within thirty (30) days (the "Cure Period") after the receipt of such notice (or, if such default cannot be cured within such thirty (30)-day period, if the Party in default does not commence actions to cure such default within the Cure Period and thereafter diligently continue such actions), the Party not in default shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement in its entirety; provided, however, that any right to terminate under this Section 10.5 shall be stayed in the event that, during any Cure Period, the Party alleged to have been in default shall have initiated dispute resolution in accordance with Section 11.7 with respect to the alleged

default, which stay shall last so long as the initiating Party diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings.

#### 10.6 Consequences of Termination by Emergent.

- 10.6.1 <u>Termination by Emergent without Cause</u>. In the event that Emergent terminates this Agreement in its entirety pursuant to Section 10.2, as of the effective date of such termination, the licenses granted by HPA to Emergent in Section 3.1, the licenses granted by Emergent to HPA in Section 3.3, and the covenants in Section 3.4 shall terminate.
- 10.6.2 <u>Termination by Emergent for Cause</u>. In the event that Emergent terminates this Agreement pursuant to Section 10.4 or 10.5, as of the effective date of such termination, the following terms and conditions shall apply:
- (a) for five (5) years after the effective date of such termination, HPA shall not compete with Emergent in the Field (subject to HPA's Retained Rights under Section 3.3), or grant to a Third Party a license under the rBOT Technology enabling such Third Party to Exploit a recombinant product that (i) comprises one or more *C. botulinum* toxin fragments, (ii) acts to stimulate an immune response, and (iii) is designed for use in the Field;
- (b) HPA shall compensate Emergent for any damages that Emergent suffers as a result of such breach, first, through a lump sum payment up to the maximum amount permitted under Section 7.4(b), and then pursuant to Section 7.4(b) through a set-off against Emergent's payment obligations under Article V, provided that upon the full payment of such compensation, the applicable royalty rate shall be reduced to [\*\*] percent ([\*\*]%) of the rate that would otherwise apply under the terms of Article V; and
- (c) The licenses granted by HPA to Emergent in Section 3.1, the royalty obligations of Emergent under Article V (as modified pursuant to subparagraph (b) above), the covenant in Section 3.4(a), and the provisions of Article IX shall survive such termination. The licenses granted by Emergent to HPA in Section 3.3 and the covenant in Section 3.4(b) shall terminate.
  - 10.6.3 Rights Cumulative. The rights and remedies in this Section 10.6 shall be cumulative and in addition to any other rights or remedies that may be available to Emergent.

#### 10.7 Consequences of Termination by HPA.

- 10.7.1 <u>Termination by HPA</u>. In the event that HPA terminates this Agreement pursuant to Section 10.3 or 10.5, as of the effective date of such termination, the licenses granted by Emergent to HPA in Section 3.3, the licenses granted by HPA to Emergent in Section 3.1, and the covenants in Section 3.4 shall terminate.
  - 10.7.2 Rights Cumulative. The rights and remedies in this Section 10.7 shall be cumulative and in addition to any other rights or remedies that may be available to HPA.

#### 10.8 Accrued Rights; Survival; Work in Progress; Return of Information.

- 10.8.1 <u>Accrued Rights</u>. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.
- 10.8.2 <u>Survival</u>. In addition to any other Section of this Agreement which by its express terms survives, or provides for survival upon the termination or expiration of this Agreement, Sections 3.2, 5.7, 7.1, 7.2, 7.3, 7.4, 9.1, 10.6, 10.7, 10.10, 11.2, 11.3, 11.5, 11.6, 11.7, 11.8, 11.9, 11.14, 11.16, and 11.17, and this Section 10.8, and Articles IV and VI, shall survive the termination or expiration of this Agreement for any reason.
- 10.8.3 <u>Work-in-Progress</u>. Upon termination of this Agreement by HPA pursuant to Section 10.7.1, Emergent shall be entitled, during the following ninety (90) days, to finish any work-in-progress and to sell any inventory of the Licensed Products that remains on hand as of the date of the termination, so long as Emergent pays HPA the royalties applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement.
- 10.8.4 Return of Information. Within ninety (90) days of the expiration or termination of this Agreement, each Party shall deliver to the other Party any and all data, files, records and other materials in its possession or under its Control that constitute the Confidential Information of such other Party, to which the first Party does not retain rights hereunder (except that each Party shall have the right to retain one copy of each of the foregoing solely for archival purposes) Except as may be provided otherwise in this Agreement, each Party shall cease using any technology of the other Party to which its license hereunder has terminated, except to the extent that such technology has entered the public domain or that such Party has secured rights under such technology through contract, agreement, arrangement or otherwise.
- 10.9 Termination upon Insolvency. Either Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a Party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.
- 10.10 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Emergent or HPA are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the United States Bankruptcy Code, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such

intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

# ARTICLE XI

- 11.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, when such failure or delay is caused by or results from causes beyond the reasonable control of the non-performing Party, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority. The non-performing Party shall notify the other Party of such force majeure within ten (10) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for one-hundred and eighty (180) days after the date of the occurrence, the Parties shall meet and discuss in good faith how best to proceed.
- 11.2 Export Control Regulations. The rights and obligations of the Parties under this Agreement shall be subject in all respects to United States laws and regulations and the analogous laws and regulations of England, as shall from time to time govern the license and delivery of technology and products between the United States and the United Kingdom, including the United States Foreign Assets Control Regulations, Transaction Control Regulations and Expert Control Regulations, as amended, and any successor legislation issued by the Department of Commerce, International Trade Administration, Office of Export Licensing. Without in any way limiting the provisions of this Agreement, each party agrees that, unless prior authorization is obtained from the Office of Export Licensing, it shall not export, re-export, or transship, directly or indirectly, to any country, any of the technical data disclosed to it by the other party if such export would violate the laws of the United States or the regulations of any department or agency of the United States Government.
- 11.3 Assignment. Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate, charge, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder, nor purport to do any of the same; provided, however, that Emergent may, without such consent, assign the benefit of this Agreement and its rights hereunder to an Affiliate, to the purchaser of all or substantially all of its assets, or to any Third Party pursuant to or in connection with any agreement and plan of merger, acquisition, reorganization, or other similar

corporate transaction; and provided, further, that HPA may, without such consent, assign the benefit of this Agreement and its rights hereunder to an Affiliate or to a Third Party pursuant to or in connection with a spin-off of its business relating to the Development Program (as defined in the rBOT Development Agreement) and the Exploitation of Licensed Products and HPA Products, provided however, that no such assignment may be made to any Third Party, or any Person controlled by any Third Party, that is at the time of such assignment a competitor of Emergent in the Field; and provided, further, that notwithstanding any other provision of this Agreement, HPA may not assign or otherwise transfer in any manner to any Third Party any of the Retained Rights, any of the icenses granted to HPA in Section 3.3(c), or any rights of HPA under Section 3.4. Any attempted assignment in violation of the preceding sentence shall be void and of no effect. All validly assigned rights of the Parties shall be binding upon and inure to the benefit of and be enforceable by the permitted assigns of Emergent or HPA, as the case may be. No assignment validly made pursuant to this Section 11.3 shall relieve the assigning Party of any of its obligations under this Agreement, unless the other Party has given its prior consent thereto.

11.4 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) the Parties agree to attempt to substitute for any such illegal, invalid or unenforceable provision as legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof prohibited or unenforceable in any respect.

11.5 Notices. All notices or other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (promptly confirmed by personal delivery or courier as provided herein) or sent by internationally-recognized overnight courier, addressed as follows:

if to HPA, to: Health Protection Agency

Porton Down

Salisbury, Wiltshire SP4 0JG England Attention: Dr. David Rhodes Facsimile No.: +44-1980-61-22-41

with a copy to: Legal Department

Health Protection Agency

Porton Down

Salisbury, Wiltshire SP4 0JG England Facsimile No.: +44-1980-61-22-41

if to Emergent, to: Emergent BioSolutions, Inc.

300 Professional Drive

Gaithersburg, Maryland 20879 USA Attention: General Counsel Facsimile No.: +1-301-590-1252

with a copy to: Covington & Burling

One Front Street, 35th Floor San Francisco, California 94111 USA

Attention: James C. Snipes, Esq. Facsimile No.: +1-415-591-6091

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication shall be deemed to have been given when delivered if personally delivered on a Business Day, when transmitted if sent by facsimile (in accordance with this Section 11.5) on a Business Day, and on the third (3rd) Business Day after dispatch if sent by internationally-recognized courier. It is understood and agreed that this Section 11.5 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

11.6 Governing Law. This Agreement shall be governed by and construed in accordance with English law, without reference to the rules of conflict of laws thereof. Subject to Section 11.7, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of (i) the courts of the State of New York and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) initiated by HPA and arising out of or relating to this Agreement, and (ii) the English courts located in London for any action, suit or proceeding (other than appeals therefrom) initiated by Emergent and arising out of or relating to this Agreement. The Parties agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts, respectively. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or the United States District Court for the Southern District of New York, or the English courts located in London, as the case may be, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Each Party hereto further agrees that service of any process, summons, notice or document by internationally recognized courier to its address set forth above shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

#### 11.7 Dispute Resolution.

11.7.1 <u>Negotiation</u>. The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement (or any document or instrument delivered in connection herewith) (each, a "Dispute"). In the event that the Parties are unable to, within ten (10) days, to reach a resolution, such Dispute shall be referred to the chief executive officers of Emergent and HPA, or their respective successors, who shall attempt in good faith to reach a resolution of the Dispute. If the foregoing procedures fail

to achieve a mutually satisfactory resolution within ten (10) days, then either Party may, by written notice to the other Party, elect to have the matter settled by binding arbitration pursuant to Section 11.7.2

- 11.7.2 <u>Arbitration</u>. Any arbitration under this Agreement shall take place at a location to be agreed by the Parties; <u>provided</u>, <u>however</u>, that in the event that the Parties are unable to agree on a location for an arbitration under this Agreement within five (5) days of the demand therefor, such arbitration shall be held in New York, New York if HPA is the Party that first demanded such arbitration or in London, England if Emergent is the Party that first demanded such arbitration arbitration under this Agreement shall be administered by the American Arbitration Association under its Commercial Arbitration Rules then in effect (the "AAA Rules"). The Parties shall appoint an arbitrator by mutual agreement. If the Parties cannot agree on the appointment of an arbitrator within thirty (30) days of the demand for arbitration, an arbitrator shall be appointed in accordance with AAA Rules. The arbitrator shall have the authority to grant any equitable and legal remedies that would be available in any judicial proceeding instituted to resolve the Dispute submitted to such arbitration in accordance with this Agreement; <u>provided</u>, <u>however</u>, that the arbitrator shall not have the power to alter, amend or otherwise affect the terms or the provisions of this Agreement. Judgment upon any award rendered pursuant to this Section may be entered by any court having jurisdiction over the Parties other assets. The arbitrator shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrator's fees and any administrative fees of arbitration, unless the arbitrator shall otherwise allocate such costs, expenses and fees between the Parties. The Parties agree that all arbitration awards shall be final and binding on the Parties and their Affiliates. The Parties hereby waive the right to contest the award in any court or other forum. Except to the extent necessary to confirm
- 11.7.3 <u>Interim Relief.</u> Notwithstanding anything herein to the contrary, nothing in this Section 11.7 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, either prior to or during any arbitration hereunder, if necessary to protect the interests of such Party. This Section 11.7.3 shall be specifically enforceable.
- 11.8 Equitable Relief. HPA acknowledges and agrees that the restrictions set forth in Section 3.4 and Article IV of this Agreement are reasonable and necessary to protect the legitimate interests of Emergent and that Emergent would not have entered into this Agreement in the absence of such restrictions, and that any violation or threatened violation of any provision of Section 3.4 or Article IV will result in irreparable injury to Emergent. HPA also acknowledges and agrees that in the event of a violation or threatened violation of any provision of Section 3.4 or Article IV, Emergent shall be entitled to preliminary and permanent injunctive relief, without the necessity of proving irreparable injury or actual damages and without the necessity of having to post a bond, as well as to an equitable accounting of all earnings, profits

and other benefits arising from any such violation. The rights provided in the immediately preceding sentence shall be cumulative and in addition to any other rights or remedies that may be available to Emergent. Nothing in this Section 11.8 is intended, or should be construed, to limit Emergent's right to preliminary and permanent injunctive relief or any other remedy for a breach of any other provision of this Agreement.

- 11.9 No Benefit to Third Parties. Article II confers a benefit on those Persons referred to in Section 2.9 (the "Emergent Beneficiaries") and, subject to the remaining provisions of this Section 11.9, is intended to be enforceable by the Emergent Beneficiaries by virtue of the Contracts (Rights of Third Parties) Act 1999 (the "Act"). The Parties do not intend that any provisions of this Agreement, apart from those of Article II, should be enforceable by virtue of the Act by any person who is not a party to this Agreement. Notwithstanding the provisions of this Section 11.9, this Agreement may be rescinded or amended in any way and at any time by the Parties in accordance with its terms, without the consent of any of the Emergent Beneficiaries.
- 11.10 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm the rights and remedies of the other Party under this Agreement.
- 11.11 English Language. This Agreement shall be written and executed in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control. All notices and other disclosure required of the Parties hereunder shall be in English.
- 11.12 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section, Paragraph, Schedule or Exhibit shall mean references to such Article, Section, Paragraph, Schedule or Exhibit of this Agreement, (b) references in any section to any clause are references to such clause of such section, and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, as so varied, replaced or supplemented and in effect at the relevant time of reference thereto.
- 11.13 Independent Contractors. It is expressly agreed that HPA and Emergent shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither HPA nor Emergent shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other Party. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

- 11.14 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or the failure to exercise, or any delay in exercising a right or remedy provided by this Agreement or by law, or the waiver of a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.
- 11.15 Counterparts. The Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument
- 11.16 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties, and no rule of strict construction shall be applied against either Party.
- 11.17 Entire Agreement; Modifications. This Agreement, together with the rBOT Development Agreement, the BT Development Agreement, the BT License Agreement, and the Distribution Agreement, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understanding, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment, modification, release or discharge hereof shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

Emergent	BioSolutions, Inc.	Heal	n Protect	ion Agency	
By:	/s/ Fuad El-Hibri Fuad El-Hibri	By:	/s/ Pat T	Ггоор Тгоор	
Title:	Chairman and CEO	Title	CEO		
		-43-			

# Schedule 1.36 HPA Know-How

# Source Materials [\*\*]

## Documented Know-how

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Batch Manufacturing Records, Process Operating Instructions & Associated SOPs

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Batch Manufacturing Records, Process Operating Instructions & Associated SOPs

[\*\*]

# Schedule 1.37 HPA Patents

## Owned HPA Patents

None.

## **Licensed HPA Patents**

None.

## Schedule 3.3(c)

# **Emergent Patents and Know-How**

## Patents

None

## Source Materials

Clostridium botulinum, strains

o [\*\*]

Know-how

o [\*\*]

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

#### **rBOT VACCINE DEVELOPMENT AGREEMENT**

THIS rBOT VACCINE DEVELOPMENT AGREEMENT (this "Agreement"), effective as of November 23, 2004, (the "Effective Date"), by and between Emergent BioSolutions, Inc., a corporation organized and existing under the laws of the State of Delaware ("Emergent"), and the Health Protection Agency, a governmental agency organized and existing under the laws of England ("HPA") (each of Emergent and HPA, a "Party").

#### WITNESSETH:

WHEREAS, Emergent, which is the parent company of BioPort Corporation, desires to develop one or more pharmaceutical products comprising Clostridium botulinum toxin fragments produced using recombinant technology, which products are designed for the prevention or treatment of illness caused by C. botulinum toxin;

WHEREAS, HPA has expertise, intellectual property and biological materials that would be useful in the development of such products;

WHEREAS, Emergent desires to engage HPA to perform certain development activities with respect to such products, on the terms and conditions set forth below;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants of the parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, do hereby agree as follows:

#### ARTICLE I Definitions

Unless specifically set forth to the contrary herein, the following terms shall have the respective meanings set forth below:

- 1.1 "AAA Rules" shall have the meaning set forth in Section 12.7.2.
- 1.2 "Act" shall have the meaning set forth in Section 12.9.
- 1.3 "Affiliate" shall mean, (a) with respect to Emergent, any Person that, directly or indirectly, through one or more intermediaries, controlls, is controlled by, or is under common control with Emergent, and (b) with respect to HPA, any Person that, directly or indirectly, through one or more intermediaries, is controlled by HPA. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, by application of applicable law, or otherwise, or (b) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity); provided that, if local law restricts foreign

ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests.

- 1.4 "Agreement" shall have the meaning set forth in the preamble hereto.
- 1.5 "Applicable Law" shall mean all laws, rules, regulations applicable to the Exploitation of the Licensed Products, including any such rules, regulations, guidelines, or other requirements of the Regulatory Authorities, that may be in effect from time to time in the Territory.
- 1.6 "BT Development Agreement" shall mean that certain BT Vaccine Development Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
- 1.7 "BT License Agreement" shall mean that certain BT Vaccine License Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
  - 1.8 "Business Day" shall mean any day other than a Saturday, Sunday, any public holiday and any bank holiday in either the United States or England.
  - 1.9 "Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
  - 1.10 "Calendar Year" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.
- 1.11 "Clinical Trials" shall mean, with respect to a Licensed Product, all tests and studies in patients that are required by the Regulatory Authorities, from time to time, pursuant to Applicable Law or otherwise, for Regulatory Approval of such product.
- 1.12 "Commercially Reasonable Efforts" shall mean, with respect to the development, Manufacture or commercialization of a Licensed Product, the level of efforts and resources customarily applied in the research-based pharmaceutical industry to a product of similar commercial potential at a similar stage in its lifecycle, taking into consideration its safety and efficacy, its cost to develop, the competitiveness of alternative products, its proprietary position, the likelihood of regulatory approval, its profitability, and all other relevant factors. Commercially Reasonable Efforts shall be determined on a country-by-country basis for each Licensed Product.
  - 1.13 "Confidential Information" shall have the meaning set forth in Section 6.3.1.
- 1.14 "Control" shall mean, with respect to any item of Information and Invention, Patent, Trademark or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such Information and Invention, Patent, Trademark or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

- 1.15 "Development Activities" shall mean (a) those tests, studies and other activities set forth in, or required to be conducted in order to obtain the information set forth in, the Development Plan; and (b) such other tests, studies and other activities with respect to the Licensed Product(s) as may be agreed to in writing from time to time by the Parties.
  - 1.16 "Development Budget" shall have the meaning set forth in Section 3.1.
  - 1.17 "Development Plan" shall mean the list and schedule of activities contained in Schedule 1.17, as may be amended by the parties from time to time in accordance with Section 12.17.
  - 1.18 "Development Program" shall mean the Development Activities carried out by the parties pursuant to this Agreement.
  - 1.19 "Development Program Term" shall have the meaning set forth in Section 2.10.2
- 1.20 "Distribution Agreement" shall mean that certain Exclusive Distribution Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms
  - 1.21 "Dispute" shall have the meaning set forth in Section 12.7.1.
- 1.22 "Drug Master File" shall mean any drug master file filed with the FDA with respect to any Licensed Product or any intermediate thereof, and any equivalent filing in other countries or regulatory jurisdictions.
  - 1.23 "Effective Date" shall mean the date of this Agreement as set forth in the preamble hereto.
  - 1.24 "Emergent" shall have the meaning set forth in the preamble hereto.
  - 1.25 "Emergent Beneficiaries" shall have the meaning set forth in Section 12.9.
  - 1.26 "Emergent Information" shall have the meaning set forth in Section 6.1.2.
- 1.27 "Emergent Technology" shall mean any Information and Inventions owned or Controlled by Emergent during the term of this Agreement that are reasonably necessary for the performance by HPA of its designated Development Activities and as to which Emergent does not have royalty obligations to a Third Party.
- 1.28 "Exploit" shall mean to make, have made, import, use, sell, or offer for sale, including to research, develop, register, modify, enhance, improve, Manufacture, have Manufactured, store, formulate, have used, export, transport, distribute, promote, market or have sold or otherwise dispose of.
- 1.29 "Exploitation" shall mean the making, having made, importation, use, sale, offering for sale or disposition of a product or process, including the research, development, registration, modification, enhancement, improvement, Manufacture, storage, formulation,

optimization, import, export, transport, distribution, promotion or marketing of a product or process.

- 1.30 "Facility" shall mean the vaccine production unit within HPA's pharmaceutical production center located at Porton Down, Salisbury, Wilshire, England, at which HPA shall conduct the Development Activities designated for HPA, or such other facilities as the Parties may mutually agree in writing.
  - 1.31 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.
  - 1.32 "FFDCA" shall mean the United States Federal Food Drug and Cosmetic Act, as amended from time to time.
  - **1.33** "Field" shall mean the prevention or treatment of illness in humans caused by *C. botulinum* toxin.
  - 1.34 "GAAP" shall mean United States generally accepted accounting principles, consistently applied.
- 1.35 "Good Manufacturing Practices" shall mean the current good manufacturing practices applicable from time to time to the Manufacturing of any Licensed Product or any intermediate thereof pursuant to Applicable Law.
  - 1.36 "HPA" shall have the meaning set forth in the preamble.
- 1.37 "Improvement" shall mean any modification, variation or revision to a compound, product or technology or any discovery, technology, device, process or formulation related to such compound, product or technology, whether or not patented or patentable, including any enhancement in the efficiency, operation, Manufacture (including any manufacturing process), ingredients, preparation, presentation, formulation, means of delivery, packaging or dosage of such compound, product or technology, any discovery or development of any new or expanded indications for such compound, product or technology, or any discovery or development that improves the stability, safety or efficacy of such compound, product or technology.
- 1.38 "IND" shall mean an investigational new drug application filed with the FDA for authorization to commence human clinical trials, and its equivalent in other countries or regulatory jurisdictions in the Territory.
  - 1.39 "Indemnification Claim Notice" shall have the meaning set forth in Section 8.3.1.
  - 1.40 "Indemnified Party" shall have the meaning set forth in Section 8.3.1.
- 1.41 "Information and Inventions" shall mean all technical, scientific and other know-how, show-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer software, apparatuses, specifications, data, cell lines, seed stock and other biological materials, pre-clinical and clinical

trial results, Manufacturing procedures, test procedures and purification and isolation techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed, and all Improvements, whether to the foregoing or otherwise, and other discoveries, developments, inventions, and other intellectual property (whether or not confidential, proprietary, patented or patentable), but excluding the Regulatory Documentation.

- 1.42 "Joint Inventions" shall mean any and all Information and Inventions that are (a) first conceived, discovered, developed or otherwise made jointly, as necessary to establish joint authorship, inventorship or ownership under applicable copyright or patent law, as the case may be, by or on behalf of, on the one hand, HPA or any of its Affiliates or their respective employees and agents, and, on the other hand, Emergent or any of its Affiliates or their respective employees and agents, during the term of this Agreement; (b) first conceived, discovered, developed or otherwise made, as necessary to establish authorship, inventorship or ownership under applicable copyright or patent law, as the case may be, by or on behalf of Emergent, its Affiliates or any of their respective employees and agents, either alone or jointly with a Third Party(ies), during the term of this Agreement, in connection with or arising from the Development Activities; or (c) first conceived, discovered, developed or otherwise made, as necessary to establish authorship, inventorship or ownership under applicable copyright or patent law, as the case may be, by or on behalf of, HPA, its Affiliates or any of their respective employees and agents, either alone or jointly with a Third Party(ies), during the term of this Agreement, in connection with or arising from the Development Activities
- 1.43 "Joint Know-How" shall mean all Information and Inventions, to the extent not generally known, that are included in the Joint Inventions, but excluding any Information and Inventions to the extent claimed or covered by the Joint Patents.
  - 1.44 "Joint Patents" shall mean any Patents to the extent that such Patents claim or cover Joint Inventions.
  - 1.45 "Joint Technology" shall mean, collectively, the Joint Patents and the Joint Know-How.
  - **1.46** "Key Personnel" shall have the meaning set forth in Section 2.3.
- 1.47 "Licensed Product" shall mean a recombinant product that (a) comprises one or more *C. botulinum* toxin fragments that acts to stimulate an immune response, (b) is developed pursuant to this Agreement for use in the Field, and (c) comprises, is comprised of (in whole or in part), or is Exploited using, rBOT Licensed Technology.
  - 1.48 "Losses" shall have the meaning set forth in Section 8.1.
- 1.49 "Manufacture" and "Manufacturing" shall mean, with respect to a product or compound, the manufacturing, processing, formulating, packaging, labeling, holding and quality control testing of such product or compound.
  - 1.50 "Marketing Authorization" shall mean a New Drug Application or Biologics License Application, each as defined in the FFDCA, and the regulations promulgated thereunder,

and any corresponding foreign application, registration or certification, necessary or reasonably useful to market a Licensed Product in the Territory, but not including pricing and reimbursement approvals.

- 1.51 "Master Services Agreement" shall mean that certain Master Services Agreement, dated as of March 17, 2004, by and between HPA and BioPort Corporation, an Affiliate of Emergent.
- 1.52 "Minimum Commitment" shall have the meaning set forth in Section 3.4
- 1.53 "Party" shall have the meaning set forth in the preamble hereto.
- 1.54 "Patents" shall mean (a) all patents and patent applications, (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patents or patent application, and (c) any foreign or international equivalent of any of the foregoing.
- 1.55 "Person" shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government (whether or not having a separate legal personality).
- 1.56 "rBOT License Agreement" shall mean that certain rBOT Vaccine License Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms
  - 1.57 "rBOT Licensed Know-How" shall have the meaning set forth in the rBOT License Agreement.
  - 1.58 "rBOT Licensed Patents" shall have the meaning set forth in the rBOT License Agreement.
  - 1.59 "rBOT Licensed Technology" shall have the meaning set forth in the rBOT License Agreement.
- 1.60 "Regulatory Approval" shall mean any and all approvals (including pricing and reimbursement approvals), governmental licenses, registrations or authorizations of any Regulatory Authority, necessary for the Exploitation of the Licensed Product(s) in a country in the Territory, including any (a) approval of any Licensed Product (including any INDs, Marketing Authorizations and supplements and amendments thereto); (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); (c) labeling approval; and (d) technical, medical and scientific licenses.
- 1.61 "Regulatory Authority" shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority

with respect to the Exploitation of the Licensed Product(s) in the Territory, but excluding HPA acting in its capacity as a Party.

- 1.62 "Regulatory Documentation" shall mean all applications, registrations, governmental licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests, relating to any Licensed Product, and all data contained in any of the foregoing, including all INDs, Marketing Authorizations, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files and Manufacturing records (including Manufacturing records maintained pursuant to Section 2.9.3 and any Drug Master Files prepared and filed by HPA).
  - 1.63 "Retained Rights" shall have the meaning set forth in Section 5.3.
  - 1.64 "Territory" shall mean all of the countries in the world.
  - 1.65 "Third Party" shall mean any Person other than Emergent, HPA and their respective Affiliates.
  - 1.66 "Third Party Claim" shall have the meaning set forth in Section 8.3.2.
- 1.67 "Trademark" shall include any word, name, symbol, color, designation or device or any combination thereof, including any trademark, trade dress, brand mark, trade name, brand name, logo or business symbol.
  - 1.68 "U.K. Public Entity" shall mean any national, local, regional or provincial governmental agency in the United Kingdom, including any component of the National Health Service.
- 1.69 "Vaccine Product" shall mean any pharmaceutical product containing one or more immunomodulators that acts to stimulate an immune response and is intended for the prevention or treatment of disease in humans.

#### ARTICLE II Development Program

- 2.1 In General. HPA shall perform, or cause to be performed, the Development Activities designated for HPA in the Development Plan, in accordance with the terms and conditions of this Agreement, including the Development Budget. The goal of the Development Plan shall be to develop one or more Licensed Products in accordance with this Agreement.
- 2.2 Conduct of Development Program. HPA shall conduct the Development Program (a) in good scientific manner, and in compliance in all material respects with all requirements of Applicable Law and agreed laboratory practices, and (b) using Commercially Reasonable Efforts to complete its designated Development Activities efficiently and expeditiously, in accordance with the schedule set forth in the Development Plan and in compliance with the Development Budget.

2.3 Key Personnel. The Development Activities shall be conducted by each Party under the direction and supervision of one ore more scientists designated by such Party. The Parties shall also designate principal contacts with respect to the Development Program. HPA's scientific and technical personnel considered by Emergent to be central to the conduct of the Development Activities by HPA (the "Key Personnel") are listed on Schedule 2.3. HPA shall not substitute other persons for the Key Personnel or otherwise materially reduce the time commitment of any Key Personnel to the Development Program below the level listed for such Key Personnel in Schedule 2.3 without the prior written approval of Emergent, which approval shall not be unreasonably withheld.

#### 2.4 Coordination

- 2.4.1 Consultation. During the Development Program Term, the primary contacts designated by the Parties shall discuss with each other the conduct and progress of the Development Program, by telephone or in person, not less frequently than weekly. Such discussions shall cover the status of the Development Activities, review relevant results and data, consider technical and other issues that have arisen, and review and advise on any scientific and budgetary matters relating to the Development Program.
- 2.4.2 Facility Visits. Emergent may arrange for a reasonable number of its employees and/or consultants to visit the Facility, at mutually agreed times, for the purpose of observing such Facility and meeting to discuss the Development Program work and its results with the employees of HPA.
- 2.4.3 Oversight and Technology Transfer. The Parties shall use good faith efforts to agree upon, in writing, suitable arrangements whereby (a) Emergent personnel can provide reasonable oversight of the Development Activities, and (b) Emergent personnel will be provided timely access to Key Personnel so as to fully understand the progress being achieved in the Development Program and to enable the prompt and effective transfer of technology from HPA to Emergent as contemplated by this Agreement.

#### 2.5 Information Disclosure; Supply of Resources.

2.5.1 Information Disclosure. HPA shall, and shall cause its Affiliates to, disclose and make available to Emergent, in whatever form Emergent may reasonably request, (a) all Regulatory Documentation under the Control of HPA or its Affiliates, (b) all rBOT Licensed Know-How (subject, in the case of the After-Acquired HPA Know-How (as defined in the rBOT License Agreement), to the rights of any Third Parties therein), (c) all Joint Know-How (to the extent not known to Emergent), (d) any other Information and Inventions claimed or covered by any rBOT Licensed Patents or Joint Patents (to the extent not known to Emergent) or otherwise relating, directly or indirectly, to the Licensed Product(s), and (e) any and all Improvements thereto under the Control of HPA or its Affiliates, promptly after the Effective Date, and thereafter immediately upon the earlier of the conception, discovery, development, or making of such Regulatory Documentation, rBOT Licensed Know-How, Joint Know-How or other Information and Inventions or Improvements; provided, however, that Emergent shall reimburse HPA for any reasonable and verifiable direct out-of-pocket costs and expenses incurred by HPA in making such disclosures, to the extent not covered in the Development

Budget. Emergent may use such Regulatory Documentation and Information and Inventions solely in the exercise of its rights under the licenses granted to Emergent by HPA in Section 5.1 and in the rBOT License Agreement.

- 2.5.2 <u>Supply of Resources</u>. Subject to Emergent's payment obligations with respect to the Development Program pursuant to Section 3.1, HPA shall dedicate to the performance of the Development Activities, and make available to Emergent upon Emergent's request, at no cost to Emergent other than the costs provided for in the Development Budget, such (a) equipment, (b) quantities of cell lines, seed stocks, compounds, components (toxoid and otherwise) and other biological materials, and (c) other resources (including scientific, clinical, medical, regulatory, Manufacturing and other personnel), in each case as are reasonably necessary for the performance of the Development Activities; <u>provided</u>, <u>however</u>, that HPA's obligations under this Section 2.5.2 shall not include any obligation to provide to Emergent a commercial supply of Licensed Products.
- 2.6 Communications with Regulatory Authorities. Subject to the obligation of HPA to respond to any inspection or investigation by governmental or Regulatory Authorities in accordance with Section 2.8, Emergent shall have the sole right, in its sole discretion, to conduct all communications with the Regulatory Authorities with regard to the Development Activities; provided, however, that HPA in conjunction with Emergent may communicate with the governmental health and safety authorities in the United Kingdom with regard to its activities pursuant to this Agreement.

#### 2.7 Records and Reports.

- 2.7.1 Records. HPA shall maintain records in good scientific manner and in sufficient detail for patent and regulatory purposes, and in compliance with Applicable Law, fully and properly documenting all work done and results achieved in the performance of the Development Program. Such records shall be retained by HPA for at least three (3) years after the termination of this Agreement, or for such longer period as may be required by Applicable Law. Upon request, HPA shall provide copies of the records it has maintained pursuant to this Section 2.7.1 to Emergent.
- 2.7.2 Copies and Inspection of Records. Emergent shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all records of HPA maintained pursuant to Section 2.7.1. Emergent shall maintain such HPA records and the information disclosed therein in confidence in accordance with Article VI.
- 2.7.3 Quarterly Reports. Within thirty (30) days following the end of each Calendar Quarter during which Development Program activities are being performed, HPA shall provide to Emergent a written progress report which shall describe the work performed to date on the Development Program, evaluate the work performed in relation to the goals of the Development Program and in relation to the Development Budget, and provide such other information as may be required by the Development Plan or reasonably requested by Emergent relating to the Development Program.

2.8 Regulatory Inspections. If any governmental or Regulatory Authority (a) contacts HPA, any of its scientific staff or any other person performing Development Activities on HPA's behalf, with respect to the Development Activities, (b) conducts, or gives notice of its intent to conduct, an inspection at any facility of HPA used in the performance of its obligations hereunder, or (c) takes, or gives notice of its intent to take, any other regulatory action alleging improper or inadequate research practices (including the issuance of a "Notice of Inspectional Observations," "Warning Letter" or the equivalent) with respect to any activity of HPA, any of its scientific staff or any other person performing Development Activities on HPA's behalf, whether or not in connection with the services provided under this Agreement, HPA shall notify Emergent with five (5) Business Days of such contact or notice, or sooner if necessary to permit Emergent to be present at, or otherwise participate in, any such inspection or regulatory action with respect to the Development Activities, and shall supply Emergent with all information pertinent thereto. Emergent shall have the right to be present at and to participate in any such inspection or regulatory action with respect to the Development Activities. HPA shall provide Emergent with copies of all documentation issued by any governmental or Regulatory Authority in connection with such inspection or regulatory action and any response thereto proposed by HPA. No such responses shall contain any false or misleading information, or omit any information necessary to make such response not false or misleading, with respect to the Development Activities of HPA.

#### 2.9 Clinical Trials.

- 2.9.1 Emergent's Rights. Emergent shall have the exclusive right, in its sole discretion, to initiate and conduct any and all Clinical Trials with respect to the Licensed Products, except for such Clinical Trials as HPA may conduct in the exercise of the Retained Rights.
- 2.9.2 <u>Supply; Drug Master Files</u>. In accordance with the Development Plan (including the product specifications and other requirements set out therein), HPA shall provide Emergent with clinical supplies of Licensed Products for any Clinical Trials that Emergent may conduct, in such quantities and at such times as Emergent shall reasonably request. HPA shall prepare and file with the FDA and such other Regulatory Authorities as Emergent may from time to time designate in writing, Drug Master Files with respect to any Licensed Product or any intermediate thereof manufactured or supplied to Emergent by or on behalf of HPA hereunder. HPA shall maintain each such Drug Master File during the Development Program Term in accordance with all Applicable Law and the Development Plan, including by filing any necessary amendments or modifications thereto. HPA shall provide to Emergent a copy of each such Drug Master File, including any amendments or modifications thereto.
- 2.9.3 <u>Manufacturing Records</u>. HPA shall maintain, or cause to be maintained, (a) all records necessary to comply with all Applicable Law relating to the Manufacture of the Licensed Products by HPA, (b) all Manufacturing records, standard operating procedures, equipment log books, batch records, laboratory notebooks and all raw data relating to the Manufacturing of Licensed Products hereunder, and (c) such other records as Emergent may reasonably require to ensure compliance by HPA with the terms hereof. All such material shall be maintained for such period as may be required by Applicable Law or for such longer period as Emergent may reasonably require; <u>provided</u>, <u>however</u>, that all records relating to the

Manufacturing, stability and quality control of each batch of Licensed Product shall be retained until at least the first (1st) anniversary of the end of the approved shelf life for all Licensed Product from such batch.

#### 2.10 Decision Point; Development Program Term.

- 2.10.1 <u>Decision Point</u>. No less than sixty (60) days prior to the first (1st) anniversary of the Effective Date the Parties shall confer, by telephone or in person, to assess the conduct and progress of the Development Activities. In light of such progress, Emergent shall determine, in its sole discretion, whether to terminate this Agreement and shall notify HPA of such determination no less than thirty (30) days prior to such anniversary.
- 2.10.2 <u>Development Program Term</u>. Except as otherwise provided herein, the term of the Development Program shall commence on the Effective Date and continue until the second (2nd) anniversary thereof (the "Development Program Term"). The Parties may extend the term of the Development Program, and, as appropriate, amend the Development Plan and the Development Budget, by written mutual agreement.
- **2.11 Rights; Subcontracting.** Any and all rights of Emergent under this Article II are intended, and shall be construed, to benefit such of its Affiliates and sublicensees as and to the extent Emergent may, from time to time, designate. Emergent shall have the right to satisfy any or all of its obligations under this Article II through one or more of its Affiliates or subcontractors. HPA may subcontract one or more of its obligations hereunder, with the prior written consent of Emergent, which may be granted or withheld in the sole and absolute discretion of Emergent.
- 2.12 Future Cooperation. The Parties acknowledge that it is their mutual intent to work together where practicable on other projects in the Field, and that Emergent afford HPA a right of first negotiation with respect to those research and development activities in the Field that Emergent shall decide, in its sole discretion, to subcontract.

# ARTICLE III Development Funding

3.1 Emergent's Obligations. In consideration of HPA's performance of its designated Development Activities, Emergent shall pay HPA the amounts set forth on Schedule 3.1 with respect to such Development Activities (the "Development Budget"). Without limitation of the foregoing, the rate HPA charges Emergent for its employee costs incurred in the performance of the Development Activities shall be no greater than the standard rate per full-time equivalent (FTE) that HPA charges to its largest non-governmental customers. To the extent that this Agreement imposes obligations (other than payment obligations or customary administrative obligations) on HPA that are (i) not budgeted for in the Development Budget or covered in HPA's standard overhead charges and (ii) not expressly required to be performed at HPA's expense or at no cost to Emergent, then HPA shall promptly notify Emergent of the obligation and provide Emergent with its budget to perform such obligation based on rates no less favorable than those charged by HPA to its largest non-governmental customers. Emergent

may elect in its sole discretion either to waive performance of the obligation or to pay HPA for the performance thereof under the agreed-upon budget.

- 3.2 Invoices and Payments. Within thirty (30) days after the end of each Calendar Quarter, HPA shall invoice Emergent for the amounts payable by Emergent pursuant to Section 3.1 for such Calendar Quarter, which invoice shall be accompanied by reasonable documentation thereof. HPA shall promptly furnish Emergent with such other information in support of such invoice as Emergent may reasonably request. Each invoice shall be payable to HPA within thirty (30) days after receipt by Emergent of such invoice and supporting documentation and information. Any delinquent payments shall accrue interest from the date on which payment was due, at the prime rate, as published in *The Wall Street Journal*, Eastern United States Edition, on the last Business Day preceding such date.
- 3.3 Books and Records. HPA shall maintain complete and accurate books, records and accounts that, in reasonable detail, fairly reflect any reimbursable Development Program costs and expenses incurred by it or its Affiliates in conformity with GAAP. HPA shall retain such books, records and accounts until the later of (a) three (3) years after the end of the period to which such books, records and accounts pertain, and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law. Emergent shall have the right to review and audit such books, records and accounts in accordance with Article IV. Further, in the event that any amounts payable by Emergent hereunder shall be funded by one or more grants from the United States Government to Emergent, HPA agrees to comply with any and all terms and conditions of such grants.
- 3.4 Minimum Commitment of Emergent. Emergent agrees that (a) on or prior to the first (1st) anniversary of the Effective Date, it and its Affiliates shall have expended an aggregate amount of at least [\*\*] United States dollars (\$[\*\*]) in support of the Development Activities, and (b) in the event that the Development Program shall continue until the second (2nd) anniversary of the Effective Date, on or prior to such second (2nd) anniversary, it and its Affiliates shall have expended an aggregate amount (including any amounts expended on or prior to the first (1st) anniversary of the Effective Date) of at least [\*\*] United States dollars (\$[\*\*]) in support of the Development Activities (the "Minimum Commitment"); provided, however, that any amounts paid by Emergent pursuant to Section 3.1 shall be credited toward such Minimum Commitment in satisfaction of Emergent's obligations under this Section 3.4. Any failure by Emergent to satisfy the Minimum Commitment obligation shall not be deemed to be a breach of this Agreement and HPA's sole remedy in the event of such failure shall be to terminate this Agreement after such second (2nd) anniversary in accordance with Section 11.3.

#### ARTICLE IV Audits

4.1 Audit. In the event that the Parties mutually agree that HPA will undertake to perform services on behalf of Emergent pursuant to this Agreement on a cost or cost-plus reimbursement basis, then the provisions of this Section 4.1 shall apply. Upon the written request of Emergent and not more than once in each Calendar Year, HPA shall permit an independent certified public accounting firm of internationally recognized standing selected by Emergent, and reasonably acceptable to HPA, to have access during normal business hours, and

upon reasonable prior written notice, to such of the records of HPA as may be reasonably necessary to verify the accuracy of the calculation of any amounts payable by Emergent hereunder, for any Calendar Year ending not more than twenty-four (24) months prior to the date of such request. The accounting firm shall disclose to HPA and Emergent only whether the financial statements and any related invoices are correct or incorrect and the specific details concerning any discrepancies. If such accounting firm concludes that Emergent has overpaid HPA during such period, HPA shall reimburse Emergent for the difference between the amount actually owed, as determined by the accounting firm, and the amount actually paid by Emergent, with interest from the date originally due at the prime rate, as published in *The Wall Street Journal*, Eastern United States Edition, on the last Business Day preceding such date, within thirty (30) days after the date on which such accounting firm's written report is delivered to HPA. If such accounting firm concludes that Emergent has underpaid HPA during such period, Emergent shall pay such difference to HPA within thirty (30) days after the date of delivery of such report. If, and only if, the amount of the overpayment is greater than five percent (5%) of the total actual amount owed as determined by the accounting firm, HPA shall bear all costs related to such audit. In all other circumstances, Emergent shall bear the cost of such audit.

**4.2 Confidentiality.** Emergent shall treat all information subject to review under this Article IV in accordance with the confidentiality provisions of Article VI and shall cause its accounting firm to enter into a reasonably acceptable confidentiality agreement with HPA obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.

# ARTICLE V License Grants and Assignments

5.1 Grants to Emergent. HPA hereby grants to Emergent and its Affiliates, and shall cause HPA's Affiliates to grant to Emergent and its Affiliates:

(a) an exclusive (even with regard to HPA and its Affiliates), perpetual and irrevocable (in each case subject to the provisions of Article XI), royalty-free license, with the right to grant sublicenses (through multiple tiers of sublicensees), under HPA's and its Affiliates' rights, title, and interest in and to the Joint Technology, to Exploit Vaccine Products and any and all Improvements thereto in the Territory (other than to make, have made, and use Vaccine Products and any and all Improvements thereto in the United Kingdom and to sell or otherwise distribute Vaccine Products and any and all Improvements thereto in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service));

(b) an exclusive (even with regard to HPA and its Affiliates), perpetual and irrevocable (in each case subject to the provisions of Article XI), royalty-free license and right of reference, with the right to grant sublicenses (through multiple tiers of sublicenses), under HPA's and its Affiliates' rights, title and interest in and to the Regulatory Documentation, to the extent not assigned to Emergent and its Affiliates pursuant to Section 5.4 or the rBOT License Agreement), to Exploit Vaccine Products and any and all Improvements thereto in the Territory for any purpose whatsoever (other than to make, have made, and use Vaccine Products and any

and all Improvements thereto in the United Kingdom and to sell or otherwise distribute Vaccine Products and any and all Improvements thereto in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service)); and

(c) a non-exclusive, perpetual and irrevocable (in each case subject to the provisions of Article XI), royalty-free license, with right to grant sublicenses (through multiple tiers of sublicenses), under HPA's and its Affiliates' rights, title, and interest in and to the Regulatory Documentation, to the extent not assigned to Emergent and its Affiliates pursuant to Section 5.4 or the rBOT License Agreement), to make, have made, and use Vaccine Products and any and all Improvements thereto in the United Kingdom and to sell or otherwise distribute Vaccine Products and any and all Improvements thereto in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service).

#### 5.2 Grant to HPA

- (a) Subject to the provisions of Article XI, Emergent hereby grants to HPA (but not its Affiliates) a nonexclusive, royalty-free license and right of reference (without the right to grant sublicenses) under all of Emergent's rights, title and interest in and to the Emergent Technology solely for use in the performance by HPA of its designated Development Activities.
- (b) HPA and its Affiliates shall have no right, express or implied, to the Emergent Technology in or outside the Field except as expressly provided in this Agreement (including Section 5.2(a)) or in a separate written agreement between Emergent, on the one hand, and HPA and/or its Affiliate(s), on the other hand. All rights of Emergent and its Affiliates in and to the Emergent Technology that are not expressly granted to HPA in this Agreement are retained by Emergent and its Affiliates.
- 5.3 HPA's Retained Rights. Subject to the provisions of Article XI, HPA hereby retains the right under all of HPA's and its Affiliates' rights, title and interest in and to the Joint Technology and the Regulatory Documentation, to the extent not assigned to Emergent and its Affiliates pursuant to Section 5.4 or the rBOT License Agreement, to make, have made, and use Vaccine Products and any and all Improvements thereto in the United Kingdom and to sell or otherwise distribute Vaccine Products and any and all Improvements thereto in the United Kingdom to meet the requirements of any U.K. Public Entity (including sales to hospitals, clinics and other similar health care organizations that purchase Licensed Products for the purpose of supplying such Licensed Products to or for the National Health Service) (collectively, the "Retained Rights"). HPA shall not, and shall cause its Affiliates not to, assign, sell or otherwise transfer, or grant any license or right of reference under, any of the Retained Rights to any Affiliate of HPA or any Third Party.
- **5.4 Assignment of Regulatory Documentation**. HPA hereby assigns to Emergent, and shall cause its Affiliates to assign to Emergent, all of HPA's and its Affiliates' rights, title and interest in and to all Regulatory Documentation, including, to the extent permitted by

Applicable law, all Regulatory Approvals, Controlled by HPA or its Affiliates as of the Effective Date and from time to time during the term of this Agreement; provided, however, that HPA shall not be required to assign any Regulatory Documentation that it may develop, at its expense, solely in connection with the exercise of the Retained Rights. HPA shall duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such agreements, documents and instruments, as may be necessary under, or as Emergent may reasonably request in connection with, or to carry out more effectively, the purposes of this Section 5.4.

#### ARTICLE VI Confidentiality and Nondisclosure

#### 6.1 Confidentiality Obligations.

- 6.1.1 <u>General Obligations</u>. Except as provided herein, the Parties agree that, during the term of this Agreement and for five (5) years after this Agreement's expiration or termination pursuant to Article XI, each Party shall hold in strict confidence and shall not publish or otherwise disclose, directly or indirectly, to any Person (other than employees, Affiliates, legal counsel, consultants, auditors and advisors who, except in the case of legal counsel, are bound in writing by confidentiality and non-use obligations no less onerous than those set forth herein) any Confidential Information of the other Party. During such period, a Party (and its Affiliates) shall not use for any purpose, directly or indirectly, Confidential Information of the other Party or its Affiliates furnished or otherwise made known to it, except as permitted hereunder.
- 6.1.2 Additional HPA Obligations. HPA recognizes that by reason of Emergent's status as an exclusive licensee pursuant to this Agreement and the rBOT License Agreement, Emergent has an interest in HPA's retention in confidence of certain information of HPA. Accordingly, HPA shall, and shall cause its Affiliates, officers, directors, employees and agents to, hold in strict confidence, and not publish or otherwise disclose, and not use directly or indirectly for any purpose, any information relating to the Licensed Product(s) or the Regulatory Documentation, including the Regulatory Approvals (collectively, the "Emergent Information"), except to the extent that (a) the Emergent Information is in the public domain through no fault of HPA, its Affiliates, or any of their respective officers, directors, employees or agents, or (b) such disclosure is reasonably necessary for the performance of HPA's obligations hereunder or the exercise of the Retained Rights, provided that any Third Party to which HPA proposes to disclose any Emergent Information is bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article VI. For clarification, the disclosure by HPA to Emergent to HPA of Emergent Information shall not cause such information to cease to be subject to the confidentiality provisions of this Section 6.1.2.
  - 6.2 Permitted Disclosures. Each Party may disclose Confidential Information or Emergent Confidential Information to the extent that such disclosure is:
- (a) Made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the receiving Party shall first have given notice to the disclosing Party and, insofar as permitted by applicable law, given the disclosing

Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and <u>provided further</u> that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

- (b) Otherwise required by law, in the opinion of legal counsel to the receiving Party as expressed in an opinion letter in form and substance reasonably satisfactory to the disclosing Party, which shall be provided to the disclosing Party at least two (2) Business Days prior to the receiving Party's disclosure of the Confidential Information pursuant to this Section 6.2(b);
- (c) Made by the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; <u>provided</u>, <u>however</u>, that reasonable measures shall be taken to assure confidential treatment of such information;
- (d) Made by Emergent to existing or potential acquirers or merger candidates; existing or potential pharmaceutical collaborators; investment bankers; existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing; each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article VI;
- (e) Made by HPA to potential investors in any spin-off entity to which HPA intends to transfer its business relating to the Development Program and the Exploitation of Licensed Products and HPA Products (as defined in the rBOT License Agreement), each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article VI; or
- (f) Made by Emergent or its Affiliates or sublicensees to Third Parties as may be necessary or reasonably useful in connection with the Exploitation of any Licensed Product, including subcontracting and sublicensing transactions in connection therewith.

#### 6.3 Confidential Information.

6.3.1 <u>Defined</u>. "Confidential Information" of a Party shall mean all information and know-how and any tangible embodiments thereof provided by or on behalf of such Party to the other Party either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement, including data; knowledge; practices; processes; ideas; research plans; engineering designs and drawings; research data; manufacturing processes and techniques; scientific, manufacturing, marketing and business plans; and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business. For the avoidance of doubt, Confidential Information shall be deemed to include any and all information provided by one Party to the other Party relating to Licensed Products, and the terms of this Agreement.

6.3.2 Exclusions. Notwithstanding the foregoing, information or know-how of a Party shall not be deemed Confidential Information with respect to the receiving Party for purposes of this Agreement if such information or know-how: (a) was already known to the receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, at the time of disclosure to, or, with respect to know-how, discovery or development by, such receiving Party; (b) was generally available or known, or was otherwise part of the public domain, after its disclosure to, or, with respect to know-how, discovery or development by, such receiving Party; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to know-how, discovery or development by, such receiving Party through no fault of the receiving Party; (d) was disclosed to such receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the Party that Controls such information and know-how not to disclose such information or know-how to others; or (e) was independently discovered or developed by such receiving Party or its Affiliates, as evidenced by their written records, without the use of Confidential Information belonging to the Party that Controls such information and know-how.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of a Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of such Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of a Party merely because individual elements of such Confidential Information are in the public domain or in the possession of such Party unless the combination and its principles are in the public domain or in the possession of such Party.

- **6.4 Use of Name.** Neither Party shall mention or otherwise use the name, symbol, trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law.
- 6.5 Press Releases; Publication. Each Party shall have the right to issue press releases and to make other public disclosures, presentations or publications with respect to this Agreement; provided, however, that no such press release or other public disclosure, presentation or publication shall disclose any Confidential Information of the other Party without the prior written consent of such other Party; and, provided further, that neither HPA nor any of its Affiliates, officers, directors, employees or agents shall be permitted to issue any press release or make any other public disclosure, presentation or publication regarding any information, data or results pertaining to or resulting from the Emergent Information, without the prior written consent of Emergent. HPA agrees to acknowledge Emergent in all such publications or other public disclosures by coauthorship or acknowledgement, as appropriate according to customary practice for such research publications and disclosures
- 6.6 Equitable Relief. Each Party acknowledges and agrees that breach of any of the terms of this Article VI would cause irreparable harm and damage to the other Party and that such damage may not be ascertainable in money damages and that as a result thereof the non-

breaching Party would be entitled to seek from a court equitable or injunctive relief restraining any breach or future violation of the terms contained herein by the breaching Party without the necessity of proving actual damages. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of law or equity, including money damages, which other remedies are subject to Section 12.7.

#### ARTICLE VII Payments

All payments to be made by a Party to the other Party under this Agreement shall be made in United States dollars and may be paid by check made to the order of the receiving party or bank wire transfer in immediately available funds to such bank account designated in writing by the receiving Party from time to time. Payments shall be free and clear of any taxes (other than withholding and other taxes imposed on the receiving Party, which shall be for the account of such Party), fees or charges, to the extent applicable. With respect to payments in currencies other than United States dollars, payments shall be calculated based on currency exchange rates for the month in which the invoice is received. For each month and each currency, such exchange rates shall equal the arithmetic average of the daily exchange rates for such month listed in *The Wall Street Journal*, Eastern United States Edition, or, if not so available, as otherwise agreed by the Parties. Any delinquent payments shall accrue interest from the date on which payment was due, at the prime rate, as published in *The Wall Street Journal*, Eastern United States Edition, on the last Business Day preceding such date.

#### ARTICLE VIII Indemnity

**8.1 Indemnification of Emergent.** Subject to Sections 8.3 and 8.4(b), HPA shall indemnify Emergent, its Affiliates and its and their respective directors, officers, employees and agents, and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) in connection with any and all suits, investigations, claims or demands (collectively, "Losses") arising from or occurring as a result of (a) any material breach by HPA of this Agreement, (b) any gross negligence or willful misconduct of HPA, its Affiliates or its other permitted subcontractors in performing HPA's obligations under this Agreement, or (c) the Manufacture of the Licensed Products by HPA pursuant to Section 2.9.2, except for those Losses for which Emergent has an obligation to indemnify HPA pursuant to Section 8.2, as to which Losses each party shall indemnify the other to the extent of their respective liability for the Losses.

**8.2 Indemnification of HPA.** Subject to Sections 8.3 and 8.4(b), Emergent shall indemnify HPA, its Affiliates and their respective directors, officers, employees and agents, and defend and save each of them harmless, from and against any and all Losses arising from or occurring as a result of (a) any material breach by Emergent of this Agreement, or (b) the gross negligence or willful misconduct of Emergent, its Affiliates or its other subcontractors in performing Emergent's obligations under this Agreement, except for those Losses for which HPA has an obligation to indemnify Emergent and its Affiliates pursuant to Section 8.1, as to which Losses each party shall indemnify the other to the extent of their respective liability for the Losses.

#### 8.3 Indemnification Procedure

- 8.3.1 Notice of Claim. The indemnified Party shall give the indemnifying Party prompt written notice (an "Indemnification Claim Notice") of any Losses or discovery of fact upon which such indemnified party intends to base a request for indemnification under Section 8.1 or Section 8.2, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses. All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "Indemnified Party").
- 8.3.2 <u>Third Party Claims</u>. The obligations of an indemnifying Party under this Article VIII with respect to Losses arising from claims of any Third Party that are subject to indemnification as provided for in Sections 8.1 or 8.2 (a "Third Party Claim") shall be governed by and be contingent upon the following additional terms and conditions:
- (a) Control of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify any Person seeking indemnification in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against any such claim for indemnifying Party. Under the indemnifying Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim, assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by any indemnified Party in connection with the Third Party Claim, the indemnifying Party assume the defense of a Third Party Claim, the indemnifying Party shall not be liable to the Indemnified Party or any other indemnified party for any legal expenses subsequently incurred by such indemnified party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless an indemnified Party from and against the Third Party Claim, the Indemnified Party Claim with respect to such indemnified Party.
- (b) <u>Right to Participate in Defense</u>. Without limiting Section 8.3.2(a), any indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; <u>provided</u>, <u>however</u>, that such employment shall be at the indemnified Party's own expense unless (i) the employment thereof has been specifically authorized by the indemnifying Party in writing or (ii) the indemnifying

Party has failed to assume the defense and employ counsel in accordance with Section 8.3.2(a) (in which case the Indemnified Party shall control the defense).

- (c) <u>Settlement</u>. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 8.3.2(a), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). The indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party.
- (d) <u>Cooperation</u>. Regardless of whether the indemnifying party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each other indemnified party to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnified parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.
- (e) Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a Calendar Quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

## 8.4 Limitation of Liability.

(a) SUBJECT TO SECTIONS 8.1 AND 8.2, AND EXCEPT IN CIRCUMSTANCES OF GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, NONE OF EMERGENT, HPA OR ANY OF THEIR RESPECTIVE AFFILIATES SHALL BE

LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING FOR LOST PROFITS, MILESTONES OR ROYALTIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (A) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR (B) THE DEVELOPMENT, USE OR SALE OF ANY PRODUCT DEVELOPED HEREUNDER; PROVIDED, HOWEVER, THAT THE FOREGOING LIMITATIONS SHALL NOT APPLY TO ANY LIABILITY OF HPA OR ITS AFFILIATES RESULTING FROM THE MANUFACTURE AND SUPPLY OF LICENSED PRODUCTS OR OTHERWISE RELATING TO SECTIONS 2.9 AND 9.3(f). NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS ATTEMPTING TO EXCLUDE OR LIMIT THE LIABILITY OF EITHER OF THE PARTIES OR THEIR RESPECTIVE AFFILIATES (A) FOR DEATH OR PERSONAL INJURY CAUSED BY THE NEGLIGENCE OF EITHER OF THE PARTIES, THEIR RESPECTIVE AFFILIATES, (B) FOR FRAUD OR FRAUDULENT MISREPRESENTATION OR (C) FOR ANY MATTER IN RESPECT OF WHICH IT WOULD BE ILLEGAL FOR EITHER PARTY TO EXCLUDE OR ATTEMPT TO EXCLUDE ITS LIABILITY

(b) SUBJECT TO THE PRECEDING SENTENCE, BUT NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, IN NO EVENT SHALL THE COMBINED AGGREGATE LIABILITY OF EITHER PARTY UNDER THIS AGREEMENT, TAKEN TOGETHER WITH SUCH PARTY'S AGGREGATE LIABILITY UNDER THE 1BOT LICENSE AGREEMENT, THE BT LICENSE AGREEMENT, THE BT DEVELOPMENT AGREEMENT AND THE DISTRIBUTION AGREEMENT, EXCEED THE COMBINED AGGREGATE AMOUNTS PAID BY EMERGENT TO HPA, WHETHER AS LUMP SUMS OR PERIODIC PAYMENTS OF ROYALTIES OR SUBLICENSE INCOME, UNDER THIS AGREEMENT, THE BTD LICENSE AGREEMENT, THE BT DEVELOPMENT AGREEMENT AND THE DISTRIBUTION AGREEMENT (THE "AGGREGATE AMOUNT"); PROVIDED, HOWEVER, THAT IN THE EVENT THAT EITHER PARTY (THE "LIABLE PARTY") SHALL BECOME LIABLE TO THE OTHER PARTY HEREUNDER FOR AN AMOUNT (THE "TOTAL LIABILITY") LARGER THAN THE AGGREGATE AMOUNT CALCULATED AS OF THE DATE THAT THE TOTAL LIABILITY BECAME DUE AND PAYABLE, THE LIABLE PARTY SHALL PROMPTLY PAY SUCH OTHER PARTY A LUMP SUM EQUAL TO THE AGGREGATE AMOUNT AS SO CALCULATED; AND PROVIDED, FURTHER, THAT IF HPA IS THE LIABLE PARTY, EMERGENT SHALL THEREAFTER HAVE A RIGHT OF OFFSET WITH RESPECT TO ANY PAYMENT OBLIGATIONS OF EMERGENT TO HPA HEREUNDER AND THEREUNDER THAT BECOME DUE AND PAYABLE AFTER SUCH DATE, UNTIL SUCH TIME AS THE TOTAL AMOUNTS OFFSET BY EMERGENT EQUAL THE DIFFERENCE BETWEEN THAT DATA AS EMERGENT SHALL MAKE PAYMENTS TO HPA THAT ARE OTHERWISE DUE AND PAYABLE HEREUNDER OR THEREUNDER, EMERGENT SHALL PAY TO HPA AS EMERGENT SHALL DAMAGES, UNTIL SUCH TIME AS THE TOTAL AMOUNTS SO PAID TO HPA AS ADDITIONAL DAMAGES EQUAL THE DIFFERENCE BETWEEN THE TOTAL LIABILITY AND SUCH LUMP SUM PAYMENT BY EMERGENT.

**8.5 Insurance**. Emergent shall use commercially reasonable efforts to obtain and maintain, with an insurance company of internationally recognized standing, such type and amounts of liability insurance, and HPA shall maintain such program of self-insurance, in each case covering the development of the Licensed Product(s), as is normal and customary in the pharmaceutical industry generally for parties similarly situated, and Emergent shall upon request provide HPA with a copy of such policies of insurance, along with any amendments and revisions thereto; <u>provided</u>, <u>however</u>, that Emergent shall promptly notify HPA in writing if, after using commercially reasonable efforts, Emergent is unable to obtain such insurance or if, after obtaining such insurance, Emergent is unable to maintain such insurance; and <u>provided</u>, <u>further</u>, that Emergent shall not be required to seek such insurance coverage to the extent that the relevant liabilities are covered by a government indemnity in favor of Emergent or precluded by applicable law.

# ARTICLE IX Representations and Warranties

- 9.1 Representations and Warranties. Each Party hereby represents, warrants and covenants to the other Party as of the Effective Date as follows:
- (a) Such Party (i) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (ii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.
- (b) Such Party is not aware of any pending or threatened litigation (and has not received any communication) that alleges that such Party's activities related to this Agreement have violated, or that by conducting the activities as contemplated herein such Party would violate, any of the intellectual property rights of any other Person.
- (c) All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.
- (d) The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable law or regulation or any provision of the articles of incorporation, bylaws, limited partnership agreement or any similar instrument of such Party, as applicable, in any material way, and (ii) do not conflict with, violate, or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

- **9.2** Additional Representations, Warranties and Covenants of Emergent. Emergent represents, warrants and covenants to HPA that Emergent is a corporation duly organized and in good standing under the laws of the State of Delaware, and has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.
  - 9.3 Additional Representations, Warranties and Covenants of HPA. HPA represents, warrants and covenants to Emergent that:
- (a) HPA is a governmental entity duly organized, validly existing and in good standing under the laws of England, and has full governmental power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.
- (b) HPA has conducted any and all studies and other development work related to the Licensed Product(s), including any such work performed pursuant to the Master Services Agreement, in accordance with Applicable Law. HPA and its Affiliates have employed (and, with respect to the Development Activities, will employ) Persons with appropriate education, knowledge and experience to conduct and to oversee the conduct of such activities with respect to the Licensed Products. Neither HPA nor any of its Affiliates is aware of any fact or circumstance that could adversely affect the acceptance, or the subsequent approval, by any Regulatory Authority of any filing, application or request for Regulatory Approval.
- (c) Neither HPA nor any of its Affiliates or Key Personnel have been debarred or are subject to debarment and neither HPA nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement or that have previously provided pursuant to the Master Services Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA, or who is the subject of a conviction described in such section. HPA agrees to inform Emergent in writing immediately if it or any Person who is performing services hereunder or the Master Services Agreement is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of HPA's knowledge, is threatened, relating to the debarment or conviction of HPA or any Person performing services hereunder or under the Master Services Agreement.
- (d) HPA agrees not to, and agrees to cause its Affiliates not to, directly or indirectly, expressly or by implication, by action or omission or otherwise (i) assign, transfer, convey or otherwise encumber any right, title or interest in or to the Regulatory Documentation or Joint Technology, (ii) grant any license or other right, title or interest in or to the Regulatory Documentation or Joint Technology in any manner, or (iii) agree to or otherwise become bound by any covenant not to sue for any infringement, misuse or other action or inaction with respect to the Regulatory Documentation or Joint Technology, in each case ((i), (ii), and (iii)) that is inconsistent with the grants, assignments and other rights reserved to Emergent and its Affiliates under this Agreement and the rBOT License Agreement.

- (e) HPA shall cause each of its Affiliates and any other Person conducting Development Activities on behalf of HPA hereunder to assign to HPA rights to any and all Information and Inventions that relate to the Licensed Product(s), such that Emergent shall, by virtue of this Agreement and the rBOT License Agreement, receive from HPA, without payment of additional consideration beyond that required by this Agreement and the rBOT License Agreement, the licenses and other rights granted to Emergent and its Affiliates hereunder and under the rBOT License Agreement.
- (f) At the time of delivery of each Licensed Product to Emergent pursuant to Section 2.9.2: (i) such Licensed Product will have been Manufactured, held and shipped in accordance with any applicable Regulatory Approvals for such Licensed Product, any applicable Good Manufacturing Practices and all other Applicable Law; (ii) such Licensed Product will have been manufactured in accordance, and be in conformity with, the product specifications for such Licensed Product (as set forth in the Development Plan) and will conform with any certificate of analysis provided by HPA; and (iii) title to such Licensed Product will pass to Emergent free and clear of any security interest, lien or other encumbrance.
- 9.4 Disclaimer of Warranties. EXCEPT FOR THOSE WARRANTIES SET FORTH IN THIS ARTICLE IX, AND SUBJECT TO SECTION 8.4(a), EACH PARTY HEREBY DISCLAIMS ANY AND ALL WARRANTIES, CONDITIONS AND TERMS, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING (A) ANY WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, (B) ANY WARRANTY WITH RESPECT TO THE VALIDITY OR ENFORCEABILITY OF ANY PATENT OR OTHER INTELLECTUAL PROPERTY, AND (C) ANY WARRANTY THAT THE PERFORMANCE OF ITS RIGHTS OR OBLIGATIONS HEREUNDER WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF ANY PERSON. SUBJECT TO SECTION 8.4(a), NO PARTY MAKES ANY REPRESENTATIONS HEREUNDER OTHER THAN THOSE SET FORTH EXPRESSLY HEREIN.

# ARTICLE X Intellectual Property Provisions

### 10.1 Intellectual Property Ownership.

- 10.1.1 Ownership of Emergent Technology and Regulatory Documentation. Subject to the license grant to HPA under Section 5.2(a), as between the Parties, Emergent shall own and retain all right, title and interest in and to the Emergent Technology. Subject to Applicable Law, as between the Parties, Emergent shall own all right, title and interest in and to the Regulatory Documentation (other than any Regulatory Documentation that HPA may develop at its expense solely in connection with the exercise of the Retained Rights).
- 10.1.2 Ownership and Exploitation of Joint Inventions and Joint Technology. Subject to the license grants under Sections 5.1 and 5.2 and the rBOT License Agreement, Emergent and HPA shall each own an equal, undivided interest in the Joint Inventions and the Joint Technology. Each Party agrees to disclose to the other Party promptly in writing any and all Joint Inventions and Joint Technology that are conceived, discovered, developed, or

otherwise made by or on behalf of such Party or its Affiliates or permitted subcontractors during the period beginning on the Effective Date and ending on the last day of the term of this Agreement, and to assign to such other Party (and to cause its Affiliates, employees and permitted subcontractors to assign to such other Party), without payment of additional consideration, an equal, undivided interest in such Joint Inventions or Joint Technology. The parties agree that (a) Emergent shall be free to Exploit any Joint Invention or Joint Technology in the Territory for any purpose, without an accounting to HPA, and (b) in addition to such rights as HPA has under Section 5.3, HPA shall be free to Exploit any Joint Inventions or Joint Technology in the Territory outside the Field.

#### 10.2 Prosecution of Patents.

- 10.2.1 Emergent Patents. Emergent shall have the sole right, at its sole cost and expense, to obtain, prosecute and maintain any Patents covering or claiming the Emergent Technology in the Territory.
- 10.2.2 Joint Patents. Emergent shall have the sole right to prepare, file, prosecute and maintain the Joint Patents in the Territory. HPA shall, and shall cause its Affiliates, to assist and cooperate with Emergent in filing, prosecuting and maintaining the Joint Patents, at Emergent's cost. Subject to the following sentence, Emergent shall bear the costs and expenses of the filing, prosecution and maintenance of the Joint Patents. If Emergent elects not (a) to pursue the filing, prosecution or maintenance of a Joint Patent in a country, or (b) to take any other action with respect to a Joint Patent in a country that is necessary or useful to establish or preserve rights thereto, then in each such case ((a) and (b)) Emergent shall so notify HPA promptly in writing and in good time to enable HPA to meet any deadlines by which an action must be taken to establish or preserve any such rights in such Joint Patent in such country. Upon receipt of each such notice from Emergent, HPA shall have the right, but not the obligation, to pursue the filing or registration, or support the continued prosecution or maintenance, of such Joint Patent, at its expense in such country. If HPA elects to pursue such filing or registration, as the case may be, or continue such support, then HPA shall notify Emergent of such election and Emergent shall, and shall cause its Affiliates to, reasonably cooperate with HPA in this regard.

## 10.3 Enforcement and Defense of Patents.

- 10.3.1 Party Patents. Except as otherwise provided in this Article X or in the rBOT License Agreement, each Party shall have the sole right, at its own expense, but not the obligation to enforce its rights under any Patents against all infringers at its sole cost and expense, and shall be entitled to any amounts it may recover from the infringer, whether by settlement or judgment.
- 10.3.2 Joint Patents. If either Party determines that any Joint Patent is being infringed by a Third Party's activities and that such infringement could affect the exercise by Emergent of its rights and obligations under this Agreement, it shall notify the other Party in writing and provide it with any evidence of such infringement that is reasonably available. In the event that any Joint Patent is being infringed by a Third Party, Emergent shall have the sole and exclusive right, but not the obligation, to attempt to remove such infringement, including by filing an infringement suit or taking other similar action. HPA shall provide reasonable

assistance to Emergent in the event that Emergent acts to enforce the Joint Patent with respect to such infringement, including by providing access to relevant documentation and other evidence, and joining the action to the extent necessary to allow Emergent to maintain the action. Emergent shall bear all costs and expenses with respect to any such enforcement, and shall be entitled to retain any amounts recovered, whether by settlement or judgment.

### 10.4 Potential Infringement of Third Party Rights.

- 10.4.1 <u>Third Party Licenses</u>. Each Party shall be responsible, in its sole discretion, (a) for determining whether to obtain any licenses from Third Parties in order to avoid infringing such Third Parties' intellectual property rights in performing its obligations hereunder, (b) for obtaining such licenses, and (c) for bearing any costs incurred in connection with obtaining such licenses.
- 10.4.2 <u>Third Party Litigation</u>. In the event that a Third Party commences litigation against a Party, its Affiliates or its sublicensees for infringement of such Third Party's Patents or other intellectual property rights, such Party shall have the sole right to defend against such infringement suit. The other Party shall use all reasonable efforts to assist and cooperating with the defending Party in connection with the defense of such suit. Each Party shall bear its own costs and expenses with respect to the defense of any suit, including any judgments or settlement against it.

## ARTICLE XI Term and Termination

11.1 Term and Expiration. This Agreement shall become effective as of the Effective Date and unless terminated earlier pursuant to Section 11.2, 11.3, 11.4, 11.5 or 11.7, the term of this Agreement shall continue in effect until the Development Activities are completed.

# 11.2 Termination by Emergent.

- 11.2.1 Without Cause. Notwithstanding anything contained herein to the contrary, Emergent shall have the right to terminate this Agreement at any time in its sole discretion by giving not less than two hundred and seventy (270) days' written notice to HPA.
  - 11.2.2 Upon First Anniversary. Emergent shall have the right to terminate this Agreement pursuant to Section 2.10.1 by giving not less than thirty (30) days' written notice to HPA.
- 11.3 Termination by HPA for Failure to Meet Minimum Commitment. In the event that Emergent fails to meet its Minimum Commitment obligation under Section 3.4, HPA shall have the right upon thirty (30) days' written notice to Emergent to terminate this Agreement.
  - 11.4 Termination by Either Party for Material Breach. Material failure by HPA to comply with any of its material obligations contained herein, or material failure by Emergent to

pay HPA amounts owed by Emergent to HPA hereunder, shall entitle the Party not in default to give to the Party in default notice specifying the nature of the default, requiring the defaulting Party to make good or otherwise cure such default, and stating its intention to terminate if such default is not cured. In the event that Emergent is the notifying Party, Emergent shall have the right, in addition to all other remedies available to it by law, in equity or pursuant to this Agreement, to suspend payment of any amounts that it would otherwise owe to HPA hereunder until such time as the material breach of HPA is cured (whereupon such suspended amounts shall be paid). If a noticed default is not cured within thirty (30) days (the "Cure Period") after the receipt of such notice (or, if such default cannot be cured within such thirty (30)-day period, if the Party in default does not commence actions to cure such default within the Cure Period and thereafter diligently continue such actions), the Party not in default shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement in its entirety; provided, however, that any right to terminate under this Section 11.4 shall be stayed in the event that, during any Cure Period, the Party alleged to have been in default shall have initiated dispute resolution in accordance with Section 12.7 with respect to the alleged default, which stay shall last so long as the initiating Party diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings.

11.5 Termination of the rBOT License Agreement. In the event that the rBOT License Agreement is terminated in its entirety for any reason, this Agreement shall automatically terminate as of the same date.

### 11.6 Accrued Rights; Survival; Return of Information.

- 11.6.1 <u>Accrued Rights</u>. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.
- 11.6.2 Survival. Sections 2.7, 2.9.3, 3.2, 3.3, 8.1, 8.2, 8.3, 8.4, 11.8, 12.2, 12.3, 12.5, 12.6, 12.7, 12.8, 12.9, 12.14, 12.16, and 12.17, and this Section 11.6, and Articles IV, VI, VII, and X shall survive the termination or expiration of this Agreement for any reason. Sections 5.1 and 5.4 shall survive (a) the expiration of this Agreement and (b) the termination of this Agreement pursuant to Section 11.5 (if such termination resulted from the termination of the rBOT License Agreement by Emergent for breach by HPA). Sections 5.1 and 5.4 shall not survive the termination of this Agreement for any other reason.
- 11.6.3 <u>Return of Information</u>. Within ninety (90) days after the termination or expiration of this Agreement, each Party shall deliver to the other Party any and all data, files, and records in its possession or under its control that constitute the Confidential Information of such other Party (or, in the case of HPA as the delivering Party, that constitute Emergent Information), to which such Party does not retain rights hereunder (except that such Party shall have the right to retain one copy of each of the foregoing solely for archival purposes).

11.7 Termination upon Insolvency. Either Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

11.8 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Emergent or HPA are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the United States Bankruptcy Code, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

### ARTICLE XII Miscellaneous

12.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, when such failure or delay is caused by or results from causes beyond the reasonable control of the non-performing Party, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority. The non-performing Party shall notify the other Party of such force majeure within ten (10) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for one-hundred and eighty (180) days after the date of the occurrence, the Parties shall meet and discuss in good faith how best to proceed.

- 12.2 Export Control Regulations. The rights and obligations of the Parties under this Agreement shall be subject in all respects to United States laws and regulations and the analogous laws and regulations of England, as shall from time to time govern the license and delivery of technology and products between the United States and the United Kingdom, including the United States Foreign Assets Control Regulations, Transaction Control Regulations and Expert Control Regulations, as amended, and any successor legislation issued by the Department of Commerce, International Trade Administration, Office of Export Licensing. Without in any way limiting the provisions of this Agreement, each Party agrees that, unless prior authorization is obtained from the Office of Export Licensing, it shall not export, re-export, or transship, directly or indirectly, to any country, any of the technical data disclosed to it by the other party if such export would violate the laws of the United States or the regulations of any department or agency of the United States Government.
- 12.3 Assignment. Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate, charge, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder, nor purport to do any of the same; provided, however, that Emergent may, without such consent, assign the benefit of this Agreement and its rights hereunder to an Affiliate, to the purchaser of all or substantially all of its assets, or to any Third Party pursuant to or in connection with any agreement and plan of merger, acquisition, reorganization, or other similar corporate transaction; and provided, further, that HPA may, without such consent, assign the benefit of this Agreement and its rights hereunder to an Affiliate, or to a Third Party in connection with the permitted assignment to such Third Party of HPA's rights under the rBOT License Agreement. Any attempted assignment in violation of the preceding sentence shall be void and of no effect. All validly assigned rights of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by the permitted assigns of Emergent or HPA, as the case may be. No assignment validly made pursuant to this Section 12.3 shall relieve the assigning Party of any of its obligations under this Agreement, unless the other Party has given its prior consent thereto.
- 12.4 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) the Parties agree to attempt to substitute for any such illegal, invalid or unenforceable provision a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof prohibited or unenforceable in any respect.
- 12.5 Notices. All notices or other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (promptly confirmed by personal delivery or courier as provided herein) or sent by internationally-recognized overnight courier, addressed as follows:

if to HPA, to: Health Protection Agency

Porton Down

Salisbury, Wiltshire SP4 0JG England Attention: Dr. David Rhodes Facsimile No.: +44-1980-61-22-41

with a copy to: Legal Department

Health Protection Agency

Porton Down

Salisbury, Wiltshire SP4 0JG England Facsimile No.: +44-1980-61-22-41

if to Emergent, to: Emergent BioSolutions, Inc.

300 Professional Drive

Gaithersburg, Maryland 20879 USA Attention: General Counsel Facsimile No.: +1-301-590-1252

with a copy to: Covington & Burling

One Front Street, 35th Floor San Francisco, California 94111 USA

Attention: James C. Snipes, Esq. Facsimile No.: +1-415-591-6091

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication shall be deemed to have been given when delivered if personally delivered on a Business Day, when transmitted if sent by facsimile (in accordance with this Section 12.5) on a Business Day, and on the third (3rd) Business Day after dispatch if sent by internationally-recognized courier. It is understood and agreed that this Section 12.5 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

12.6 Governing Law. This Agreement shall be governed by and construed in accordance with English law (without reference to the rules of conflict of laws thereof). Subject to Section 12.7, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of (i) the courts of the State of New York and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) initiated by HPA and arising out of or relating to this Agreement, and (ii) the English courts located in London for any action, suit or proceeding (other than appeals therefrom) initiated by Emergent and arising out of or relating to this Agreement. The Parties agree not to commence any action, suit or proceeding (other than appeals therefrom) except in such courts, respectively. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or the United States District Court for the Southern District of New York, or the English courts located in London, as the case may be, and hereby further irrevocably and unconditionally waive and agree

not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Each Party hereto further agrees that service of any process, summons, notice or document by internationally recognized courier to its address set forth above shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

### 12.7 Dispute Resolution.

12.7.1 Negotiation. The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement (or any document or instrument delivered in connection herewith) (each, a "Dispute"). In the event that the Parties are unable to, within ten (10) days, to reach a resolution, such Dispute shall be referred to the chief executive officers of Emergent and HPA, or their respective successors, who shall attempt in good faith to reach a resolution of the Dispute. If the foregoing procedures fail to achieve a mutually satisfactory resolution within ten (10) days, then either Party may, by written notice to the other Party, elect to have the matter settled by binding arbitration pursuant to Section 12.7.2.

12.7.2 <u>Arbitration</u>. Any arbitration under this Agreement shall take place at a location to be agreed by the Parties; <u>provided, however</u>, that in the event that the Parties are unable to agree on a location for an arbitration under this Agreement within five (5) days of the demand therefor, such arbitration shall be held in New York, New York if HPA is the Party that first demanded such arbitration or in London, England if Emergent is the Party that first demanded such arbitration arbitration Rules then in effect (the "AAA Rules"). The Parties shall appoint an arbitrator by mutual agreement. If the Parties cannot agree on the appointment of an arbitrator within thirty (30) days of the demand for arbitration, an arbitrator shall be appointed in accordance with AAA Rules. The arbitrator shall have the authority to grant any equitable and legal remedies that would be available in any judicial proceeding instituted to resolve the Dispute submitted to such arbitration in accordance with this Agreement; <u>provided, however</u>, that the arbitrator shall not have the power to alter, amend or otherwise affect the terms or the provisions of this Agreement. Judgment upon any award rendered pursuant to this Section may be entered by any court having jurisdiction over the Parties other assets. The arbitrator shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrator's fees and any administrative fees of arbitration, unless the arbitrator shall otherwise allocate such costs, expenses and fees between the Parties. The Parties agree that all arbitration awards shall be final and binding on the Parties and their Affiliates. The Parties hereby waive the right to contest the award in any court or other forum. Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or result

- 12.7.3 Interim Relief. Notwithstanding anything herein to the contrary, nothing in this Section 12.7 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, either prior to or during any arbitration hereunder, if necessary to protect the interests of such Party. This Section 12.7.3 shall be specifically enforceable.
- 12.8 Equitable Relief. HPA acknowledges and agrees that the restrictions set forth in Article VI of this Agreement are reasonable and necessary to protect the legitimate interests of Emergent and that Emergent would not have entered into this Agreement in the absence of such restrictions, and that any violation or threatened violation of any provision of Article VI will result in irreparable injury to Emergent. HPA also acknowledges and agrees that in the event of a violation or threatened violation of any provision of Article VI, Emergent shall be entitled to preliminary and permanent injunctive relief, without the necessity of proving irreparable injury or actual damages and without the necessity of having to post a bond, as well as to an equitable accounting of all earnings, profits and other benefits arising from any such violation. The rights provided in the immediately preceding sentence shall be cumulative and in addition to any other rights or remedies that may be available to Emergent. Nothing in this Section 12.8 is intended, or should be construed, to limit Emergent's right to preliminary and permanent injunctive relief or any other remedy for a breach of any other provision of this Agreement.
- 12.9 No Benefit to Third Parties. Article II confers a benefit on those Persons referred to in Section 2.11 (the "Emergent Beneficiaries") and, subject to the remaining provisions of this Section 12.9, is intended to be enforceable by the Emergent Beneficiaries by virtue of the Contracts (Rights of Third Parties) Act 1999 (the "Act"). The Parties do not intend that any provisions of this Agreement, apart from those of Article II, should be enforceable by virtue of the Act by any person who is not a party to this Agreement. Notwithstanding the provisions of this Section 12.9, this Agreement may be rescinded or amended in any way and at any time by the Parties in accordance with its terms, without the consent of any of the Emergent Beneficiaries.
- 12.10 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm the rights and remedies of the other Party under this Agreement.
- 12.11 English Language. This Agreement shall be written and executed in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control. All notices and other disclosure required of the parties hereunder shall be in English
- 12.12 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section, Schedule or Exhibit shall mean references to such Article, Section, Schedule or Exhibit of this Agreement, (b) references in any section to any clause are references to such clause of such section, and (c) references to any agreement, instrument or other document in this

Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, as so varied, replaced or supplemented and in effect at the relevant time of reference thereto.

- 12.13 Independent Contractors. It is expressly agreed that HPA and Emergent shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither HPA nor Emergent shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other Party. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.
- 12.14 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder, or the failure to exercise, or delay in exercising a right or remedy provided by this Agreement or by law, or the waiver of a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.
- 12.15 Counterparts. The Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 12.16 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties, and no rule of strict construction shall be applied against either Party.
- 12.17 Entire Agreement; Modifications. This Agreement, together with the rBOT License Agreement, the BT Development Agreement, the BT License Agreement, and the Distribution Agreement, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understanding, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment, modification, release or discharge hereof shall be binding upon the parties unless in writing and duly executed by authorized representatives of both Parties.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first set forth above.

Emergent BioSolutions, Inc.	Health Protection Agency
By: /s/ Fuad El-Hibri Fuad El-Hibri	By: /s/ Pat Troop Pat Troop
Title: Chairman and CEO	Title: CEO
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# Schedule 1.17

# **Development Plan**

A framework for the proposed development plan to produce a botulinum pentavalent (A, B, C, E & F) vaccine based on recombinant botulinum toxin LHN fragments is given below. The framework consists of a number of work packages the scope of which are provided as outlines. It is intended that each work programme will be presented as a detailed, fully-costed proposal for written approval by Emergent BioSolutions prior to commencement. Whilst an attempt has been made to cover all work packages currently envisaged, further work may arise during the development programme and may be agreed between HPA and Emergent at a later date.

Early Development Studies

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Process/Analytical Development

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Process Confirmation/Technology Transfer

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**GMP** Manufacture

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## Schedule 2.3

# **Key Personnel**

HPA operates a project management system and will nominate a project management team for this project. The lead will be taken by a General Project Manager who will provide the chief contact between HPA and Emergent BioSolutions. The following HPA staff have previous experience in the manufacture and testing of botulinum toxin fragments and/or expression and purification of recombinant proteins and as such will provide form part of the project team or provide input into this project.

Such key staff and their time allocation to the various work packages will be provided as part of the detailed HPA proposals for agreement by Emergent prior to commencement of work.

Process Development

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**GMP** Manufacture

[\*\*]

Project Management

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# Schedule 3.1

# **Development Budget**

The following budget figures are provided for indicative purposes only and should not be regarded as firm or complete. Firm prices will be prepared for each work package requested under the development programme and agreed with Emergent.

# **Early Development Studies**

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Process/Analytical Development

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**Process Confirmation** 

\$[\*\*]

GMP Manufacture

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Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

#### EXCLUSIVE DISTRIBUTION AGREEMENT

THIS EXCLUSIVE DISTRIBUTION AGREEMENT (this "Agreement"), effective as of November 23, 2004, (the "Effective Date"), by and between Emergent BioSolutions, Inc. a corporation organized and existing under the laws of the State of Delaware ("Emergent"), and the Health Protection Agency, a governmental agency organized and existing under the laws of England ("Supplier") (each of Emergent and Supplier, a "Party").

## WITNESSETH:

WHEREAS, Emergent desires to obtain exclusive rights from Supplier to distribute and sell the Products (as defined herein) to Approved Customers (as defined herein) in the Territory (as defined herein), and Supplier desires to grant such rights, on the terms set forth below.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants of the Parties contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending to be legally bound, do hereby agree as follows:

# ARTICLE I

Unless specifically set forth to the contrary herein, the following terms shall have the respective meanings set forth below:

- 1.1 "AAA Rules" shall have the meaning set forth in Section 9.6.2.
- 1.2 "Affiliate" shall mean, (a) with respect to Emergent, any Person that, directly or indirectly, through one or more intermediaries, controlls, is controlled by, or is under common control with Emergent, and (b) with respect to HPA, any Person, that, directly or indirectly, through one or more intermediaries, is controlled by HPA. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with," shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, by application of applicable law, or otherwise, or (b) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity); provided that, if local law restricts foreign ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests.
  - 1.3 "Agreement" shall have the meaning set forth in the preamble hereto.
- 1.4 "Applicable Law" shall mean all laws, rules, and regulations applicable to the Exploitation of the Products, including any such rules, regulations, guidelines, guidances, or other requirements of the Regulatory Authorities, that may be in effect from time to time in the

Territory, including current good manufacturing practices applicable to the Manufacturing of the Products.

- 1.5 "Approved Customer" shall mean any Person in the Territory other than a Restricted Customer.
- 1.6 "BT Development Agreement" shall mean that certain BT Vaccine Development Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms
- 1.7 "BT License Agreement" shall mean that certain BT Vaccine License Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
  - 1.8 "Business Day" shall mean any day other than a Saturday, Sunday, any public holiday and any bank holiday in either the United States or England.
- 1.9 "Certificate of Analysis" shall mean a certificate in the form reasonably agreed by the Parties evidencing the analytical tests conducted on a specific lot of a Product and setting forth, *inter alia*, the items tested, specifications and test results.
- 1.10 "Corresponding Emergent Product" shall mean, with respect to any Product, a "Licensed Product" as defined in the BT License Agreement or "Licensed Product" as defined in the rBOT License Agreement, in each case in finished, packaged form, that is substantially equivalent to such Product from a regulatory perspective.
  - 1.11 "Confidential Information" shall have the meaning set forth in Section 4.3.1.
  - 1.12 "Cure Period" shall have the meaning set forth in Section 8.3.
  - 1.13 "Customer Orders" shall have the meaning set forth in Section 2.4.1.
  - 1.14 "Dispute" shall have the meaning set forth in Section 9.6.1.
  - 1.15 "Effective Date" shall mean the date of this Agreement as set forth in the preamble hereto.
  - 1.16 "Emergent" shall have the meaning set forth in the preamble hereto.
  - 1.17 "Expert" shall have the meaning set forth in Section 3.6.1.
- 1.18 "Exploitation" shall mean the making, having made, importation, use, sale, offering for sale or disposition of a product or process, including the research, development, registration, modification, enhancement, improvement, Manufacture, storage, formulation, optimization, import, export, transport, distribution, promotion or marketing of a product or process.
  - **1.19** "Indemnification Claim Notice" shall have the meaning set forth in Section 6.3.1.

- 1.20 "Indemnified Party" shall have the meaning set forth in Section 6.3.1.
- 1.21 "Inquiries" shall have the meaning set forth in Section 3.1.1.
- 1.22 "Losses" shall have the meaning set forth in Section 6.1.
- 1.23 "Manufacture" and "Manufacturing" shall mean, with respect to a product, the manufacturing, processing, formulating, packaging, labeling, holding and quality control testing of such product.
  - 1.24 "Manufacturing Costs" shall mean the then current manufacturing costs for a product calculated in accordance with Exhibit 3.3.
- 1.25 "Person" shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government (whether or not having a separate legal personality).
- 1.26 "Product" shall mean (a) an "HPA Product" as defined in the BT License Agreement or (b) an "HPA Product" as defined in the rBOT License Agreement, in each case in finished, packaged form
  - 1.27 "Product Trademarks" shall mean all Trademarks owned, used or held for use by Supplier in connection with the Products.
  - 1.28 "Purchase Orders" shall have the meaning set forth in Section 3.1.3.
- 1.29 "rBOT Development Agreement" shall mean that certain rBOT Vaccine Development Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
- 1.30 "rBOT License Agreement" shall mean that certain rBOT Vaccine License Agreement, of even date herewith, by and between the Parties, as amended from time to time in accordance with its terms.
- 1.31 "Regulatory Approval" shall mean any and all approvals (including pricing and reimbursement approvals), governmental licenses, registrations or authorizations of any Regulatory Authority, necessary for the Exploitation of the Products or the Corresponding Emergent Products, as the case may be, in a country in the Territory, including any (a) approval of any Product or Corresponding Emergent Product (including any marketing authorizations and supplements and amendments thereto); (b) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); (c) labeling approval; and (d) technical, medical and scientific licenses.
- 1.32 "Regulatory Authority" shall mean any applicable supra-national, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to

the Exploitation of the Products in the Territory, but excluding HPA acting in its capacity as Supplier.

- 1.33 "Reply" shall have the meaning set forth in Section 3.1.2.
- 1.34 "Restricted Customer" shall mean (a) any national, local, regional or provincial governmental agency of the United Kingdom, including any components of the National Health Service, or (b) any hospital, clinic or other similar health care organization to the extent of such entity's purchases of Products for the purpose of supplying Products to or for the National Health Service.
  - 1.35 "Supplier" shall have the meaning set forth in the preamble hereto.
  - 1.36 "Term" shall have the meaning set forth in Section 8.1.
  - 1.37 "Territory" shall mean all countries of the European Union and Norway, Iceland and Liechtenstein.
  - 1.38 "Third Party" shall mean any Person other than Emergent, Supplier and their respective Affiliates.
  - 1.39 "Third Party Claim" shall have the meaning set forth in Section 6.3.2.
- 1.40 "Trademarks" shall include any word, name, symbol, color, designation or device or any combination thereof, including any trademark, trade dress, brand mark, trade name, brand name, logo or business symbol.

# ARTICLE II Appointment and Grant

- 2.1 Exclusive Distributor. Supplier hereby appoints Emergent, for the duration of the Term, to distribute, offer for sale and sell the Products to Approved Customers in the Territory on an exclusive basis (even with regard to Supplier and its Affiliates), and Emergent hereby accepts such appointment. Supplier acknowledges and agrees that during the Term it shall not, and it shall cause its Affiliates not to, market, promote, distribute, offer for sale or sell any Product to (a) any Approved Customer in the Territory and (b) any Person (other than Emergent or its Affiliates) outside the Territory that (i) is reasonably likely, directly or indirectly, to market, promote, distribute, offer for sale or sell any Product to Approved Customers in the Territory or assist another Person to do so, or (ii) has directly or indirectly marketed, promoted, distributed, offered for sale or sold the Product to Approved Customers in the Territory or assisted another Person to do so.
- 2.2 Sub-distributors. Supplier acknowledges and agrees that Emergent shall have the right to appoint sub-distributors (which may be Affiliates of Emergent), as determined from time to time in Emergent's sole discretion, to distribute, offer for sale and sell the Products to Approved Customers in the Territory.

2.3 Trademark License. Supplier hereby grants to Emergent an exclusive license for the duration of the Term, with the right to grant sub-licenses to sub-distributors, under the Product Trademarks to distribute, offer for sale and sell the Products to Approved Customers in the Territory.

#### 2.4 Product Orders

- 2.4.1 Supplier promptly shall forward to Emergent all orders for, or inquiries related to, the Products, whether oral or written, that Supplier or its Affiliates receive from any Approved Customer ("Customer Orders")
- 2.4.2 Emergent shall use commercially reasonable efforts to satisfy all Customer Orders received from Supplier. Supplier acknowledges and agrees that Emergent shall have the right, in its sole discretion, to satisfy any and all Customer Orders by supplying Corresponding Emergent Products to the applicable Approved Customer in lieu of Products, to the extent that Emergent legally may do so.
- 2.5 Terms of Sale. Supplier acknowledges and agrees that Emergent, in its sole discretion, shall determine the price and other terms and conditions of sale on which it shall distribute, offer for sale and sell the Products (or Corresponding Emergent Products) to Approved Customers (including sales pursuant to Customer Orders). All sales of Products by Emergent shall be in its own name and for its own account.
- 2.6 Compliance with Law. Emergent shall store and handle all Products sold to it by Supplier hereunder in accordance with the labeling therefor and in material compliance with all Applicable Law. Emergent shall sell and distribute the Products in material compliance with all Applicable Law. Emergent shall maintain complete and accurate records of its distribution and sale of the Products in accordance with Applicable Law to enable appropriate procedures to be implemented in the event that a recall or market withdrawal of any Product is required or appropriate.

## ARTICLE III Product Supply

### 3.1 Purchase Orders.

- 3.1.1 From time to time during the Term, Emergent may submit to Supplier written inquiries ("Inquiries") with respect to possible orders of Products, each of which shall specify (a) the quantity of each Product to be ordered by Emergent, (b) the required delivery date therefor, (c) the place of delivery, and (d) the type of customer.
- 3.1.2 Supplier shall, within ten (10) days after Supplier receives each Inquiry submitted in accordance with Section 3.1.1, inform Emergent in writing (a) whether it is willing to supply such Products on such terms and conditions, and (b) if so, the purchase price payable by Emergent pursuant to Section 3.3 and the additional warranties and indemnities that Supplier would provide to Emergent in connection with such sale of Products (a "Reply").

- 3.1.3 Within thirty (30) days after receipt of a Reply from Supplier, Emergent may submit to Supplier a written purchase order ("Purchase Order") for Products, which shall contain the items of information listed in Section 3.1.1 and the warranties and indemnities that the customer will require in connection with such purchase. In the event that the Purchase Order is consistent with the applicable Inquiry and Reply (including as to the warranties and indemnities to be provided), then Supplier shall accept such Purchase Order in writing within five (5) days after receipt thereof.
- 3.1.4 Emergent shall be obligated to purchase, and Supplier shall be obligated to sell and deliver by the delivery date set forth therein, such quantity of each Product as is set forth in each such Purchase Order. In the event that the terms of any Purchase Order are inconsistent with the terms of this Agreement, the terms of this Agreement shall control.
- 3.2 Delivery. Supplier shall deliver the quantities of Products set forth in each Purchase Order CIP (as defined in Incoterms 2000) at the place specified in such Purchase Order, not later than the required delivery date specified therein. Title to and risk of loss of all Products shall pass to Emergent at the time of delivery. All Products shall be packed for shipping in accordance with Applicable Law and packing instructions provided by Emergent. All Product delivered hereunder shall be accompanied by a Certificate of Analysis.
- 3.3 Purchase Price. The purchase price payable by Emergent for each unit of Product purchased hereunder shall be equal to [\*\*]% of Supplier's actual Manufacturing Costs for such Product, allocated on a per unit basis.
- 3.4 Invoicing. Supplier promptly shall invoice Emergent for all quantities of Products delivered in accordance herewith. Subject to Section 3.6, payment with respect to each shipment of Product delivered shall be due forty-five (45) days after receipt by Emergent of the invoice and the related Certificate of Analysis; provided, however, that if Emergent notifies Supplier pursuant to Section 3.6 that such Product is not conforming, then payment shall be due within forty-five (45) days after determination that such Product is conforming Product in accordance with Section 3.6 or the receipt by Emergent of replacement Product if so elected by Emergent, as the case may be. In the event of any inconsistency between an invoice and this Agreement, the terms of this Agreement shall control
- 3.5 Warranty. Supplier warrants to Emergent that, at the time of delivery pursuant to Section 3.2, all Products delivered hereunder following Regulatory Approval thereof (a) will have been Manufactured and released in accordance with the applicable Regulatory Approvals and Applicable Law, (b) will comply with any specifications therefor set forth in the applicable Regulatory Approvals, and (c) may legally be distributed or sold by Emergent to the Approved Customer under Applicable Law. Supplier acknowledges and agrees that Emergent and its sub-distributors may extend the foregoing warranties to all Approved Customers.

### 3.6 Rejection of Product.

3.6.1 In the event that Emergent determines that any Product delivered by Supplier does not conform to the warranty set forth in Section 3.5, Emergent shall give Supplier written notice thereof and the reasons for such nonconformance (including a sample of such

Product) within forty-five (45) days after delivery (or within ten (10) days after discovery of any nonconformity that could not reasonably have been detected by a customary visual inspection on delivery). Supplier shall undertake appropriate testing of such sample and shall notify Emergent whether it has confirmed such nonconformity within thirty (30) days after receipt of such notice from Emergent. If Supplier notifies Emergent that it has not confirmed such nonconformity, then the Parties shall mutually select an independent laboratory or other applicable expert (the "Expert") to evaluate if the Products comply with the warranty set forth in Section 3.5 and each Party shall cooperate with the Expert's reasonable requests for assistance in connection with its analysis hereunder. The findings of the Expert shall be binding on the Parties, absent manifest error. The expenses of the Expert shall be borne by Supplier if the Expert confirms the nonconformity and otherwise by Emergent. If the Expert or Supplier confirms that a batch of Product does not conform to the warranty set forth in Section 3.5, Supplier, at Emergent's option, promptly shall (a) supply Emergent with a conforming quantity of Product at Supplier's expense or (b) reimburse Emergent for any purchase price paid by Emergent with respect to such Product. In any event Supplier promptly shall reimburse Emergent for all costs incurred by Emergent with respect to such Product, which costs Emergent shall have the right to offset against any payments owed by Emergent to Supplier under this Agreement.

3.6.2 The rights and remedies provided in this Section 3.6 shall be cumulative and in addition to any other rights or remedies that may be available to Emergent.

#### 3.7 Audit Rights

- 3.7.1 Supplier shall keep, or shall cause to be kept, complete and accurate books and records of all information necessary, and in sufficient detail, to determine its Manufacturing Costs for products.
- 3.7.2 Upon the written request of Emergent and not more than once in each calendar year, Supplier shall permit an independent certified public accounting firm of internationally recognized standing selected by Emergent, and reasonably acceptable to Supplier, to have access during normal business hours, and upon reasonable prior written notice, to such of the books and records of Supplier as may be reasonably necessary to verify the accuracy of the amounts invoiced to Emergent, based on Supplier's Manufacturing Costs, in any calendar year ending not more than twenty-four (24) months prior to the date of such request. The accounting firm shall disclose to Emergent and Supplier only whether the invoices are correct or incorrect and the specific details concerning any discrepancies. If such accounting firm concludes that Emergent owed additional amounts to Supplier during such period, Emergent shall pay Supplier the difference between the amount actually owed, as determined by the accounting firm, and the amount actually paid by Emergent, with interest from the date originally due at the prime rate, as published in *The Wall Street Journal*, Eastern United States Edition, on the last business day preceding such date, within thirty (30) days after the date on which such accounting firm's written report is delivered to Supplier. If such accounting firm concludes that Emergent has overpaid Supplier during such period, Supplier shall pay such difference to Emergent, with interest from the date originally paid at the prime rate, as published in *The Wall Street Journal*, Eastern United States Edition, on the last business day preceding such date, within thirty (30) days after the date of delivery of such report. If, and only if, the amount of the overpayment is

greater than five percent (5%) of the total actual amount owed as determined by the accounting firm, Supplier shall bear all costs related to such audit. In all other cases, Emergent shall bear the cost of such audit.

- 3.7.3 Emergent shall treat all information of Supplier subject to review under this Section 3.7 in accordance with the confidentiality provisions of Article IV and shall cause its accounting firm to enter into a reasonably acceptable confidentiality agreement with Supplier obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.
  - 3.8 Currency. All amounts invoiced to Emergent hereunder shall be expressed and paid in United Kingdom Pounds Sterling.

# ARTICLE IV Confidentiality and Nondisclosure

- 4.1 Confidentiality Obligations. Except as provided herein, the Parties agree that, during the term of this Agreement and for five (5) years after this Agreement's expiration or termination pursuant to Article VIII, each Party shall hold in strict confidence and shall not publish or otherwise disclose, directly or indirectly, to any Person (other than employees, Affiliates, legal counsel, consultants, auditors and advisors who, except in the case of legal counsel, are bound in writing by confidentiality and non-use obligations no less onerous than those set forth herein) any Confidential Information of the other Party. During such period, a Party (and its Affiliates) shall not use for any purpose, directly or indirectly, Confidential Information of the other Party or its Affiliates furnished or otherwise made known to it, except as permitted hereunder.
  - **4.2 Permitted Disclosures**. Each Party may disclose Confidential Information to the extent that such disclosure is:
- 4.2.1 Made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the receiving Party shall first have given notice to the disclosing Party and, insofar as permitted by applicable law, given the disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order.
- 4.2.2 Otherwise required by law, in the opinion of legal counsel to the receiving Party as expressed in an opinion letter in form and substance reasonably satisfactory to the disclosing Party, which shall be provided to the disclosing Party at least two (2) Business Days prior to the receiving Party's disclosure of the Confidential Information pursuant to this Section 4.2.2;

- 4.2.3 Made by the receiving Party to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information:
- 4.2.4 Made by Emergent to existing or potential acquirers or merger candidates; existing or potential pharmaceutical collaborators; investment bankers; existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing; each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article IV; or
- 4.2.5 Made by HPA to potential investors in any spin-off entity to which HPA intends to transfer its business relating to the Development Program (as defined in each of the BT Development Agreement and the rBOT Development Agreement) and the Exploitation of Licensed Products (as defined in each of the BT License Agreement and the rBOT License Agreement) and HPA Products (as defined in each of the BT License Agreement and the rBOT License Agreement), each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article IV.

### 4.3 Confidential Information.

- 4.3.1 <u>Defined</u>. "Confidential Information" of a Party shall mean all information and know-how and any tangible embodiments thereof provided by or on behalf of such Party to the other Party in the course of performing this Agreement, including data; knowledge; practices; processes; ideas; research plans; engineering designs and drawings; research data; manufacturing processes and techniques; scientific, manufacturing, marketing and business plans; and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business. For the avoidance of doubt, Confidential Information shall be deemed to include any and all information provided by one Party to the other Party relating to the Products and the terms of this Agreement.
- 4.3.2 Exclusions. Notwithstanding the foregoing, information or know-how of a Party shall not be deemed Confidential Information with respect to the receiving Party for purposes of this Agreement if such information or know-how: (a) was already known to the receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, at the time of disclosure to, or, with respect to know-how, discovery or development by, such receiving Party; (b) was generally available or known, or was otherwise part of the public domain, at the time of its disclosure to, or, with respect to know-how, discovery or development by, such receiving Party; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to know-how, discovery or development by, such receiving Party through no fault of the receiving Party; (d) was disclosed to such receiving Party or its Affiliates, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the Party that controls such information and know-how not to disclose such information or know-how to others; or (e) was independently discovered or developed by such receiving Party or its Affiliates, as evidenced by their written records, without the use of Confidential Information belonging to the Party that controls such information and know-how.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of a Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of such Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of a Party merely because individual elements of such Confidential Information are in the public domain or in the possession of such Party unless the combination and its principles are in the public domain or in the possession of such Party.

4.4 Equitable Relief. Each Party acknowledges and agrees that breach of any of the terms of this Article IV would cause irreparable harm and damage to the other Party and that such damage may not be ascertainable in money damages and that as a result thereof the non-breaching Party would be entitled to seek from a court equitable or injunctive relief restraining any breach or future violation of the terms contained herein by the breaching Party without the necessity of proving actual damages. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of law or equity, including money damages, which other remedies are subject to Section 9.6.

# ARTICLE V Regulatory Approvals, Complaints, Adverse Event Reporting and Product Recall

### 5.1 Regulatory Approvals.

- 5.1.1 Supplier shall inform Emergent promptly after each Regulatory Approval of a Product has been obtained in the Territory, and of any amendments thereto. Supplier shall take all actions reasonably necessary to have Emergent recorded as a distributor of the Product in the Territory during the Term in accordance with Section 2.1. To the extent permitted by Applicable Law, Emergent shall cooperate with, and provide reasonable assistance to, Supplier in obtaining Regulatory Approvals of the Products in the Territory, including by attending meetings with Regulatory Authorities if reasonably requested by Supplier.
- 5.1.2 Supplier shall be solely responsible for (a) taking all actions, paying all fees and conducting all communication with the appropriate Regulatory Authority in respect of all Regulatory Approvals, including preparing and filing all reports (including adverse event and complaint reports) with the appropriate Regulatory Authority, (b) taking all actions and conducting all communication with Third Parties in respect of Products sold by Emergent and its sub-distributors, including responding to all Product complaints in respect thereof, including complaints related to tampering or contamination, and (c) investigating all Product complaints and adverse events in respect of Products sold by Emergent. Emergent shall, at Supplier's expense, cooperate with all of Supplier's reasonable requests and use its commercially reasonable efforts to assist Supplier in connection with (x) preparing any and all such reports for Regulatory Authorities (including, without limitation, supplying distribution information necessary to prepare annual reports), (y) preparing and disseminating all such communications with Third Parties, and (z) investigating and responding to any Product complaint or adverse event related to a Product sold by Emergent or its sub-distributors.
  - 5.1.3 Each Party promptly shall provide notice to the other Party of any material communications with any Regulatory Authority concerning the Products. To the extent

permitted by Applicable Law, copies of all such material communications shall be attached to the notice sent pursuant to this Section 5.1.3.

- 5.1.4 Each Party shall immediately notify the other of any information received regarding any threatened or pending action by any Regulatory Authority that may affect the Products or the continued Manufacture, distribution, sale or use of the Products in the Territory. Upon receipt of any such information, the Parties shall consult in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing set forth in this Section 5.1 shall be construed as restricting the right of either Party to make a timely report of such matter to any Regulatory Authority or take other action that it deems appropriate under Applicable Law.
- **5.2 Complaints**. Each Party shall maintain a record of any and all complaints it receives with respect to the Products. Each Party shall notify the other Party in reasonable detail of any complaint received by it within thirty (30) days or such shorter period as may be required by Applicable Law.
- **5.3** Adverse Event Reporting. Each Party shall provide notice to the other Party within twenty-four (24) hours from the time it becomes aware of an adverse event associated with use of a Product (whether or not the reported effect is (a) described in the prescribing information or the published literature with respect to such Product or (b) determined to be attributable to such Product) of any information in or coming into its possession or control concerning such adverse event.

#### 5.4 Product Recall.

- 5.4.1 Notification and Recall. In the event that any Regulatory Authority issues or requests a recall or market withdrawal or takes similar action in connection with any Product sold or distributed by Emergent or its sub-distributors, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal of any Product sold or distributed by Emergent or its sub-distributors, the Party notified of or desiring such recall or similar action shall, within twenty-four (24) hours, advise the other Party thereof by telephone or facsimile. Following such notification, within seventy-two (72) hours, Supplier shall decide in its sole discretion whether to conduct a recall or market withdrawal (except in the case of a government-mandated recall) and the manner in which any such recall or market withdrawal shall be conducted. Emergent shall cooperate with Supplier as reasonably requested by Emergent in the implementation of any recall or market withdrawal.
- 5.4.2 <u>Recall Expenses</u>. Supplier promptly shall reimburse Emergent for all expenses incurred by Emergent in connection with any recall or market withdrawal of any Product, except to the extent that such recall or market withdrawal results from Emergent's gross negligence or willful misconduct. Such expenses of recall or market withdrawal shall include expenses for notification, destruction or return of the recalled or withdrawn Product, and any refund of amounts paid for the recalled or withdrawn Product, legal and administrative costs incurred in connection with the recall (including any such expenses incurred in meeting with and responding to any issues raised by any Regulatory Authority).

### ARTICLE VI Indemnity

- 6.1 Indemnification of Emergent. Subject to Section 6.3, Supplier shall indemnify Emergent, its Affiliates and its and their respective directors, officers, employees and agents, and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) in connection with any and all suits, investigations, claims or demands (collectively, "Losses") arising from or occurring as a result of (a) any material breach by Supplier of this Agreement, (b) any gross negligence or willful misconduct of Supplier in performing Supplier's obligations under this Agreement, (c) any death or personal injury caused by the negligence of Supplier or its Affiliates and resulting from the purchase, use or consumption of any Product, or (d) any claim or allegation that the use of the Product Trademarks by Emergent or its sub-distributors in accordance with the terms hereof infringes or misappropriates the intellectual property rights of any Third Party, except for those Losses for which Emergent has an obligation to indemnify Supplier pursuant to Section 6.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses. Any additional indemnities to be provided to Emergent by Supplier in connection with specific Purchase Orders shall be mutually agreed pursuant to Section 3.1 on a case-by-case basis, and shall be subject to the procedure set forth in Section 6.3.
- **6.2 Indemnification of Supplier.** Subject to Section 6.3, Emergent shall indemnify Supplier, its Affiliates and their respective directors, officers, employees and agents, and defend and save each of them harmless, from and against any and all Losses arising from or occurring as a result of (a) any material breach by Emergent of this Agreement or (b) the gross negligence or willful misconduct of Emergent, its Affiliates or its other sub-contractors in performing Emergent's obligations under this Agreement, except for those Losses for which Supplier has an obligation to indemnify Emergent and its Affiliates pursuant to Section 6.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

#### 6.3 Indemnification Procedure

- 6.3.1 Notice of Claim. The indemnified Party shall give the indemnifying Party prompt written notice (an "Indemnification Claim Notice") of any Losses or discovery of fact upon which such indemnified Party intends to base a request for indemnification under Section 6.1 or Section 6.2, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses. All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents shall be made solely by such Party to this Agreement (the "Indemnified Party").
- 6.3.2 Third Party Claims. The obligations of an indemnifying Party under this Article VI with respect to Losses arising from claims of any Third Party that are subject to indemnification as provided for in Sections 6.1 or 6.2 (a "Third Party Claim") shall be governed by and be contingent upon the following additional terms and conditions:

- (a) Control of Defense. At its option, the indemnifying Party may assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within thirty (30) days after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify any Person seeking indemnification in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against any such claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall indemnifying Party assume the defense of a Third Party Claim, the indemnifying Party assume the defense of a Third Party Claim, the indemnifying Party assume the defense of a Third Party Claim, the indemnifying Party shall not be liable to the Indemnified Party in connection with the Third Party Claim, the indemnifying Party in connection with the analysis, defense or settlement of the Third Party Claim. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless an indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in its defense of the Third Party Claim with respect to such indemnified Party.
- (b) <u>Right to Participate in Defense</u>. Without limiting Section 6.3.2(a), any indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment shall be at the indemnified Party's own expense unless (i) the employment thereof has been specifically authorized by the indemnifying Party in writing or (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 6.3.2(a) (in which case the Indemnified Party shall control the defense).
- (c) <u>Settlement</u>. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the Indemnified Party hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 6.3.2(a), the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed). The indemnifying Party shall not be liable for any settlement or other disposition of a Loss by an Indemnified Party that is reached without the written consent of the indemnifying Party. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnified Party shall admit any liability with respect to,

or settle, compromise or discharge, any Third Party Claim without the prior written consent of the indemnifying Party.

- (d) <u>Cooperation</u>. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall, and shall cause each other indemnified Party to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making indemnified Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.
- (e) Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim shall be reimbursed on a calendar quarter basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

### 6.4 LIMITATION ON DAMAGES.

6.4.1 SUBJECT TO SECTIONS 6.1 AND 6.2, AND EXCEPT IN CIRCUMSTANCES OF GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, NONE OF EMERGENT, SUPPLIER OR ANY OF THEIR RESPECTIVE AFFILIATES SHALL BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING FOR LOST PROFITS), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (A) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT, OR (B) THE DEVELOPMENT, MANUFACTURE, USE OR SALE OF ANY PRODUCT DEVELOPED, MANUFACTURED OR MARKETED HEREUNDER. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS ATTEMPTING TO EXCLUDE OR LIMIT THE LIABILITY OF EITHER OF THE PARTIES OR THEIR RESPECTIVE AFFILIATES (A) FOR DEATH OR PERSONAL INJURY CAUSED BY THE NEGLIGENCE OF EITHER OF THE PARTIES, THEIR RESPECTIVE AFFILIATES, OR OF THE OFFICERS, EMPLOYEES OR AGENTS OF THE PARTIES OR THEIR RESPECTIVE AFFILIATES, (B) FOR FRAUD OR FRAUDULENT MISREPRESENTATION OR (C) FOR ANY MATTER IN RESPECT OF WHICH IT WOULD BE ILLEGAL FOR EITHER PARTY TO EXCLUDE OR ATTEMPT TO EXCLUDE ITS LIABILITY.

6.4.2 SUBJECT TO THE PRECEDING SENTENCE, BUT NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, IN NO EVENT SHALL THE COMBINED AGGREGATE LIABILITY OF EITHER PARTY UNDER THIS AGREEMENT, TAKEN TOGETHER WITH SUCH PARTY'S AGGREGATE LIABILITY

UNDER THE 180T LICENSE AGREEMENT, THE 180T DEVELOPMENT AGREEMENT, THE BT LICENSE AGREEMENT, AND THE BT DEVELOPMENT AGREEMENT, EXCEED THE COMBINED AGGREGATE AMOUNTS PAID BY EMERGENT TO HPA, WHETHER AS LUMP SUMS OR PERIODIC PAYMENTS OF ROYALTIES OR SUBLICENSE INCOME, UNDER THIS AGREEMENT, THE 180T LICENSE AGREEMENT, THE 180T DEVELOPMENT AGREEMENT, THE BT LICENSE AGREEMENT, AND THE BT DEVELOPMENT AGREEMENT (THE "AGGREGATE AMOUNT"); PROVIDED, HOWEVER, THAT IN THE EVENT THAT EITHER PARTY (THE "LIABLE PARTY") HPA SHALL BECOME LIABLE TO THE OTHER PARTY HEREUNDER OR THEREUNDER FOR AN AMOUNT (THE "TOTAL LIABILITY") LARGER THAN THE AGGREGATE AMOUNT CALCULATED AS OF THE DATE THAT THE TOTAL LIABILITY BECAME DUE AND PAYABLE, THE LIABLE PARTY SHALL PROMPTLY PAY SUCH OTHER PARTY A LUMP SUM EQUAL TO THE AGGREGATE AMOUNT AS SO CALCULATED AND PROVIDED, FURTHER, THAT IF HPA IS THE LIABLE PARTY, EMERGENT SHALL THEREAFTER HAVE A RIGHT OF OFFSET WITH RESPECT TO ANY PAYMENT OBLIGATIONS OF EMERGENT TO HPA HEREUNDER AND THEREUNDER THAT BECOME DUE AND PAYABLE AFTER SUCH DATE, UNTIL SUCH TIME AS THE TOTAL AMOUNTS OFFSET BY EMERGENT EQUAL THE DIFFERENCE BETWEEN THE TOTAL LIABILITY AND SUCH LUMP SUM PAYMENT BY HPA; AND PROVIDED, FURTHER, THAT IF EMERGENT IS THE LIABLE PARTY, THEN THEREAFTER, AT SUCH TIMES AS EMERGENT SHALL MAKE PAYMENTS TO HPA THAT ARE OTHERWISE DUE AND PAYABLE HEREUNDER OR THEREUNDER, EMERGENT SHALL PAY TO HPA AN EQUAL AMOUNT AS ADDITIONAL DAMAGES, UNTIL SUCH TIME AS THE TOTAL AMOUNTS SO PAID TO HPA AS ADDITIONAL DAMAGES EQUAL THE DIFFERENCE BETWEEN THE TOTAL LIABILITY AND SUCH LUMP SUM PAYMENT BY EMERGENT.

6.5 Insurance. Supplier shall have and maintain such program of self-insurance covering the Exploitation of the Products as is normal and customary in the pharmaceutical industry generally for parties similarly situated.

# ARTICLE VII Representations and Warranties

- 7.1 Representations and Warranties. Each Party hereby represents, warrants and covenants to the other Party as of the Effective Date as follows:
- 7.1.1 Such Party (a) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (b) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

- 7.1.2 Such Party is not aware of any pending or threatened litigation (and has not received any communication) that alleges that such Party's activities related to this Agreement have violated, or that by conducting the activities as contemplated herein such Party would violate, any of the intellectual property rights of any other Person.
- 7.1.3 All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.
- 7.1.4 The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable law or regulation or any provision of the articles of incorporation, bylaws, limited partnership agreement or any similar instrument of such Party, as applicable, in any material way, and (b) do not conflict with, violate, or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.
- **7.2** Additional Representations, Warranties and Covenants of Emergent. Emergent represents, warrants and covenants to Supplier that Emergent is a corporation duly organized and in good standing under the laws of the State of Delaware, and has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.
- 7.3 Additional Representations, Warranties and Covenants of Supplier. Supplier represents, warrants and covenants to Emergent that Supplier is a governmental entity duly organized, validly existing and in good standing under the laws of England, and has full governmental power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.
- 7.4 Disclaimer of Warranties. EXCEPT FOR THOSE WARRANTIES SET FORTH IN THIS ARTICLE VII, AND SUBJECT TO SECTION 6.4.1, EACH PARTY HEREBY DISCLAIMS ANY AND ALL WARRANTIES, CONDITIONS AND TERMS, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING (A) ANY WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, (B) ANY WARRANTY WITH RESPECT TO THE VALIDITY OR ENFORCEABILITY OF ANY PATENT OR OTHER INTELLECTUAL PROPERTY, AND (C) ANY WARRANTY THAT THE PERFORMANCE OF ITS RIGHTS OR OBLIGATIONS HEREUNDER WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF ANY PERSON. SUBJECT TO SECTION 6.4.1, NO PARTY MAKES ANY REPRESENTATIONS HEREUNDER OTHER THAN THOSE SET FORTH EXPRESSLY HEREIN.

# ARTICLE VIII Term and Termination

- **8.1 Term and Expiration**. This Agreement shall become effective as of the Effective Date and unless terminated earlier pursuant to Section 8.2, 8.3, 8.4, or 8.6, the term of this Agreement (the "Term") shall continue in effect until the tenth (10th) anniversary of the date on which Supplier obtains or is issued the last Regulatory Approval for any Product.
- 8.2 Termination by Emergent without Cause. Notwithstanding anything contained herein to the contrary, Emergent shall have the right to terminate this Agreement in its entirety or with respect to one or more countries in the Territory at any time in its sole discretion by giving one hundred and eighty (180) days' written notice to Supplier.
- **8.3 Termination of this Agreement by Either Party for Material Breach**. Material failure by a Party to comply with any of its material obligations contained herein shall entitle the Party not in default to give to the Party in default notice specifying the nature of the default, requiring the defaulting Party to make good or otherwise cure such default, and stating its intention to terminate if such default is not cured. In the event that Emergent is the notifying Party, Emergent shall have the right, in addition to all other remedies available to it by law, in equity or pursuant to this Agreement, to suspend payment of any amounts that it would otherwise owe to Supplier hereunder until such time as the material breach of Supplier is cured. If a noticed default is not cured within thirty (30) days (the "Cure Period") after the receipt of such notice (or, if such default cannot be cured within such thirty (30)-day period, if the Party in default does not commence actions to cure such default within the Cure Period and thereafter diligently continue such actions), the Party not in default shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement in its entirety; provided, however, that any right to terminate under this Section 8.3 shall be stayed in the event that, during any Cure Period, the Party alleged to have been in default shall have initiated dispute resolution in accordance with Section 9.6 with respect to the alleged default, which stay shall last so long as the initiating Party diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings.

# 8.4 Accrued Rights; Survival.

- 8.4.1 <u>Accrued Rights</u>. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.
  - 8.4.2 Survival. Sections 3.6, 3.7, and this Section 8.4, and Articles I, IV, V, VI, and IX, shall survive the termination or expiration of this Agreement for any reason.
  - 8.4.3 Product Sell-Off. Emergent shall have a period of ninety (90) days from the effective date of termination or expiration of this Agreement during which it may sell in the

Territory in accordance with the terms hereof any stocks of Products in its possession at the effective date of such termination or expiration.

**8.5 Termination upon Insolvency.** Either Party may terminate this Agreement if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a Party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors.

### ARTICLE IX Miscellaneous

- **9.1 Force Majeure.** Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, when such failure or delay is caused by or results from causes beyond the reasonable control of the non-performing Party, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority. The non-performing Party shall notify the other Party of such force majeure within ten (10) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for one-hundred and eighty (180) days after the date of the occurrence, that Parties shall meet and discuss in good faith how best to proceed.
- 9.2 Assignment. Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, charge, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder, nor purport to do any of the same; provided, however, that Emergent may, without such consent, assign this Agreement and its rights hereunder to an Affiliate, to the purchaser of all or substantially all of its assets, or to any Third Party pursuant to or in connection with any agreement and plan of merger, acquisition, reorganization, or other similar corporate transaction; and provided, further, that HPA may, without such consent, assign the benefit of this Agreement and its rights hereunder to an Affiliate, or to a Third Party in connection with the permitted assignment to such Third Party of HPA's rights under the rBOT License Agreement and the BT License Agreement. Any attempted assignment in violation of the preceding sentence shall be void and of no effect. All validly assigned rights of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by the permitted assigns of Emergent or Supplier, as the case may be. No assignment validly made pursuant to this Section 9.2 shall relieve the

assigning Party of any of its obligations under this Agreement, unless the other Party has given its prior consent thereto.

- 9.3 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) the Parties agree to attempt to substitute for any such illegal, invalid or unenforceable provision as legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof prohibited or unenforceable in any respect.
- 9.4 Notices. All notices or other communications which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (promptly confirmed by personal delivery or courier as provided herein) or sent by internationally-recognized overnight courier, addressed as follows:

if to Supplier, to: Health Protection Agency

Porton Down

Salisbury, Wiltshire SP4 0JG England Attention: Dr. David Rhodes Facsimile No.: +44-1980-61-22-41

with a copy to: Legal Department

Health Protection Agency

Porton Down

Salisbury, Wiltshire SP4 0JG England Facsimile No.: +44-1980-61-22-41

if to Emergent, to: Emergent BioSolutions, Inc.

300 Professional Drive

Gaithersburg, Maryland 20879 USA Attention: General Counsel Facsimile No.: +1-301-590-1252

with a copy to: Covington & Burling

One Front Street, 35th Floor

San Francisco, California 94111 USA Attention: James C. Snipes, Esq. Facsimile No.: +1-415-591-6091

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication shall be deemed to have been given when delivered if personally delivered on a Business Day, when

transmitted if sent by facsimile (in accordance with this Section 9.4) on a Business Day, and on the third (3rd) Business Day after dispatch if sent by internationally-recognized courier. It is understood and agreed that this Section 9.4 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

9.5 Governing Law. This Agreement shall be governed by and construed in accordance with English law (without reference to the rules of conflict of laws thereof). Subject to Section 9.6, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of (a) the courts of the State of New York and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) initiated by HPA and arising out of or relating to this Agreement, and (b) the English courts located in London for any action, suit or proceeding (other than appeals therefrom) initiated by Emergent and arising out of or relating to this Agreement. The Parties agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts, respectively. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or the United States District Court for the Southern District of New York, or the English courts located in London, as the case may be, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such action, suit or proceeding brought in any such court that any such action, suit or proceeding brought in an inconvenient forum. Each Party hereto further agrees that service of any process, summons, notice or document by internationally recognized courier to its address set forth above shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

#### 9.6 Dispute Resolution.

- 9.6.1 <u>Negotiation</u>. The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement (or any document or instrument delivered in connection herewith) (each, a "Dispute"). In the event that the Parties are unable to, within ten (10) days, to reach a resolution, such Dispute shall be referred to the chief executive officers of Emergent and Supplier, or their respective successors, who shall attempt in good faith to reach a resolution of the Dispute. If the foregoing procedures fail to achieve a mutually satisfactory resolution within ten (10) days, then either Party may, by written notice to the other Party, elect to have the matter settled by binding arbitration pursuant to Section 9.6.2.
- 9.6.2 <u>Arbitration</u>. Any arbitration under this Agreement shall take place at a location to be agreed by the Parties; provided, however, that in the event that the Parties are unable to agree on a location for an arbitration under this Agreement within five (5) days of the demand therefor, such arbitration shall be held in New York, New York if Supplier is the Party that first demanded such arbitration or in London, England if Emergent is the Party that first demanded such arbitration under this Agreement shall be administered by the American Arbitration Association under its Commercial Arbitration Rules then in effect (the "AAA Rules"). The Parties shall appoint an arbitrator by mutual agreement. If the Parties cannot agree on the appointment of an arbitrator within thirty (30) days of the demand for

arbitration, an arbitrator shall be appointed in accordance with AAA Rules. The arbitrator shall have the authority to grant any equitable and legal remedies that would be available in any judicial proceeding instituted to resolve the Dispute submitted to such arbitration in accordance with this Agreement; provided, however, that the arbitrator shall not have the power to alter, amend or otherwise affect the terms or the provisions of this Agreement. Judgment upon any award rendered pursuant to this Section may be entered by any court having jurisdiction over the Parties' other assets. The arbitrator shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrator's fees and any administrative fees of arbitration, unless the arbitrator shall otherwise allocate such costs, expenses and fees between the Parties. The Parties agree that all arbitration awards shall be final and binding on the Parties and their Affiliates. The Parties hereby waive the right to contest the award in any court or other forum. Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable English statute of limitations.

- 9.6.3 Interim Relief. Notwithstanding anything herein to the contrary, nothing in this Section 9.6 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, either prior to or during any arbitration hereunder, if necessary to protect the interests of such Party. This Section 9.6.3 shall be specifically enforceable.
- 9.7 Equitable Relief. Supplier acknowledges and agrees that the restrictions set forth in Section 2.1 and Article IV of this Agreement are reasonable and necessary to protect the legitimate interests of Emergent and that Emergent would not have entered into this Agreement in the absence of such restrictions, and that any violation or threatened violation of any provision of Section 2.1 or Article IV will result in irreparable injury to Emergent. Supplier also acknowledges and agrees that in the event of a violation or threatened violation of any provision of Section 2.1 or Article IV, Emergent shall be entitled to preliminary and permanent injunctive relief, without the necessity of proving irreparable injury or actual damages and without the necessity of having to post a bond, as well as to an equitable accounting of all earnings, profits and other benefits arising from any such violation. The rights provided in the immediately preceding sentence shall be cumulative and in addition to any other rights or remedies that may be available to Emergent. Nothing in this Section 9.7 is intended, or should be construed, to limit Emergent's right to preliminary and permanent injunctive relief or any other remedy for a breach of any other provision of this Agreement.
- **9.8** No Benefit to Third Parties. The Parties do not intend that any term of this Agreement should be enforceable by virtue of the Contracts (Rights of Third Parties) Act 1999 by any person who is not a party to this Agreement.
- 9.9 Further Assurances. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and

instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm the rights and remedies of the other Party under this Agreement.

- 9.10 English Language. This Agreement shall be written and executed in the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control. All notices and other disclosure required of the Parties hereunder.
- 9.11 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section, or Exhibit shall mean references to such Article, Section, or Exhibit of this Agreement, (b) references in any section to any clause are references to such clause of such section, and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently varied, replaced or supplemented from time to time, as so varied, replaced or supplemented and in effect at the relevant time of reference thereto.
- 9.12 Independent Contractors. It is expressly agreed that Supplier and Emergent shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Supplier nor Emergent shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior consent of the other Party. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.
- **9.13 Waiver**. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or the failure to exercise, or any delay in exercising a right or remedy provided by this Agreement or by law, or the waiver of a breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.
- 9.14 Counterparts. The Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument
- 9.15 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties, and no rule of strict construction shall be applied against either Party.

9.16 Entire Agreement; Modifications. This Agreement, together with the rBOT Development Agreement, the rBOT License Agreement, the BT Development Agreement and the BT License Agreement, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understanding, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment, modification, release or discharge hereof shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

[SIGNATURE PAGE FOLLOWS.]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first set forth above.

Emergent BioSolutions, Inc.	Health Protection Agency
By: /s/ Fuad El-Hibri Fuad El-Hibri	By: /s/ Pat Troop Pat Troop
Title: Chairman and CEO	Title: CEO
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# Exhibit 3.3

#### Manufacturing Costs

A "final cost objective" will be established in order to segregate manufacturing costs that are incurred as a result of this project. A cost objective is a function, organizational subdivision, contract, or other work unit for which cost data are desired and for which provision is made to accumulate and measure the cost of processes, products, jobs, capitalized projects, etc.

The Supplier's accounting system may have both intermediate and final cost objectives. An intermediate cost objective is one to which costs are allocated for purposes of accumulating similar costs. Once accumulated, the costs are allocated to another intermediate cost objective or a final cost objective.

For purposes of this Agreement, "Manufacturing Costs" shall mean, for each Product, the sum of the following costs incurred by Supplier in connection with the Manufacture of such Product: (i) direct labor costs; (ii) direct materials cost (e.g. raw materials, intermediate compounds, active compounds, excipients, components and packaging materials used in the Manufacture of such Product, including shipping and taxes therefor) net of manufacturers' discounts; (iii) other direct costs, meaning amounts paid to Third Party contract manufacturers or service providers to acquire such Product (which amount will be net of rebates or discounts, if any, from such manufacturers or service providers), and (iv) indirect costs, meaning a reasonable allocation of overhead, facilities expense (including depreciation over the expected life of the buildings and equipment), and costs for administration and for management of material procurement and other activities directly in support of Supplier's Manufacturing operation, calculated by Supplier in accordance with Supplier's cost accounting policies and procedures methods in effect from time to time, consistently applied.

- (a) For purposes of this Exhibit, a direct cost is any cost that can be identified specifically with a final cost objective. In this instance, the manufacturing cost associated with each Product.
  - (1) <u>Direct Labor Costs</u>. For purposes of this Exhibit, "direct labor costs" are the costs of employees engaged in production activities that are directly identifiable with manufacturing the Product, including first line supervision and project management. Direct labor costs include:
    - Base pay, overtime, vacation and holidays, illness, personal time with pay and shift differential.
    - Cost of employee fringe benefits such as health and life insurance, payroll taxes, welfare pension and profit sharing.
  - (2) <u>Direct Material Costs</u>. For purposes of this Exhibit, "direct material costs" are the costs of materials used in the manufacturing process that are traced to the completed Product, or are consumed in the process.
  - (3) Other Direct Costs. For purposes of this Exhibit, "other direct costs" include amounts paid to Third Party contract manufacturers or service providers to acquire such Product (which amount will be net of rebates or discounts, if any, from such manufacturers or service providers).
- (b) For purposes of this Exhibit, an "indirect cost" is any cost that cannot be identified specifically with a final cost objective but provides benefit to contract performance and other work, and can be distributed to them in reasonable proportion to the benefits received. Indirect costs that are properly allowable and

allocable to the project are to be included in the definition of "Manufacturing Costs" under this Agreement.

Any disputes about what is properly allowable and allocable to the contract shall be governed by the cost allowability provisions of the U.S. Federal Acquisition Regulations (primarily, but not limited to, FAR part 31) and any applicable case law. Final indirect rates, as negotiated with the U.S. Federal Government, will be deemed as reasonable for the purpose of this Agreement. If the Supplier does not have a current manufacturing agreement, or establish indirect rates, with the U.S. Government, support necessary to establish the fairness of such rates shall be provided, upon request, and will be subject to audit.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

# DATED 18th Day of March 2005

(1) THE WELLCOME TRUST
AND
(2) MICROSCIENCE HOLDINGS PLC
AND
(3) MICROSCIENCE LIMITED

INVESTMENT AGREEMENT
RELATING TO
MICROSCIENCE HOLDINGS PLC

Ref: NKM/SJM/WELTR.0011

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THIS AGREEMENT is made and entered into as of day of March 2005

#### BETWEEN:

- (1) **THE WELLCOME TRUST LIMITED** a company registered in England under number 2711000 as Trustee of the Wellcome Trust, a charity registered in England under number 210183, whose registered office is at 215 Euston Road, London NW1 2BE (the "**Trust**"); and
- (2) MICROSCIENCE HOLDINGS PLC a company registered in England and Wales under number 5106930 whose registered office is at 545 Eskdale Road, Winnersh, Wokingham, Berkshire, RG41 5TU ("Microscience"); and
- (3) MICROSCIENCE LIMITED a company registered in England and Wales under number 3270465 whose registered office is at 545 Eskdale Road, Winnersh, Wokingham, Berkshire, RG41 5TU ("Microscience Limited")

#### RECITALS:

- (A) Microscience is a company which was incorporated in England as a private company limited by shares on 20th April 2004 under the provisions of the Companies Act 1985.
- (B) At the date of this Agreement, Microscience has an authorised share capital of £4,025,702 divided into [\*\*] 'A' ordinary shares, [\*\*] 'B' ordinary shares, [\*\*] 'A' preferred ordinary shares and [\*\*] 'B' preferred ordinary shares of 5p each all of which have been issued fully paid.
- (C) Microscience has invented or acquired a stable formulation for vaccines which may be suitable for development of a novel, single-dose oral typhoid vaccine.
- (D) In order to further its charitable objectives, the Trust wishes to make a Programme Related Investment by way of subscribing for ordinary shares in Microscience and providing further funding to Microscience to undertake research and development of Microscience's single-dose, oral typhoid vaccine ("Award").

## 1. INTERPRETATION

In this Agreement and the Schedules to this Agreement, the following words and phrases shall have the following meanings unless the context requires otherwise:

"Affiliate" means any entity that, directly or indirectly, through one or more intermediates, is controlled by, controls, or is under common control with a specified entity, and for the purposes of this definition:

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- (a) the term "control" means the possession of the power to direct or cause the direction of the management and policies of an entity, whether by ownership of voting stock by partnership interest, by contract or otherwise, including direct or indirect ownership of more than fifty percent (50%) of the voting interest in the specified entity; and
- (b) if at any time an entity no longer controls and is no longer controlled and is no longer under the common control with a Party, this entity will no longer qualify as an Affiliate of that Party as of that time and that Party will have no further obligations on behalf of this former Affiliate under this Agreement;

"Agreement" means this agreement;

- "Application" means Microscience's application to the Trust for a Strategic Translation Award which is attached as Schedule 2;
- "Articles" means the articles of association of Microscience, as amended from time to time;

## "Background Intellectual Property" means:

- (a) the patent applications and patents set out in Schedule 3 and all associated Patent Rights, excluding any claims relating to the method known as signature tagged mutagenesis;
- (b) the Background Know-How; and
- (c) any and all and copyright relating to typhoid vaccines owned or controlled by Microscience at the Effective Date or at any time thereafter, but excluding the Project Intellectual Property and excluding any copyright relating to the method known as *signature tagged mutagenesis*;
- "Background Know-How" means any and all Know-How relating to the manufacture, development, sale or other exploitation of Microscience's typhoid vaccine which is actually used by Microscience at the Effective Date or at any time thereafter, but excluding the Project Intellectual Property; For the avoidance of doubt, "Background Know-How" does not include any Know-How relating to the method known as signature tagged mutagenesis;
- "Board" means the board of Directors of Microscience from time to time;
- "Business Day" means a day other than Saturday, Sunday, bank or other public holiday in England;
- "Change of Control" means, in relation to any company, where a person (or persons acting in concert) directly or indirectly, including through any subsidiary or holding company or subsidiary or such holding company:

- (a) has beneficial ownership over more than 50 per cent of the total voting rights conferred by all the issued shares in the capital of that company which are ordinarily exercisable in general meeting; or
- (b) has the right to appoint or remove a majority of its directors; or
- (c) has power to direct that the affairs of the company are conducted in accordance with its wishes,

in each case where such person or persons did not have such beneficial ownership, right or power at the Effective Date;

- "Combination Product" means a product that contains a Product together with one or more other therapeutically or prophylactically active ingredient(s) that are sold either as a fixed dose or as separate doses in a single package;
- "Competent Authority" means any local or national agency, authority, department, inspectorate, minister, ministery official or public or statutory person (whether autonomous or not) of, or of any government of, any country having jurisdiction over this Agreement or any of the Parties or over the development or marketing of vaccine products including the European Commission and the European Court of Justice;
- "Completion" means completion of the matters set out in Clause 2;
- "Customer" means a third party;
- "Directors" means the directors of Microscience appointed pursuant to the Articles;
- "Documents" means paper, notebooks, books, files, ledgers, records, tapes, discs, diskettes, CD-ROMs and any other media on which Know-How can be permanently stored;
- "Effective Date" means the date of this Agreement as set out on page 1;
- "Encumbrance" means any claim, charge, mortgage, security, lien, option, equity, power of sale; hypothecation or other third party rights, retention of title, right of pre-emption, right of first refusal or security interest of any kind;
- "First Instalment" means the amount payable by the Trust to Microscience on Completion as set out in Schedule 1;
- "Force Majeure" means any event or circumstance which is beyond the reasonable control of either Party, which the Party could not reasonably be expected to have taken into account at the Effective Date and which results in or causes the failure of it to perform any or all of its obligations under this Agreement, except that lack of funds shall not be interpreted as a cause beyond the reasonable control of either Party;

"Instalment" means the amount payable by the Trust to Microscience on the achievement by Microscience of a Project Milestone on or before the relevant Project Milestone Date, as set out in Schedule 1;

"Key Scientist" means a senior member of staff having sufficient knowledge and experience, involved in performing Microscience's obligations under this Agreement;

"Know-How" means unpatented technical and other information which is not in the public domain including:

- a) information comprising or relating to inventions, concepts, discoveries, data (including, for the avoidance of doubt, data necessary or desirable for regulatory submission), designs, formulae and ideas;
- b) information relating to Materials;
- c) methods, models, assays, research plans, procedures, designs for experiments and tests;
- d) records and results of experimentation, testing research and development;
- e) processes including manufacturing process, specifications and techniques;
- f) drawings and manuals;
- g) instrumentation;
- h) chemical, pharmacological, toxicological, clinical, analytical and quality control data;
- i) clinical trial data, data analyses, reports or summaries and information contained in submissions to and information from regulatory authorities; and
- j) any Documents containing any of the foregoing

and the fact that an item is known to the public shall not be taken to exclude the fact that a compilation including the item, and/or a development relating to the item, is not known to the public;

"Materials" means any chemical or biological substances including any:

- a) nucleotide or nucleotide sequence including DNA and RNA sequences;
- b) organic or inorganic element or compound;
- c) protein including any peptide or amino acid sequence, enzyme, antibody or protein conferring targeting properties and any fragment of a protein or a peptide enzyme or antibody;

- d) assay or reagent;
- e) cell line, culture medium;
- f) vaccine; or
- g) any other genetic or biological material;
- "Microscience Territory" means the countries and territories set out in Schedule 4;
- "Microscience Option Territory" means the countries and territories set out in Schedule 5;
- "Net Sales" means the gross invoiced amount billed for sales of Products to a Customer by Microscience, its Affiliates or licensees, less the following items to the extent they are paid or incurred or allowed and included in the invoice price:
- a) quantity, trade and/or cash discounts or rebates actually granted or accrued;
- b) amounts repaid or credited and allowances including cash, credit or free goods allowances, given by reason of billing errors, discounts, actually allowed or paid or accrued;
- c) taxes, tariffs, customs duties and surcharges and other governmental charges incurred in connection with the sale, exportation or importation of Products;

provided that the transfer of Products by Microscience to Affiliates and licensees shall not be considered a sale and in such cases, Net Sales shall be determined on the gross amount invoiced by the Affiliate or licensee on the Customer, less the aforementioned deductions to the extent they are allowed, paid or accrued;

- "Parties" means Microscience and the Trust and "Party" shall mean either of them;
- "Patent Rights" means patent applications, patents, author certificates, inventor certificates, utility certificates, improvement patents and models and certificates of addition and all foreign counterparts of them and includes all divisions, renewals, continuations, continuations, reissues, substitutions, confirmations, registrations, revalidations and additions of or to them, as well as any supplementary protection certificate, or like form of protection in respect thereof;
- "Product" means the oral typhoid vaccine developed by Microscience including all formulations thereof but for the avoidance of doubt excluding spi-VEC Constructs;
- "Project" means the programme of research and development relating to Microscience's oral typhoid vaccine as further described in the Application including the Project Milestones, Project Milestone Dates and Instalments which are set out in Schedule 1;

- "Project Intellectual Property" means Know-How and copyright relating to oral typhoid vaccines invented, created or produced by Microscience as a result of the performance of the Project, together with all Patent Rights relating thereto;
- "Project Materials" means Materials acquired, created, manufactured or used by Microscience for, or during performance of, the Project;
- "Project Milestone" means a milestone set out in Schedule 1, or as subsequently agreed in writing between the Parties, the achievement of which by Microscience on or before the relevant Project Milestone Date, shall trigger the payment to Microscience of the relevant Instalment by the Trust;
- "Project Milestone Criteria" means the objective criteria agreed between the parties and set out at Schedule 1 for determining whether a Project Milestone has been met;
- "Project Milestone Date" means a date for the achievement of a Project Milestone as set out in Schedule 1, or as subsequently revised to a later date in accordance with Clause 3.2;
- "Quarter" means a period of three consecutive calendar months commencing on 1 January, 1 April, 1 July or 1 October in any year and "Quarterly" shall be construed accordingly;
- "Royalty" means the sums payable by Microscience to the Trust or by the Trust to Microscience under Clauses 6.1, 6.2 and 6.3;
- "Second Instalment" means the amount payable by the Trust to Microscience on the achievement by Microscience of the Second Project Milestone on or before the relevant Second Project Milestone Date, as set out in Schedule 1;
- "Shareholder" means a holder of shares in the capital of Microscience;
- "Shares" means A ordinary shares of £0.05 each in the capital of Microscience;
- "Site Visit Group" means the group of people appointed by the Trust in accordance with Clause 3.11;
- "spi-VEC Constructs" means constructs based on the attenuated typhoid bacterium developed by Microscience that have been further engineered to deliver non-typhoid related antigens;
- "Subscription Shares" means the Shares to which the Trust is entitled to subscribe pursuant to Clauses 8.1 and 8.2;
- "Third Instalment" means the amount payable by the Trust to Microscience on the achievement by Microscience of the Third Project Milestone as set out in Schedule 1;

"Trust Direct Costs" means any costs and expenses directly incurred by the Trust in respect of the commercialisation of the Product, including cost of goods, manufacturing costs, costs of delivery, marketing costs, distribution costs and regulatory costs;

"Trust Indirect Costs" means any reasonable costs and expenses incurred by the Trust in respect of the commercialisation of the Product other than Trust Direct Costs, including by way of example, costs of an educational health awareness campaign or professional costs incurred in negotiations with governments beyond the normal regulatory process;

"Trust Net Receipts" means, in relation to any individual Product, the monetary amount received by the Trust which is attributable to sale of that Product by it, its Affiliates or licensees after deduction of Trust Indirect Costs but prior to deduction of the Trust Direct Costs which are attributable to the sale of the relevant Product, and

"Trust Territory" means those countries and territories which become part of the Trust Territory pursuant to the provisions of Clauses 10.4, 10.5, 10.6, 10.7 or 10.8.

# 1.1 In this Agreement:

- 1.1.1 unless the context otherwise requires, all references to a particular Clause or Schedule shall be a reference to that clause in, or schedule to, this Agreement, as it may be amended from time to time pursuant to this Agreement;
- 1.1.2 the table of contents and headings are inserted for convenience only and shall be ignored in construing this Agreement;
- 1.1.3 unless the contrary intention appears, words importing the masculine gender shall include the feminine and vice versa and words in the singular include the plural and vice versa;
- 1.1.4 any reference to persons includes natural persons, firms, partnerships, limited liability partnerships, companies, corporations, unincorporated associations, local authorities, governments, states, foundations and trusts (in each case whether or not having separate legal personality) and any agency of any of the above;
- 1.1.5 any phrase introduced by the terms "including", "include", "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;
- 1.1.6 any reference to a statute, statutory provision or subordinate legislation ("Legislation") (except where the context otherwise requires);
  - 1.1.6.1 shall be deemed to include any bye-laws, licences, statutory instruments, rules, regulations, orders, notices, directions, consents or permissions made under that Legislation; and

- 1.1.6.2 shall be construed as referring to any Legislation which replaces, re-enacts, amends or consolidates such Legislation (with or without modification) at any time;
- 1.1.7 any reference to an English legal expression for any action, remedy, method of judicial proceeding, legal document, legal status, court, official or any legal concept or thing shall, in respect of any jurisdiction other than England, be deemed to include a reference to what most nearly approximates in that jurisdiction to the English legal expression;
- 1.1.8 any reference to a Party includes a reference to their respective successors-in-title and permitted assignees;
- 1.1.9 any obligation imposed upon Microscience may be satisfied by Microscience or by its wholly owned subsidiary, Microscience Limited; and
- 1.1.10 any statement that a licence is granted or is to be granted by Microscience shall mean that the licence is granted or is to be granted by Microscience Climited.

## 2. COMPLETION

- 2.1 Completion shall take place immediately following execution of this Agreement by both Parties.
- 2.2 The Trust shall pay to Microscience the First Instalment within ten (10) Business Days of Completion.

## 3. PROJECT

- 3.1 Microscience shall further develop a single-dose, oral typhoid vaccine in accordance with the work plan set out in the Application and shall use its reasonable endeavours to achieve each Project Milestone on or before the relevant Project Milestone Date. The Parties acknowledge that unforeseen circumstances and technical issues can affect the progress of any scientific research and development work and could delay the achievement of any of the Project Milestones.
- 3.2 Microscience hereby undertakes diligently to perform the research and development work and other tasks, including project management of the Project, as set out in the Application. In the event that Microscience fails to achieve a Project Milestone on or before the relevant Project Milestone Date, the Parties shall meet to discuss the matter and, provided Microscience has acted diligently in its work towards the Project Milestone, the Parties shall change the relevant Project Milestone Date to a later date which would, realistically, give Microscience sufficient time to achieve the Project Milestone by the new date.
- 3.3 If there is any disagreement between the Application and the terms of this Agreement, the terms of this Agreement shall prevail.

- 3.4 Microscience undertakes to use all funding received from the Trust pursuant to this Agreement solely for the purposes of the Project. Microscience shall obtain the Trust's prior written consent to any other use of any funding received from the Trust pursuant to this Agreement.
- 3.5 Upon achievement by Microscience of a Project Milestone in accordance with the Project Milestone Criteria on or before the relevant Project Milestone Date, Microscience shall notify the Trust of such achievement in writing ("Project Milestone Notice"). The Project Milestone Notice shall specify the relevant Project Milestone and shall give reasonable details as to how the specified Project Milestone has been achieved.
- 3.6 If Microscience has achieved the relevant Project Milestone by the relevant Project Milestone Date, the Trust shall, within thirty (30) days of receipt of an invoice from Microscience, pay the relevant Instalment set out in Schedule 1 to Microscience by transfer of funds to the bank account referred to in Clause 6.8.
- 3.7 If the Trust believes that Microscience has not achieved the specified Project Milestone on or before the relevant Project Milestone Date, it shall, within thirty (30) days of receipt of the relevant invoice, inform Microscience of its reasons and the Parties shall meet to discuss the matter. If the Parties fail to settle the matter at such meeting, the matter shall be dealt with in accordance with the procedure set out in Clause 22.
- 3.8 At the end of each Quarter following the Effective Date, Microscience shall provide the Trust with a summary written report on the progress made and results obtained in performance of the Project during that Quarter.
- 3.9 As and when required, but not less than twice per calendar year, the Head of Business Development, Technology Transfer Division of the Trust or his nominee and Rod Richards, Chief Executive Officer of Microscience, shall meet to discuss the progress made by Microscience on the Project.
- 3.10 The obligations of Clauses 3.1, 3.2, and 3.4 shall be considered to be material obligations for the purposes of Clause 15.
- The Trust at its sole cost, shall be entitled to establish and appoint up to four members of a group ("Site Visit Group") which, upon reasonable notice to Microscience, shall be permitted twice per calendar year to visit each of Microscience's facilities where Project work is being carried out and sites where any Project clinical trials are being conducted and meet a Key Scientist for the purpose of updating the Trust on the progress of the Project. Microscience may suggest to the Trust appropriate candidates for appointment to the Site Visit Group, but the decision to appoint, or replace, any individual shall be at the Trust's sole discretion.
- 3.12 At the Effective Date, the Key Scientist is [\*\*]. If Microscience intends to appoint an additional Key Scientist or a replacement for a Key Scientist involved in performing Microscience's obligations under this Agreement, it shall, prior to such appointment, seek the Trust's written approval to the appointment. However the Trust shall not unreasonably withhold its consent to such an appointment.

## 4. OWNERSHIP OF PROJECT IP

- 4.1 All Project Intellectual Property (including data produced in the course of performing the Project) shall be owned solely by Microscience.
- 4.2 Microscience shall be responsible, at its sole cost, for filing, prosecuting and maintaining all Patents Rights which are Project Intellectual Property. Microscience shall consult the Trust on all material aspects of the filing, prosecution and maintenance of such Patent Rights and shall consider in good faith all reasonable representations made by the Trust in relation thereto. Microscience shall keep the Trust informed of all Patent Rights which are Project Intellectual Property and which are granted and the progress of all applications relating to those Patent Rights.
- 4.3 If Microscience chooses not to pursue filing, prosecution or maintenance of any Patent Rights which are Project Intellectual Property in any country, it shall immediately notify the Trust of this fact in writing. The Trust shall be entitled, but not obliged, at its own cost, to pursue or maintain such Patent Rights in the relevant country or countries in Microscience's name and, subject to payment by the Trust of Microscience's reasonable costs, Microscience shall provide such assistance to the Trust as may be reasonably be required by the Trust.
- 4.4 Microscience shall not enforce its rights under any Project Intellectual Property for infringement or potential infringement by:
  - 4.4.1 any not-for-profit or charitable organisation which is conducting non-commercially sponsored research;
  - 4.4.2 any person carrying out non-commercially sponsored research on behalf of any not-for-profit or charitable organisation.
- 4.5 This Clause 4 shall not prevent Microscience enforcing its rights under any Background Intellectual Property.
- 4.6 Microscience hereby grants to the Trust a non-exclusive, worldwide, royalty-free, perpetual, irrevocable, sub-licenseable licence under all its right, title and interest in and to the Project Intellectual Property to conduct non-commercial research.

## 5. MARKETING

- To the extent that it is commercially viable to do so, Microscience shall use its reasonable endeavours, itself or through its Affiliates or licensees, to:
  - 5.1.1 advertise, promote, demonstrate, market, sell and distribute the Product in the Microscience Territory;
  - 5.1.2 maximise the use, sales and penetration in the market of the Product in the Microscience Territory; and

- 5.1.3 actively promote and develop market opportunities for the Product in the Microscience Territory.
- For the avoidance of doubt the costs of the activities described in this Clause 5.1 shall not be borne by the Trust.
- 5.2 The Trust shall use its reasonable endeavours throughout the Trust Territory to ensure that it fulfils its charitable objectives by taking such action as it reasonably anticipates will result in a substantial uptake of the Product in the Trust Territory. For the avoidance of doubt the costs of the activities described in this Clause 5.2 shall not be borne by Microscience.

#### 6. ROYALTY

- 6.1 Microscience shall pay the Trust a Royalty of [\*\*]% of all lump sum or milestone payments received by Microscience in connection with the grant of any licence to a third party to develop, manufacture, sell, distribute or supply the Product, where such lump sum or milestone payments are payable upon the signature of the agreement granting the licence or are payable upon the achievement of technical development milestones prior to the first commercial sale of the Product.
- Microscience shall pay the Trust a Royalty on all worldwide Net Sales of Product by Microscience, its Affiliates and licensees (excluding sales to or by the Trust or its Affiliates) during the first ten years following the end of the first Quarter in which the first invoices to Customers for sales of Product became due, as follows. Where such Net Sales in any calendar year are less than US\$ [\*\*], the Royalty rate shall be [\*\*]%. Where such Net Sales in any calendar year are greater than US\$ [\*\*], the Royalty rate shall be [\*\*]% for the first US\$ [\*\*] of Net Sales, [\*\*]% for the Net Sales in the range US\$ [\*\*] to US\$ [\*\*] and [\*\*]% for any Net Sales in excess of US\$ [\*\*] in the calendar year concerned.
- 6.3 The Trust shall pay Microscience a Royalty of [\*\*]% of Trust Net Receipts during the first 10 years following the end of the first Quarter in which the first Product is made available by the Trust, its Affiliates or licensees.
- 6.4 If:
  - 6.4.1 any sale or other disposal of Product by Microscience, its Affiliates or its licensees to a third party is other than in a bona fide arm's length transaction exclusively for money; or
  - 6.4.2 any Product is sold or disposed of by Microscience, its Affiliates or its licensees or allowed by Microscience, its Affiliates or its licensees to be used for consideration other than cash, then such sale, disposal or use shall be deemed to be a sale for the purposes of Clause 6.2 at the relevant open market price in the country in which the sale, disposal or use occurs. If such open market price is not ascertainable, a reasonable price shall be assessed based

on an arm's length basis or the value of the goods or services provided in exchange for the supply of the Product.

6.5 With respect to Combination Products sold or disposed of by Microscience, its Affiliates or licensees, the Net Sales used for the calculation of the Royalties under Clause 6.2 shall be determined as follows:

A/(A+B) x (Net Sales of the Combination Product), where:

- A= standard sales price of the Product, containing the same amount of the oral typhoid vaccine as the sole active ingredient as the Combination Product in question, in the given country; and
- B= standard sales price of the ready-for-sale form of a product containing the same amount of the other therapeutically active ingredient(s) that is contained in the Combination Product in question, in the given country

provided that if, in a specific country: (a) the other therapeutically active ingredient(s) in such Combination Product are not sold separately in such country, Net Sales shall be adjusted by multiplying actual Net Sales of such Combination Product by the fraction A/C, where C is the standard sales price in such country of such Combination Product; and (b) if a Product is not sold separately, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction (C-B)/C, where B is the standard sales price in such country of the other therapeutically active ingredient(s) in the Combination Product and C is the standard sales price in such country of the Combination Product. The standard sales price for the Product and for each other active ingredient shall be for a quantity comparable to that used in such Combination Product and of the same class, purity and potency. If, in a specific country, both a Product and a product containing the other active ingredients in such Combination Product are not sold separately, a market price for such Product and such other active ingredients shall be negotiated by the Parties in good faith based upon the costs, overhead and profit as are then incurred for such Combination Product and all products then being made and marketed by Microscience and having an ascertainable market price that are comparable to such Product or such other active ingredients, as applicable. If, in a specific country, the foregoing calculations do not fairly represent the value of the various active ingredients included in a Combination Product, the allocation of Net Sales for such Combination Product shall be negotiated by the Parties in good faith.

The Parties acknowledge that Microscience may be liable to pay royalties and make other payments to third parties in respect of the development, manufacture or sale of Product and that the Trust may be liable to pay royalties and make other payments to third parties in respect of the manufacture or sale of Product. The Parties agree that each Party shall be solely responsible, at its own cost, for all such payments to third parties and any Royalties payable under this Agreement shall not be reduced as a consequence.

Unless otherwise agreed between the Parties in writing, all payments due to the Trust under this Agreement shall be made in pounds sterling to the following account:

Account Name: The Wellcome Trust

Account Number: [\*\*]

Bank: HSBC Bank Plc Sort Code: 40-03-28 Swift: MIDLGB21

31 Holborn Circus, London, EC1N 2HR. Branch Address:

Unless otherwise agreed between the Parties in writing, all payments due to Microscience under this Agreement shall be made in pounds sterling to the following account:

MICROSCIENCE LIMITED Account Name:

Account Number:

BARCLAYS Bank: 20-72-17 Sort Code:

Branch Address: Richmond & Twickenham Business Centre,

PO BOX 13, 8 George Street Richmond, TW9 1JU

- Within 150 days of the end of each Quarter, each Party shall deliver a statement to the other Party setting out all sales of Product made in the relevant Quarter by that Party, its Affiliates and licensees and the amount of Royalty which is due to the other Party ("Quarterly Statement"). Each Party shall deliver to the other Party an invoice for the amount due to it as set out in the Quarterly Statement. The Royalty amount invoiced shall be payable to the other Party within thirty days of receipt of the invoice.
- Where sales of Product on which Royalty payments are payable under Clauses 6.1, 6.2 or 6.3 are invoiced or calculated in a currency other than pounds sterling, conversion into pounds sterling shall be calculated by reference to the relevant foreign exchange selling rate for the currency in which they are invoiced or calculated of the Financial Times newspaper at the close of business in London on the last day of the Quarter to which the Royalty relates.
- If either Party does not receive payment of any sums due to it under this Clause 6 within the time specified, interest shall accrue on such sums at the rate equivalent to three per cent (3%) per annum over the then current base rate of HSBC bank, calculated on a daily basis.
- If, for any reason, either Party ("Payee") does not receive by the due date any amount due to it from the other Party ("Payer") in accordance with the terms of this Agreement, the Payee shall be entitled to off-set the amount due (together with any interest payable thereon in accordance with Clause 6.11) against any amount which the Payee is due to pay to the Payer.

- All payments under this Agreement are expressed to be exclusive of goods, sales, value added or any similar tax ("Value Added Tax") howsoever arising, and the Party obliged to make payment shall pay the other Party, in addition to those payments, all Value Added Tax for which the other Party is liable to account to any Competent Authority in relation to any supply made or deemed to be made for Value Added Tax purposes pursuant to this Agreement. The Party obliged to make payment shall pay any payments due to the other Party under this Clause 6.13 at the same time as the relevant payment is due under this Agreement.
- 6.14 If either Party is required by law to make any withholding or similar tax payment on behalf of the other Party, with respect to any of the payments to be made to the other Party under this Agreement, the amount of such required withholding or tax payment shall be deducted from the amount of payments otherwise due to the other Party and paid or deposited by the paying Party in accordance with the applicable law.
- 6.15 With respect to such deduction and payment of any withholding or similar taxes required under clause 6.14, the paying Party shall provide such assistance to the other Party as may be reasonably necessary to enable or assist the other Party to claim exemption therefrom or (if that is not possible) to obtain a credit for the deduction or withholding under any applicable double taxation or similar agreement from time to time in force, and shall provide the other Party with proper evidence as to the payment of such tax.
- 6.16 The obligation on each Party to pay the other Party the Royalties in accordance with Clauses 6.1, 6.2 and 6.3 shall be material obligations of this Agreement for the purposes of Clause 15.

## 7. BOOKS AND RECORDS

- .1 Each Party shall:
  - 7.1.1 keep true and accurate records and books of account for six years following the end of the calendar year to which they relate; and
  - 7.1.2 procure that its Affiliates and licensees shall keep true and accurate records and books of account for three years following the end of the calendar year to which they relate, which contain all data necessary for the calculation of the Royalties payable by it to the other Party ("Books").
- 7.2 Once per calendar year following the Effective Date, each Party may request that an independent accountant of its choice be allowed to certify any Quarterly Statements of the other Party, provided always that each individual Quarterly Statement may be certified only once.
- 7.3 Each Party shall, and shall procure that its Affiliates and licensees shall, make available to the independent accountant all Books which are required for the purpose of certifying the relevant Quarterly Statement, provided that the independent accountant agrees to be

bound by terms of confidentiality and non-use which are no less onerous than the terms of Clause 14. The Quarterly Statements so certified shall be final and binding between the Parties.

- 7.4 If any Quarterly Statement is shown to have underestimated the monies payable by more than five percent (5%), the cost of the certification shall be the responsibility of the Party shown to have underpaid. Otherwise, the cost shall be the responsibility of the Party requesting the certification.
- 7.5 Any outstanding payments which are identified as a result of carrying out the certification (including interest payments thereon under Clause 6.11) shall be paid immediately.

## 8. EOUITY ISSUE

- 8.1 In consideration of and upon payment of the First Instalment being made by the Trust, Microscience shall, subject to obtaining any necessary regulatory approvals, within 45 days of the date of payment, allot and issue to the Trust [\*\*] Shares. The nominal subscription price for such Shares shall be £[\*\*] per Subscription Share. Microscience undertakes to obtain any regulatory approvals required for the issue of the Subscription Shares as soon as practicable.
- 8.2 In consideration of and upon payment of the Third Instalment being made by the Trust, Microscience shall, subject to obtaining any necessary regulatory approvals, within 45 days of the date of payment, allot and issue to the Trust [\*\*] Shares. The nominal subscription price for such Shares shall be £[\*\*] per Subscription Share. Microscience undertakes to obtain any regulatory approvals required for the issue of the Subscription Shares as soon as practicable.
- 8.3 Microscience warrants that it has obtained all board, shareholder and other approvals and consents required for it to enter into this Agreement and issue the Subscription Shares to the Trust in accordance with this Agreement.
- 8.4 If Microscience Shares are admitted to trading on the Alternative Investment Market of the London Stock Exchange, the main London Stock Exchange or any recognised investment exchange and such admission becomes effective in accordance with the relevant rules of the London Stock Exchange (or relevant recognised exchange), Microscience shall ensure that all Shares allotted to, or to be allotted to, the Trust in accordance with this Agreement are also admitted to trading on the Alternative Investment Market of the London Stock Exchange, the main London Stock Exchange or the relevant recognised investment exchange, as the case may be. In connection with the admission to trading, Microscience shall provide such information and documents, pay all fees and execute and deliver all such documents as shall be necessary and shall generally do and procure to be done all such things as may properly be required so as to enable admission to take place.

# 9. FURTHER FUNDING

- 9.1 In Microscience's first investment round subsequent to the Effective Date, where such round is led by an institutional investor, or venture capital fund manager that is a member of the British Venture Capital Association or an overseas equivalent, Microscience may propose (but is not obliged to propose) that the Trust participate in such investment round in an amount not exceeding ten per cent (10%) of such investment round. If Microscience makes such a proposal, it shall do so when the terms of the investment round have been agreed with other potential investors. If the Trust participates in the investment round, the Trust shall subscribe for the same class of shares at the same price per share as other investors, or enter into an instrument convertible into shares on the same terms as other investors. For this purpose, the Company will provide the Trust access to Company information that is appropriate for a potential investor.
- 9.2 If Microscience wishes to raise further funding in respect of the Project, it shall promptly inform the Trust in writing, including reasonable details of the funding required, and may make an application to the Trust for funding. The Trust will consider such application but, for the avoidance of doubt, shall have no obligation to grant Microscience any further funding.

## 10. ACCESS TO PRODUCT THROUGHOUT THE WORLD

- 10.1 The Parties have agreed to divide the world into the Microscience Territory, the Microscience Option Territory and the Trust Territory.
- 10.2 Microscience shall have the sole right, itself or through its Affiliates or licensees, to make, have made, sell, offer to sell, use, import, export and keep Product in the Microscience Territory.
- 10.3 Except as provided in Clause 10.11, Microscience shall have the sole right, itself or through its Affiliates or licensees, to make, have made, sell, offer to sell, use, import, export and keep Product in the Microscience Option Territory.
- 10.4 Subject to Clause 10.6, if within the period of [\*\*] years commencing on the date of the first commercial sale of Product anywhere in the world (the "[\*\*] Year Period"), Microscience has not:
  - 10.4.1 provided the Trust with a credible business plan which provides for the sale of Product in any particular country within the Microscience Option Territory (which Microscience intends to implement within [\*\*] years of delivery of its business plan to the Trust); or
  - 10.4.2 granted a licence to a third party which provides for the sale of Product in any particular country within the Microscience Option Territory; or
  - 10.4.3 sold Product in any particular country within the Microscience Option Territory

and the Trust provides Microscience with a credible business plan providing for sale of Product in that country (which the Trust intends to implement), that country shall cease to be part of the Microscience Option Territory and shall be deemed to be part of the Trust Territory. [\*\*] months after the commencement of the [\*\*] year period referred to in Clause 10.4.1, Microscience shall, upon request by the Trust, report on its progress towards implementing the business plan in the country concerned.

- 10.5 If Microscience decides, at any time during the [\*\*] year period referred to in Clause 10.4.1, that it is no longer interested in commercialising Product in the country concerned, it shall forthwith inform the Trust accordingly and, if the Trust provides Microscience with a credible business plan providing for sale of Product in that country (which the Trust intends to implement), that country shall cease to be part of the Microscience Option Territory and shall be deemed to be part of the Trust Territory.
- 10.6 With respect to any particular country within the Microscience Option Territory, Microscience may extend the [\*\*] Year Period set out in Clause 10.4 to a period of [\*\*] years commencing on the date of the first commercial sale of Product anywhere in the world by giving written notice to the Trust within the [\*\*] Year Period, provided that:
  - 10.6.1 Microscience shall not unreasonably exercise its right to extend the [\*\*] Year Period and thereby block the Trust's access to the relevant country for the two year extension period; and
  - 10.6.2 Microscience demonstrates every six months during the two year extension of the [\*\*] Year Period that it is taking steps towards the sale of Product in the relevant country at a reasonable rate. If the Parties do not agree on whether Microscience has satisfied the requirements of this sub-clause 10.6.2, the dispute shall be resolved in accordance with Clause 22.
- 10.7 If no commercial sale of a Product has taken place in any country in the Microscience Territory or the Microscience Option Territory within the period of 12 years commencing on the Effective Date and Microscience has not:
  - 10.7.1 provided the Trust with a credible business plan which provides for the sale of Product in any particular country within the Microscience Option Territory (which Microscience intends to implement within [\*\*] months of delivery of its business plan to the Trust); or
  - 10.7.2 granted a licence to a third party which provides for the sale of Product in any particular country within the Microscience Option Territory
  - and the Trust provides Microscience with a credible business plan providing for sale of Product in that country (which the Trust intends to implement), that country shall be deemed to be part of the Trust Territory and shall no longer be part of the Microscience Option Territory.
- 10.8 If Microscience terminates this Agreement under the provisions of Clause 15.3 and Microscience has not:

- 10.8.1 granted a licence to a third party which provides for the sale of Product in any particular country within the Microscience Option Territory; or
- 10.8.2 sold Product in any particular country within the Microscience Option Territory

and the Trust provides Microscience with a credible business plan providing for sale of Product in that country (which the Trust intends to implement), that country shall cease to be part of the Microscience Option Territory and shall be deemed to be part of the Trust Territory.

- 10.9 The Trust may at any time propose that it be licensed to commercialise the Product in countries of the Microscience Territory on such terms as the Trust wishes to put forward but Microscience shall not have any obligation to agree to any such proposals or to discuss or negotiate with the Trust concerning such proposals.
- 10.10 Microscience hereby grants to the Trust, subject to the provisions of this Agreement, a licence under the Project Intellectual Property and the Background Intellectual Property to:
  - 10.10.1 make, dispose of, offer to dispose of, use and keep Product in the Trust Territory and to import and export Product between countries in the Trust Territory; and
  - 10.10.2 carry out commercial research and development in relation to the manufacture of the Product in any countries in the Trust Territory and the Microscience Option Territory. For the avoidance of doubt, the Trust shall not have any rights under this Agreement to perform signature tagged mutagenesis.

The licence granted under Sub-Clause 10.10.1 shall be an exclusive licence of Microscience's rights under the Project Intellectual Property and the Background Intellectual Property for the purposes mentioned in Sub-Clause 10.10.1 and the licence granted under Sub-Clause 10.10.2 shall be non-exclusive. The Trust may make Product in the Microscience Territory if it obtains Microscience's prior written consent, but Microscience shall not have any obligation to grant such consent.

- 10.11 In the event that the Trust wishes to manufacture and keep Product in a country of the Microscience Option Territory or the Trust wishes to transport Product through a country of the Microscience Option Territory solely for the purposes of exporting that Product to, and using and disposing of that Product in, countries of the Trust Territory, the Trust shall notify Microscience accordingly. Provided that:
  - (a) it would be lawful under the laws of that country for Microscience to grant a licence to the Trust under the Project Intellectual Property and the Background Intellectual Property allowing the Trust to manufacture and keep the Product in that country (or allowing the Trust to transport Product through that country) solely for export and prohibiting the Trust and any sub-licensees from selling, using or disposing of the Product in that country; and

(b) such restrictions on the license would be effective and enforceable under the laws of that country.

Microscience shall, within 45 days of receipt of such notification from the Trust, grant a licence to the Trust under the Project Intellectual Property and the Background Intellectual Property allowing the Trust to manufacture and keep the Product in the country concerned solely for export to the Trust Territory (or allowing the Trust to transport Product through that country) but prohibiting the Trust and any sub-licensees from selling, using or disposing of the Product in the country concerned.

In the event that the provisos set out in sub-paragraphs (a) and (b) of this Clause 10.11 are no longer satisfied in the country concerned, any licence granted pursuant to this Clause 10.11 shall immediately terminate in the country concerned.

- 10.12 The licence granted under Clause 10.10 and any licence that may be granted under Clause 10.11 shall continue until the expiry of the last to expire of the Patents Rights comprised in the Project Intellectual Property and the Background Intellectual Property in each country in the Trust Territory and the Microscience Option Territory.
- 10.13 Subject to Clause 10.14, the Trust shall be entitled to sub-license its rights under Clause 10.10 and any rights that are granted to the Trust pursuant to Clause 10.11.
- 10.14 In relation to any sub-licence:
  - 10.14.1 the Trust shall promptly notify Microscience of the execution of any sub-licence agreement and shall at the request of Microscience promptly provide Microscience with a true and complete copy of the sub-licence agreement;
  - 10.14.2 the provisions contained in any sub-licence agreement shall be consistent with the provisions of this Agreement;
  - 10.14.3 the sub-licence agreement shall prohibit further sub-licensing by the sub-licensee provided that further sub-licensing shall be permitted with Microscience's prior written consent, but Microscience shall not have any obligation to grant such consent, and
  - 10.14.4 the Trust shall at all times ensure the observance and performance by each sub-licensee of the provisions of the sub-licence and indemnify Microscience against any loss, damages, costs, claims or expenses which are awarded against or incurred by Microscience as a result of any breach by any sub-licensee of any of the provisions of the sub-licence, as if the breach had been that of the Trust.
- 10.15 Microscience shall:
  - 10.15.1 upon request, deliver to the Trust, or to a person nominated by the Trust (if that person has entered into a confidentiality agreement with Microscience), all Know-How comprised in the Project Intellectual Property, Background Know-

How and Materials reasonably required by the Trust to exercise the Trust's rights under the licence granted under Clause 10.10; and

- 10.15.2 upon request, provide to the Trust, or to a person nominated by the Trust (if that person has entered into a confidentiality agreement with Microscience), at the Trust's sole cost, at least 24 person-days of scientific support at the Trust's or the nominated person's premises, at a time mutually agreed between the Parties to enable the Trust to exercise its rights under the licence granted under Clause 10.10. The Trust shall pay to Microscience within 30 days of receipt of an invoice from Microscience the costs of such scientific support charged at industry standard rates plus overhead and any necessary travelling and hotel expenses relating to such scientific support.
- 10.16 Microscience shall have the option of proposing that it supplies the Trust's requirements of Product for distribution within the Trust Territory at a price or at prices to be agreed between the Parties, but Microscience shall have no obligation to supply Product to the Trust and the Trust shall have no obligation to purchase Product from Microscience.
- Product produced and distributed by the Trust, its Affiliates or licensees in the Trust Territory shall be manufactured according to the same manufacturing process, and shall be comparable to, Product produced and sold by Microscience, its Affiliates or licensees in the Microscience Territory. Determinations of Product comparability shall be based on the product release and characterisation specifications and associated assays that Microscience uses to release its own Product. All costs associated with determining Product comparability (including the costs of the necessary transfer of assays) shall be borne by the Trust. If Microscience, its Affiliates or licensees discontinue the manufacture and sale of the Product due to termination of this Agreement, the Product produced and distributed by the Trust, its Affiliates or licensees shall be an oral typhoid vaccine (excluding spi-VEC Constructs). Product sold or supplied by the Trust, its Affiliates or licensees shall have packaging which is substantially different from that used by Microscience (save that the Trust shall not be obliged to make alterations to its existing packaging if Microscience changes its own packaging), and shall be labelled with the words "Product sold under licence from Microscience Holdings PLC."
- 10.18 Microscience hereby grants to the Trust a non-exclusive, royalty free, sub-licenseable licence throughout the Trust Territory, for a period of time equivalent to the term of the licence granted to the Trust under Clause 10.10, to use Microscience's trade mark "MICROSCIENCE" solely to label Product with the wording given in Clause 10.17 in order to comply with the provisions of Clause 10.17.

## 11. COMPLIANCE WITH LAWS

11.1 Each Party shall ensure that each employee working on the Project or performing other obligations under this Agreement is employed under a contract compliant with all relevant laws and regulations.

- 11.2 Microscience shall be responsible for the management, monitoring and control of all research, development, regulatory, commercialisation, marketing, distribution and sales work undertaken pursuant to this Agreement except where the Trust undertakes any such work in accordance with Clauses 5.2 or 10. In performing the obligations imposed on it by this Agreement, each Party shall comply with the requirements of all applicable laws and regulatory authorities governing the use of radioactive isotopes, animals, pathogenic organisms genetically modified organisms (GMOs), toxic and hazardous substances, research on human subjects and human embryos, and include appropriate ethical approvals and consents, including for example but not limited to, such approvals and consents for obtaining tissues and other human samples.
- 11.3 Except in accordance with Clauses 5.2 and 10, the Trust shall have no obligation, express or implied, to supervise, monitor, review or otherwise assume responsibility for the production, manufacture, testing, marketing, sale or disposal of any Product.

## 12. PUBLICITY

- 12.1 Microscience shall not use the "Wellcome Trust" name or logo except with the prior written consent of the Trust and in the manner approved by the Trust and the Trust shall not use the name or logo of Microscience except with the prior written consent of Microscience and in the manner approved by Microscience.
- 12.2 Neither Party shall disclose any of the terms of this Agreement to any person other than to its professional advisors, except that Microscience may disclose the terms of this Agreement to other persons to the extent required in connection with any fundraising of Microscience and provided Microscience makes such disclosure under terms of confidentiality.
- 12.3 Subject to Clauses 12.4 and 12.5, neither Party may issue any press release or public announcement regarding this Agreement without the other Party's prior written consent. When requesting such consent from the other Party, each Party shall submit all of the proposed content of any such press release or public announcement at least ten days before its proposed release.
- 2.4 Clause 12.3 shall not apply if and to the extent that such public announcement is required by:
  - 12.4.1 law; or
  - 12.4.2 any securities exchange or regulatory or governmental body having jurisdiction over it (including but not limited to the London Stock Exchange, the Panel on Takeovers and Mergers and the Serious Fraud Office) and whether or not the requirement has the force of law

and provided that any such announcement shall be made only after consultation with the other Party.

12.5 Microscience may issue the press release set out in Part A of Schedule 6 upon Completion and the Trust shall be permitted to use the statement set out in Part B of Schedule 6 in its annual report, reviews and summaries of awards.

# 13. WARRANTIES AND INDEMNITY

- 13.1 Each Party warrants to the other Party that:
  - 13.1.1 it has legal power, authority and right to enter into this Agreement and to perform its respective obligations hereunder;
  - 13.1.2 it is not at the Effective Date a party to any agreement, arrangement or understanding with any third party which in any significant way prevents it from fulfilling any of its material obligation hereunder;
  - 13.1.3 this Agreement has been duly authorised, executed, and delivered by that Party and is valid, binding, and legally enforceable obligation of that Party;
  - 13.1.4 no consent, approval, authorisation, or order of any court or governmental agency or body is required for the consummation of the transactions contemplated by this Agreement (except that the manufacture, use, distribution and sale of Product will require regulatory approval); and
  - 13.1.5 the execution, delivery, and performance of this Agreement will not result in a breach or violation of, or constitute a default under, any statute, regulation, or other law or agreement or instrument to which it is a party or by which it is bound, or any order, rule, or regulation of any court or governmental agency or body having jurisdiction over it or any of its properties.
- 13.2 Microscience and Microscience Limited represent and warrant to the Trust that:
  - 13.2.1 Microscience Limited is the sole legal and beneficial owner and, where registered, the sole registered proprietor of all patent applications and patents set out in Schedule 3 free from all Encumbrances, except as set out in Schedule 3;
  - 13.2.2 Microscience Limited has the right to disclose the Background Know-How to the extent required by Clause 10.15.1;
  - 13.2.3 as far as they are aware, the Background Intellectual Property comprises all the materially significant intellectual property rights required by the carrying on of the Project as set out in this Agreement;
  - 13.2.4 Microscience Limited is able to grant to the Trust the licences under the Background Intellectual Property as set out in Clause 10;
  - 13.2.5 as far as they are aware, the patent applications and patents set out in Schedule 3 are valid and enforceable and not subject to any pending or threatened claims, challenges or proceedings;

- 13.2.6 as far as they are aware, no third party has made unauthorised use of any Background Intellectual Property, nor threatened to do so;
- 13.2.7 as far as they are aware, Microscience Limited has taken all steps and made all payments which are required to prosecute, maintain and renew the patent applications and patents set out in Schedule 3 within the required timescales; and
- 13.2.8 as far as they are aware, none of the activities of Microscience or Microscience Limited relating to typhoid vaccines infringe, or have been alleged to infringe, the intellectual property rights of any third party.
- 13.3 Save as provided in this Clause 13, nothing in this Agreement shall be deemed to be, or construed as, a representation or warranty by Microscience or Microscience Limited:
  - 13.3.1 as to the accuracy, safety, efficacy, or usefulness, for any purpose, of any matter claimed in any of Microscience Limited's Patent Rights which are Background Intellectual Property;
  - 13.3.2 that any patent will issue based upon any pending patent application included in the Background Intellectual Property, or
  - 13.3.3 that any patent included in the Background Intellectual Property which issues will be valid.
- 13.4 Subject to Clause 13.5, neither Party shall be liable to the other of any of the other Party's Affiliates, licensees or sublicensees for any of the following types of loss, damage, cost or expense arising (whether in contract, tort, negligence, breach of statutory duty or otherwise) under or in relation to this Agreement or the subject-matter of this Agreement:
  - 13.4.1 any loss of profits, business, contracts, anticipated savings, goodwill, or revenue;
  - 13.4.2 any loss or corruption of data; or
  - 13.4.3 any indirect or consequential loss or damage whatsoever,
  - even if that Party was advised in advance of the possibility of such loss or damage.
- 13.5 Nothing in Clause 13.4 shall prohibit or hinder the exercise of either Party's rights in respect of any of the following matters, notwithstanding that any loss or damage that Party may be seeking to recover is of the type referred to in Clause 13.4:
  - 13.5.1 death and personal injury caused by negligence of the other Party; and
  - 13.5.2 any liability for fraud or fraudulent misrepresentation.
- 13.6 Each Party shall be responsible for and indemnify and keep fully indemnified the other Party and its Affiliates, officers, servant, agents, licensees and sublicensees (collectively the "Indemnified Party") against any and all liability, loss, damage, cost or expense

("Losses") incurred or suffered by the Indemnified Party as a result of any claim by a third party arising directly out of the research, development, marketing, sale, commercialisation or distribution of the Product by, or on behalf of, that Party, except to the extent such Losses result from the negligence or intentional misconduct of the Indemnified Party (including, in particular, any act or omission by the Indemnified Party which is not in accordance with the product release and characterization specifications referred to in Clause 10.17).

- 13.7 Each Party shall maintain, at its sole cost, adequate general and product liability insurance for such period as that Party continues to supply Product pursuant to this Agreement plus three years, and shall ensure that the other Party's interest is noted on the policy, if so requested by the other Party. Each Party shall promptly, on request, supply the other Party with a copy of each such policy of insurance.
- 13.8 Each Party shall promptly inform the other Party of, and deliver comprehensive written details to the other Party of any safety or environmental concerns or issues reportable to, or raised by, any Competent Authority which relate to the Product or other oral vaccine using Microscience technology which might have an impact on the Product. Upon request of either Party, the other Party shall use all reasonable endeavours to assist that Party in taking any action with respect to the Product which is necessary or reasonably desirable as a consequence of those safety or environmental concerns or issues.
- In the event that either Party (the "First Party") intends to seek indemnification under Clause 13.6, it shall promptly inform the other Party (the "Second Party") and the First Party shall permit the Second Party and/or its insurers to direct and control the defence of the claim, which shall use independent legal representation for the First Party where reasonably necessary. The First Party shall provide such reasonable assistance as reasonably requested by the Second Party (at the Second Party's cost) in the defence of the claim, provided always that nothing in this Clause 13.9 shall permit the First Party to make any admission on behalf of the Second Party, or to settle any litigation without the prior written consent of, the Second Party, which consent is not to be unreasonably withheld or delayed (except that the Second Party may always withhold such consent on the instructions of its insurers).
- 13.10 The rights, powers and remedies provided in this Agreement are (except as expressly provided) cumulative and not exclusive of any rights, powers and remedies provided by law, or otherwise

## 14. CONFIDENTIALITY

- 14.1 The Trust undertakes and agrees not at any time, for any reason whatsoever, to disclose, or permit to be disclosed, to any third party, or otherwise make use of, or permit use to be made of (except as expressly permitted by this Agreement) any trade secrets or confidential information relating, amongst other things, to:
  - 14.1.1 Microscience's technology;
  - 14.1.2 the business affairs or finances of Microscience; or

- 14.1.3 the business affairs or finances of any Affiliate, licensee, sublicensee, supplier, agent, distributor or customer of Microscience
- ("Confidential Information") which comes into its possession pursuant to this Agreement.
- 14.2 This Clause 14 shall apply to the Background Intellectual Property and the Project Intellectual Property on the basis that it is Confidential Information owned by Microscience such that, except so far as is reasonably necessary for the Trust to exploit any Licence granted to it in accordance with Clause 10, the Trust shall not disclose it without the consent of Microscience, or otherwise than in accordance with the provisions of this Clause 14.
- 14.3 The Trust shall ensure that only those of its officers and employees and those of its licensees, sublicensees, potential licensees or sublicensees and Affiliates who have a need to know for the purposes of carrying out this Agreement are given access to Microscience's Confidential Information and that all such persons, prior to the disclosure of Confidential Information to them, agree to be bound by the obligations of the Trust under this Clause 14. The Trust shall enforce such obligations of all such persons.
- 14.4 The obligations of confidence referred to in this Clause 14 shall not extend to any Confidential Information which:
  - 14.4.1 is at the time of disclosure, or thereafter becomes, generally available to the public otherwise than by reason of a breach by the recipient of the provisions of this Clause 14;
  - 14.4.2 is known to the recipient without obligations of confidence prior to its receipt from the disclosing Party, as can be shown by written record;
  - 14.4.3 is subsequently disclosed to the recipient without obligations of confidence by another party owing no such obligations in respect thereof;
  - 14.4.4 is required to be disclosed by any applicable law or any Competent Authority to which the recipient is from time to time subject; or
  - 14.4.5 is independently developed by a person or persons with no access to the Confidential Information disclosed by the disclosing Party, as demonstrated by written records,

but the fact that an item is known to the public shall not be taken to preclude the possibility that a compilation including the item, and/or a development relating to the item, is not known to the public.

14.5 The obligations of the Trust (and all persons referred to in Clause 14.3) under this Clause 14 shall survive until ten years after the expiry or termination for whatever reason of this Agreement.

14.6 Each Party undertakes that, prior to any of its Affiliates ceasing to be an Affiliate, it will procure that any such Affiliate that holds Confidential Information of the other Party will give confidentiality and non-use undertakings to the other Party on terms no less onerous than the terms of this Clause 14.

# 15. TERMS AND TERMINATION

- 15.1 This Agreement shall come into effect on the Effective Date and, subject to earlier termination in accordance with this Clause 15, shall continue in full force until the expiry of all rights and obligations hereunder.
- 15.2 Either Party ("Terminating Party") shall have the right to terminate this Agreement forthwith at any time upon giving written notice of termination to the other Party ("Defaulting Party"), upon the occurrence of any of the following events:
  - 15.2.1 the Defaulting Party commits a breach of a material obligation set out in this Agreement which is not capable of remedy;
  - 15.2.2 the Defaulting Party commits a breach of a material obligation set out in this Agreement which is capable of remedy but has not been remedied within sixty (60) days of the receipt by it of a notice from the other Party identifying the breach and requiring its remedy;
  - 15.2.3 the Defaulting Party becomes insolvent or any notice is issued for convening a meeting at which a resolution is to be proposed or any petition is presented (which notice or petition is not withdrawn or discharged within 14 days) for the winding up of the Defaulting Party (other than voluntarily for the purpose of solvent amalgamation or reconstruction), or an order is made or a resolution is passed for the winding up of the Defaulting Party (other than voluntarily for the purpose of solvent amalgamation or reconstruction);
  - 15.2.4 any notice is given or petition presented or other step is taken in relation to the appointment of an administrator, administrative receiver, receiver or liquidator in respect of a material part of the Defaulting Party's assets or business which is not withdrawn or discharged within 14 days;
  - 15.2.5 the Defaulting Party makes any composition with its creditors or takes or suffers any similar or analogous action in consequence of debt;
  - 15.2.6 a mortgagee, chargee or other encumbrancer takes possession of, any part of the Defaulting Party's assets or undertaking;
  - 15.2.7 the Defaulting Party ceases to continue its business; or
  - 15.2.8 the Defaulting Party becomes unable to pay its debts as and when they fall due.
- 15.3 Microscience shall have the right to terminate this Agreement upon written notice to the Trust in the event that Microscience decides that it would not be commercially viable to

- perform further work on the Project or to commercialise Product further or that there is a technical issue precluding further progress of the Project.
- 15.4 Subject to Clause 15.5, if Microscience undergoes a Change of Control, the Trust shall have the right to terminate this Agreement immediately if, in its reasonable opinion, the Change of Control or its consequences would be incompatible with or have an adverse effect, on the Trust's charitable objectives.
- 15.5 At any time, Microscience may notify the Trust that a transaction is proposed that would result in a Change of Control of Microscience. In the event that Microscience so notifies the Trust, the Trust shall notify Microscience within 30 days of the date of receipt of such notice if it will or will not terminate this Agreement following such Change of Control. In the event that the Trust notifies Microscience that it will not terminate this Agreement following such Change of Control or the Trust fails to respond to Microscience's notice within 30 days of receipt, the Trust shall not be entitled to terminate this Agreement under Clause 15.4 following such Change of Control.

# 16. CONSEQUENCES OF TERMINATION

- 16.1 Upon termination of this Agreement for whatever reason, Microscience shall return all funding received from the Trust under this Agreement, which is unspent at the date of termination (after deduction of costs and non-cancellable commitments incurred prior to the date of termination).
- 16.2 In the event of termination of this Agreement by the Trust under Clause 15.2, or by Microscience under clause 15.3:
  - 16.2.1 the Trust shall retain its rights under Clauses 6.1 and 6.2 and, for the avoidance of doubt, Microscience's corresponding obligations under those Sub-Clauses to pay Royalties to the Trust shall continue:
  - 16.2.2 Microscience shall retain its rights under Clause 6.3 and, for the avoidance of doubt, the Trust's corresponding obligation to pay a Royalty to Microscience under that Sub-Clause shall continue;
  - 16.2.3 the Trust's rights and Microscience's obligations under Clause 8 shall continue; and
  - 16.2.4 each Party shall retain its rights under, and be subject to its obligations under, Clause 10.
- 16.3 In the event of termination of this Agreement by Microscience under Clause 15.2:
  - 16.3.1 the Trust's rights under Sub-Clauses 6.1 and 6.2 and under Clause 10 shall terminate; and

- 16.3.2 the Trust's rights and Microscience's obligations under Clause 8 shall continue.
- 16.4 In the event of termination of this Agreement by the Trust under Clause 15.4:
  - 16.4.1 the Trust's rights under Sub-Clauses 6.1 and 6.2, and, for the avoidance of doubt, Microscience's corresponding obligations to pay Royalties under those Sub-Clauses, shall be amended so that Microscience shall pay to the Trust amended Royalties depending on the Instalments paid by the Trust as at the date of termination as follows:

Payment made	Percentage of the Royalty set out in Clauses 6.1 and 6.2 which is payable
First Instalment	[**]%
Second Instalment	[**]%
Third Instalment	[**]%

- 16.4.2 the Trust's rights and Microscience's obligations under Clause 8 shall continue; and
- 16.4.3 the Trust's rights under Clause 10 shall terminate.
- 6.5 Termination or expiry of this Agreement for whatever reason shall not affect: (a) rights or obligations which are expressed or intended to continue in force following termination or expiry of this Agreement; or (b) the accrued rights of the Parties arising in any way out of this Agreement as at the date of termination or expiry including in particular, but without limitation, the right to recover damages and interest. Subject to the provisions of Clauses 16.2, 16.3 and 16.4, the provisions of Clauses 4 (Ownership of Project IP), 6 (Royalty), 7 (Books and Records), 8 (Equity Issue), 10 (Access to Product Throughout the World), 13 (Warranties and Indemnity), 14 (Confidentiality), 16 (Consequences of Termination), 22 (Dispute Resolution) and 26 (Third Party Rights) shall remain in full force and effect following termination or expiry of this Agreement.

# 17. WAIVER

17.1 Neither Party shall be deemed to have waived any of its rights or remedies conferred by this Agreement unless the waiver is made in writing and signed by a duly authorised representative of that Party. In particular, no delay or failure of either Party in exercising or enforcing any of its rights or remedies conferred by this Agreement shall operate as a waiver of those rights or remedies or so as to preclude or impair the exercise or enforcement of those rights or remedies nor shall any partial exercise or enforcement of any right or remedy by either Party preclude or impair any other exercise or enforcement of that right or remedy by that Party.

#### 18 ENTIRE AGREEMENT AND VARIATION

- 18.1 This Agreement and the Application constitute the entire agreement and understanding between the Parties and supersedes all prior oral or written understandings, arrangements, representations or agreements between them relating to the subject matter of this Agreement including, for the avoidance of doubt, the Letter of Intent between the Parties dated 3rd May 2004 and which became effective on 6th May 2004. No director, employee or agent of either Party is authorised to make any representation or warranty to another party not contained in this Agreement, and each Party acknowledges that it has not relied on any such oral or written representations or warranties provided always that nothing in this Clause 18.1 shall operate to limit or exclude either Party's liability for fraud or fraudulent misrepresentation.
- 18.2 No variation, amendments, modification or supplement to this Agreement shall be valid unless made in writing and signed by a duly authorised representative of each Party.

#### 19. NOTICES

19.1 Any notice to be given pursuant to this Agreement shall be in writing and shall be delivered by hand, sent by registered or recorded delivery, airmail post or sent by facsimile confirmed by registered or recorded delivery post to the address or facsimile number of the recipient Party set out below or such other address or facsimile number as a Party may from time to time designate by written notice to the other Party:

### Address of the Trust:

215 Euston Road, London NW1 2BE Fax Number: +44 (0)207 611 8857

All notices to be marked for the attention of the Head of Business Development, cc The Awards Officer, Technology Transfer Division.

#### Address of Microscience:

540-545 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire, RG41 5TU

Fax Number: +44 (0)118 944 3301

All notices to be marked for the attention of Rod Richards, Chief Executive Officer.

Any notice given pursuant to this Clause 19 shall be deemed to have been received:-

19.2.1 in the case of delivery by hand, when delivered; or

- 19.2.2 in the case of sending by post:
  - 19.2.2.1 where posted in the country of the addressee, on the third Business Day following the day of posting; and
  - 19.2.2.2 where posted in any other country, on the seventh Business Day following the day of posting; or
- 19.2.3 in the case of facsimile, on acknowledgement by the recipient facsimile receiving equipment on a Business Day if the acknowledgement occurs before 1700 hours local time of the recipient and in any other case on the following Business Day.

### 20. ASSIGNMENT

20.1 Neither Party shall, assign, charge or declare a trust over the benefit and/or burden of this Agreement, except to the extent that the same occurs as a result of the Encumbrances referred to in Schedule 3.

# 21. FORCE MAJEURE

- 21.1 If either Party is unable to carry out any of its obligations under this Agreement due to Force Majeure, this Agreement shall remain in effect but the relevant obligations of the Party unable to carry out its obligations under this Agreement shall be suspended for a period equal to the duration of the circumstances of Force Majeure, provided that:
  - 21.1.1 the suspension of performance is of no greater scope than is required by the Force Majeure;
  - 21.1.2 the Party unable to carry out its obligations under this Agreement gives the other Party prompt notice of the circumstance of Force Majeure, including the nature of the occurrence and its expected duration, and continues to furnish regular reports during the period of Force Majeure;
  - 21.1.3 the Party unable to carry out its obligations under this Agreement uses all reasonable efforts to remedy its inability to perform and to mitigate the effects of the circumstances of Force Majeure; and
  - 21.1.4 as soon as practicable after the event which constitutes Force Majeure, the Parties shall discuss how best to continue their operations as far as possible in accordance with this Agreement.
- 21.2 If Force Majeure is continuing at the expiry of six (6) months from its first occurrence, the Parties shall enter into bona fide discussions with a view to alleviating its effects, or to agreeing upon such alternative arrangements as may be fair and reasonable.

### 22. DISPUTE RESOLUTION

- 22.1 Any question, difference or dispute which may arise concerning the construction meaning or effect of this Agreement or concerning the rights and liabilities of the Parties hereunder or any other matter arising out of or in connection with this Agreement shall first be submitted to the Director of the Technology Transfer Division of the Trust and Rod Richards, Chief Executive Officer of Microscience for resolution, who may call on others to advise them as they see fit.
- 22.2 If the Director of the Technology Transfer Division of the Trust and the Chief Executive Officer of Microscience fail to resolve the dispute within 28 days, such dispute shall be referred to and finally resolved by arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce by one arbitrator appointed in accordance with those Rules. This Agreement shall be governed by the laws of England and Wales, the arbitration shall have its seat in London and the language to be used in the arbitration shall be English.

### 23. SEVERANCE OF TERMS

- 23.1 If the whole or any part of this Agreement is or becomes, or is declared illegal, invalid or unenforceable in any jurisdiction for any reason (including both by reason of the provisions of any legislation and also by reason of any court or Competent Authority which either has jurisdiction over this Agreement or has jurisdiction over any of the Parties):
  - 23.1.1 in the case of the illegality, invalidity or unenforceability of the whole of this Agreement, it shall terminate only in relation to the jurisdiction in question; or
  - 23.1.2 in the case of the illegality, invalidity or unenforceability of part of this Agreement, that part shall be severed from this Agreement in the jurisdiction in question and that illegality, invalidity or unenforceability shall not in any way whatsoever prejudice or affect the remaining parts of this Agreement, which shall continue in full force and effect.
- 23.2 If, in the reasonable opinion of either Party, any severance under this Clause 23 materially affects the commercial basis of this Agreement, the Parties shall discuss, in good faith, ways to eliminate the material effect.

#### 24. NO PARTNERSHIP

24.1 None of the provisions of this Agreement shall be deemed to constitute a partnership between the Parties and neither Party shall have any authority to bind the other in any way except as provided in this Agreement.

# 25. COSTS AND EXECUTION

25.1 Each Party shall bear its own legal costs, legal fees and other expenses incurred in the preparation and execution of this Agreement.

25.2 Each Party shall, at its own cost and expense, carry out, or use all reasonable endeavours to ensure the carrying out of, whatever further actions (including the execution of further documents) the other Party reasonably requires from time to time for the purpose of giving that other Party the full benefit of the provisions of this Agreement both during and after the term of this Agreement.

# 26. THIRD PARTY RIGHTS

26.1 This Agreement is not intended by the Parties to create rights or benefits in favour of any person not party to this Agreement, or make any rights or benefits enforceable by, or on behalf of, such third parties. For the avoidance of doubt, all laws providing to the contrary in any country including the relevant provisions of the Contracts (Rights of Third Parties) Act 1999 in the United Kingdom are hereby excluded to the fullest extent permitted.

This Agreement shall come into force on the date given at the beginning of this Agreement.

Signed for and on behalf of	)	
THE WELLCOME TRUST	)	
LIMITED as trustee of	)	
The Wellcome Trust	)	/s/ [Illegible]
by its authorised signatory	)	Authorised Signatory
Signed for and on behalf of	)	
THE WELLCOME TRUST	)	
LIMITED as trustee of	)	
The Wellcome Trust	)	/s/ [Illegible]
by its authorised signatory	)	Authorised Signatory
Signed for and on behalf of	)	
MICROSCIENCE	)	/s/ [Illegible]
HOLDINGS PLC	)	Director

Signed for and on behalf of MICROSCIENCE LIMITED

/s/ R. Richards Chief Executive

Director

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# Schedule 1

# The Project

The Trust shall pay the following amounts to Microscience upon the achievement of the following Project Milestones:

Project Milestone Completion	Project Milestone Criteria Signature of this agreement	Project Milestone Date [**]	Instalment £[**]	
Preparation, conduct and completion of Phase II Adult Study in Vietnam as set out in the Application	Completion of ID steps 0-15, as described in Schedule 2 under the heading "Revised Gantt chart"	[**]	£[**]	
Decision to initiate the phase III surveillance based on commercial partnering/NGO funding	Letter to the Trust signed by Microscience's CEO and chairman of the board, or their equivalent positions, setting out the key terms on which funding will be made available for the phase III study	[**]	£[**]	
Instalments of Programme Related Investment payable upon achievement of each Project Milestone on or before the relevant Project Milestone Date.				

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# Schedule 2 Documents relating to the performance of the Project

# 2.1 Microscience's Application for a Strategic Translation Award dated [ ]

Application for a Strategic Translation Award

Please return this form and six copies (unfolded) to:

Technology Transfer

The Wellcome Trust

183 Euston Road

London NW1 2BE

Tel: 020 7611 8202

Fax: 020 7611 8857

E-mail: techtransfer@wellcome.ac.uk
Web: www.wellcome.ac.uk/techtransfer

The Wellcome Trust is a charity whose mission is to foster and promote research with the aim of improving human and animal health (registered charity no. 210183). Its able Trustee is The Wellcome Trust Limited, a company registered in England, no. 27711030, whose registered office is 183 Euston Road, London NW1 2BE.

TA-2211 [Illegible]

**The Wellcome Trust** 

#### USE OF YOUR INFORMATION

The Wellcome Trust is committed to protecting the privacy of your personal information. Information that you supply in connection with this application and any funding arising from it will be treated in confidence, used for processing and evaluating your application, and will be stored by the Wellcome Trust, its agents and/or advisors in accordance with the Data Protection Act 1998. It may also be disclosed to external peer reviewers, some of whom may be based outside of the EU. The Wellcome Trust may publish basic details of successful awards, e.g. on its website or in its Annual Report, and contact you for your views on its funding schemes and application processes. Please contact the Wellcome Trust if you have any further questions about its policy on data protection.

The Wellcome Trust would like to be able to contact you to let you know about new award schemes and initiatives that may be of interest to you. If you would prefer **not** to be contacted about these, please check this box. o

# Q1 Principal applicant:

 Surname:
 [\*\*]

 Forename
 [\*\*]

 Title:
 [\*\*]

 Position:
 [\*\*]

Employing Organization: Microscience Ltd

Q2 Title of project (no more than 220 characters):

Cumulative cost to Objective 2\*:

Cumulative cost to Objective 3\*:

Q3 Period for which support is sought (state in months):

Q4 Proposed start date (dd/mm/yy):

Q5 Does the proposal arise from previous Wellcome Trust funding?

Q6 Total requested cost (\*deleted as appropriate):

Cumulative cost to Objective 1:

£1,410,788
£222,061

The safety and immunogenicity of a single dose oral typhoid vaccine in Vietnamese healthy adults and children and identification and preparation of a field site for a Phase III efficacy study

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£1,290,576 £1,410,788

rincipal	applicant:	ľ	**]	

Project title:

The safety and immunogenicity of a single dose oral typhoid vaccine in Vietnamese healthy adults and children and identification and preparation of a field site for a Phase III efficacy study

### Undertakings

- In signing the application form where shown below, and in consideration of the receipt of this application by the Wellcome Trust, all applicants (principal applicant, coapplicant, sponsors, technology transfer office/group representatives) UNDERTAKE that the information provided in the application form and otherwise in connection with this application is to the best of their knowledge and belief accurate and complete and that, in relation to any award of grant resulting from the application, they will:
  - 1. Take all reasonable actions to ensure that the Wellcome Trust's contribution to the funding of the research is suitably acknowledged.
  - 2. If research papers (whether based wholly or partly upon the research to be funded by the grant) are published, forward copies to the Wellcome Trust upon publication
  - Comply as Wellcome Trust-funded researchers with the Wellcome Trust's principles and policies on relationships between Wellcome Trust-funded researchers and commercial 3. entities as set out in Annex A to the Wellcome Trust's grant conditions.
  - Meet the requirements of the Wellcome Trust, as set out in the grant conditions, prior to entering into an arrangement with any enterprise that will provide for the exploitation of any results arising from any activity funded under a Wellcome Trust award.
  - Promptly inform the Wellcome Trust of any material changes during the period of the grant to any of the details provided in this application. 5.

I have read the conditions under which grants are awarded and the undertakings detailed above and, if a grant is made, I agree to abide by them. I shall be actively engaged in the day-to-day control of the project. I consent to the information provided in this application being used and disclosed in accordance with the principles set out in the Wellcome Trust Data Protection statement which appears on this form

Signa	ture of a	applicant	N/A		Date:
Signa	ture of t	technology transfer office/group joint applicant			Date:
Signa	ture of	coapplicant	N/A		Date:
Signa	ture of s	sponsor (if applicable)			Date:
(II)	Trans	ning the application form where shown below, and in consideration sfer Office/Group UNDERTAKE that the information provided in ate and complete and that, in relation to any award of grant resulting	the application	form and otherwise in connection with this appl	
	1.	Ensure compliance with the Wellcome Trust's principles and polithe Wellcome Trust's grant conditions.	cies on relations	ships between Wellcome Trust-funded researche	rs and commercial entities as set out in Annex A to
	2.	Meet the requirements of the Wellcome Trust, as set out in the gra- results arising from any activity funded under a Wellcome Trust a		prior to entering into an arrangement with any er	nterprise that will provide for the exploitation of any
	3.	Promptly inform the Wellcome Trust of any material changes dur	ing the period o	f the grant to any of the details provided in this	application.
		he conditions under which grants are awarded and the undertakings that I agree to this research being carried out in my department, and			
Signa	ture of l	Head of Department N/A		Date:	
Signa	ture of l	Head of Technology Transfer Office/Group N/A		Date:	

- In signing the application form where shown below, and in consideration of the receipt of this application by the Wellcome Trust, the institution UNDERTAKES that the information provided in the application form and otherwise in connection with this application is to the best of its knowledge and belief accurate and complete, and that it will
  - Ensure compliance with the Wellcome Trust's principles and policies on relationships between Wellcome Trust-funded researchers and commercial entities as set out in Annex A to 1. the Wellcome Trust's grant conditions.
  - Meet the requirements of the Wellcome Trust, as set out in the grant conditions, prior to entering into an arrangement with any enterprise that will provide for the exploitation of any 2. results arising from any activity funded under a Wellcome Trust award.
  - 3. Obtain from all individuals, subsequently funded as a result of the application, the equivalent undertakings as required from the applicants ab initio (i.e. before funding takes place).
  - Apply with full rigour all relevant arrangements for the protection of any patentable intellectual property rights arising from any research funded as a result of this application, as 4. detailed in the grant conditions. However, if the institution decides not to proceed with the protection of any patentable intellectual property rights, it will co-operate fully (and ensure that its employees, students, contractors, and representatives co-operate) with Technology Transfer at the Wellcome Trust such that the Wellcome Trust will have an unreserved and unrestricted right, but not a duty, to seek patent protection.
  - Take full responsibility for the management, monitoring and control (including the requirements of all regulatory authorities governing the use of radioactive isotopes, animals, pathogenic organisms, genetically manipulated organisms (GMOs), toxic and hazardous substances, and research on human subjects and human embryos) of all the research work funded as the result of the application and all those staff (permanent, temporary and students) employed in or involved in any research funded as a result of the application.
  - Ensure that all permanent and temporary staff and students employed in or involved in the research receive training appropriate to their duties, in accordance with the regulations set 6. down under the COSHH, ACDP and ACGM guidelines, the Health and Safety at Work regulations, and any other statutory or regulatory requirements as may apply from time to time.
  - Promptly inform the Wellcome Trust of any material changes during the period of the grant to any of the details provided in this application.

If a grant is made I will ensure that the funds provided are used for the purpose for which they have been given. I confirm that it is the institution's intention to maintain its support for the department of the applicant[s] during the period for which this grant is requested. I also confirm that this institution holds/is not required to hold a Certificate of Designation under the Animals (Scientific Procedures) Act 1986. I also confirm that I have read and I accept for and on behalf of the institution the conditions under which grants are awarded and these undertakings.

belief

Signature of Secretary of Institution/Finance Officer:		Date:	
Institution:			
Position:	<u> </u>		
Please complete this form with reference to the associated guidance notes.			
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\*Delete as appropriate

# Principal applicant (Scientist)

[\*\*] [\*\*] Title [\*\*] Name: Post

Address: Tel: 540-545 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire RG41 5TU [\*\*] Fax: E-mail:

Technology transfer office/group joint applicant

Name: Post N/A Title

Address:

Tel: Fax:

E-mail: Sponsor (if applicable)

Title

Name: N/A Post Address:

Tel: Fax:

E-mail:

Coapplicant

Name: Title [\*\*]

Post Address: Tel:

Fax:

E-mail:

# Coapplicant

Name: Post	[**] [**] [**]	Title	[**]
Address: Tel: E-mail:	[**] [**]	Fax:	[**]
Coapplicant			
Name: Post	[**] [**]	Title	[**]
Address: Tel: E-mail:	[**] [**] [**]	Fax:	[**]

Please complete if the principal applicant does not hold an established position.		
N/A		
Signed:	Date:	
Name:	Position:	
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Recommended by sponsor

#### Q7 Summaries of University Translation Award research and commercialization objectives

(Both parts combined should be no more than 400 words.)

(a) For technically qualified assessors:

A breakthrough has been made in the development of an improved oral typhoid vaccine through the application of functional genomics sciences. This has led to the identification of several genes in *Salmonella* species that are essential for virulence providing new gene targets for attenuation, resulting in the development of a novel live attenuated typhoid vaccine that can be administered orally and is safe and immunogenic at a single dose.

The live attenuated Salmonella typhi strain S. typhi (Ty2 aroC ssaV) ZH9 contains defined (independently attenuating) non-reverting deletions in two genes, aroC and ssaV. The ssaV gene is encoded on SPI-2, Salmonella Pathogenicity Island 2. SPI-2 encodes a type III secretion system and ssaV encodes a structural component of the secretory apparatus. SPI-2 is required for growth and survival within macrophages, one of the mechanisms by which S. typhi is spread systemically. Therefore, a mutation in this gene will prevent systemic spread of the vaccine strain, an important safety consideration for live vaccines.

The vaccine has been tested in clinical studies involving over 100 US and UK subjects and has shown to have an excellent safety profile (no bacteraemias or persistent shedding detected) and after a single dose, stimulates strong mucosal and systemic immune responses comparable to those stimulated by four doses of the currently licensed vaccine.

A single dose vaccine that does not require a needle for administration would bring enormous healthcare benefits to developing countries where typhoid is endemic and it is difficult to maintain the cold chain. The vaccine offers a new opportunity for the control and possibly the future eradication of typhoid from the wild.

The objectives of the project are to clinically evaluate the vaccine in healthy Vietnamese adults and children in Phase II studies and to set up a field site in preparation for efficacy testing. The project will be carried out in collaboration with the Oxford University Wellcome Trust Unit in Viet Nam, [\*\*] bringing together considerable expertise in vaccinology and specifically on the development of typhoid vaccines.

The STA is critical to the eventual commercialisation of the product in any territory. The commercial market for typhoid vaccines is not large and it is difficult for Microscience to justify funding the whole programme required to gain approval of the product, either as a traveller's vaccine, or in developing countries, given that the Company has a number of more commercially attractive vaccines in the portfolio.

However, Microscience recognises the importance of this vaccine in providing substantial healthcare benefits in the developing world and would like to ensure that if the vaccine is successful, those benefits are delivered.

The route to commercialisation of the vaccine whether it is for travellers or the developing world will involve carrying out a large efficacy study in a country where typhoid is endemic. The STA proposal is critical for taking the first steps in this process and addressing one of the key technical barriers relating to transfer of vaccines from the developed to the developing world, that is whether the safety and immunogenicity profiles will be similar, particularly in children who will form the bulk of the cohort in the efficacy study. It will be difficult to obtain further investment into the project until this key question has been answered. It is also essential, in parallel to the clinical studies, to establish a field site than can subsequently be used for the efficacy study. Establishing the incidence rate for typhoid will allow detail planning of the efficacy study, particularly in terms of the numbers of subjects that will need to be involved giving an accurate view of what future funding will be required for the efficacy study which will be privatal for gaining approval of the product.

If the vaccine proves to be successful in the stepping stone studies and in the establishment of the field site in Viet Nam it should provide leverage for obtaining additional funding, either from commercial or NGO sources.

(b) For lay readers:

Typhoid fever remains a major disease of the developing world. The spread of bacteria that are resistant to all affordable antibiotics raises the possibility of untreatable typhoid fever and a return to the pre-antibiotic era when 30% of patients died. There is no currently available affordable vaccine that offers long term protection after a single dose. The application of genomic sciences has resulted in a breakthrough in the development of an improved typhoid vaccine that can be given orally and is effective at a single dose. The vaccine has been tested in studies involving over 100 subjects in the US and UK and has shown to have an excellent safety profile and after a single dose, stimulates the body to make immune responses equivalent to those stimulated by four doses of the currently licensed vaccine. A single dose vaccine that does not require a needle for administration would bring enormous healthcare benefits to developing countries where typhoid is endemic and it is difficult to maintain the cold chain. The vaccine offers a new opportunity for the control and possibly the future eradication of typhoid from the wild. The objectives of the project are to clinically evaluate the vaccine in healthy Vietnamese adults and children and to identify and set up a field site in Viet Nam where a future study can be carried out to assess whether it can protect against typhoid fever.

The STA is critical to the eventual commercialisation of the product in any territory. The commercial market for typhoid vaccines is not large and it is difficult for Microscience to justify funding the whole programme required to gain approval of the product, either as a traveller's vaccine, or in developing countries, given that the Company has a number of more commercially attractive vaccines in the portfolio.

However, Microscience recognises the importance of this vaccine in providing substantial healthcare benefits in the developing world and would like to ensure that if the vaccine is successful, those benefits are delivered

The route to commercialisation of the vaccine whether it is for travellers or the developing world will involve carrying out a large efficacy study in a country where typhoid is endemic. The STA proposal is critical for taking the first steps in this process and addressing one of the key technical barriers relating to transfer of vaccines from the developed to the developing world, that is whether the safety and immunogenicity profiles will be similar, particularly in children who will form the bulk of the cohort in the efficacy study. It will be difficult to obtain further investment into the project until this key question has been answered. It is also essential, in parallel to the clinical studies, to establish a field site that can subsequently be used for the efficacy study. Establishing the incidence rate for typhoid will allow detail planning of the efficacy study, particularly in terms of the numbers of subjects that will need to be involved, giving an accurate view of what future funding will be required for the efficacy study which will be pivotal for gaining approval of the product.

If the vaccine proves to be successful in the stepping stone studies and in the establishment of the field site in Viet Nam it should provide leverage for obtaining additional funding, either from commercial or NGO sources.

Q8. How did you hear about this award scheme?			
Wellcome Trust website o	Other Wellcome Trust contact o	University or technology transfer office/group ☑	
Press o Other (please specify)			
			43

# Q9 Previous applications to the Wellcome Trust

In a covering letter briefly state how this application differs from the original.

(a)	Is this the principal applicant's first application to the Wellcome Trust?		
	If no, please give details of previous approaches over the last five years.		
	Indicate with an (*) those awards (if any) which have contributed to the background of	f this proposal.	
	N/A		
(b)	Is this application a resubmission of an application previously considered by the	o Yes 🗹 No	
	Wellcome Trust?		
	If yes, when and where was it considered?	N/A	
	Please give the Wellcome Trust's reference number:	N/A	

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# Q10 Details of other sources of funding

State name of awarding body, title of project, amount awarded, dates of support and proportion of time spent on each project.

(a) Current sources of funding

Indicate with an (\*) those awards (if any) which have contributed to the background of this proposal.

To date the only source of funding has been through Microscience Ltd, a privately owned UK company working on the development of novel vaccines and immunotherapeutics for prevention an treatment of infectious disease. The Company was founded on vaccine technology developed at Imperial College and was spun out in 1997. To date the Company has raised £[\*\*] in the form of private equity investment. The major investors are Merlin, Apax Partners, Advent Venture Partners and J.P. Morgan Partners. The funding has enabled Microscience to develop five vaccine produincluding the oral typhoid vaccine, all of which are now undergoing clinical testing in the U.K. and U.S.

To date approximately  $\mathfrak{L}[**]$  has been spent by Microscience on the development of the oral typhoid vaccine over the past five years. It is estimated that approximately  $\mathfrak{L}[**]$  is still required to complete all the activities required to commercialise the product.

(b)	Any other source of funding that has directly contributed to the background of this proposal.
	No

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Q11	Pater	Patent Information		
	(Plea	se continue on an additional sheet if necessary.)		
		any patent(s) or patent application(s) been filed by the applicant(s) h relate to this proposal?	☑ Yes o No	
	If yes	s, please provide details:		
	1)	Application number or publication number:	W096/17951	
		Priority date:	11 December 1995	
		Inventors:	D W Holden, J E Shea, M Hensel	
		Applicant:	RPMS (now co-owned by Microscience Ltd)	
		Funding source:	N/A	
	2)	Application number or publication number:	W000/68261	
		Priority date:	10 May 1999	
		Inventors:	G Dougan, J D Santengelo, D W Holden, J E Shea, Z Hindle	
		Applicant:	Microscience Ltd	
		Funding source:	N/A	

The typhoid vaccine candidate contains mutations in aroC and ssaV.

How do these patent(s) or patent application(s) relate to this proposal?

Name of applicant: [\*\*]

 $W096/17951 — Contains \ claims \ to \ use \ of \ strains \ harbouring \ mutations \ in \ Salmonella \ Pathogenicity \ Island \ 2, \ including \ the \ \textit{ssaV} \ gene.$ 

W000/68261 — Claims to the combination of aroC and ssaV. Claim for the combination being particularly useful for making attenuated mutants of Salmonellae.

# Q12 Details of the investigation

Please refer to the guidelines notes before completing this section.

a) Please detail the key objectives of the proposal, relating these to the proposed project Objectives.

The overall objective of the proposal is to translate the Phase I/II clinical findings from an improved oral typhoid vaccine being developed in the UK and US, to a country where typhoid is endemic, in order to prepare for a large field study in which the vaccine can be evaluated for efficacy. This will be achieved by carrying out a Phase II programme in Viet Nam in healthy adult subjects and school age children in order to confirm the safety and immunogenicity of the vaccine in a Vietnamese population, providing assurance that the vaccine is suitable for use in a large efficacy study in the Mekong Delta of Viet Nam. The proposal will address one of the key technical barriers associated with transfer of vaccines from developed to developed to developing countries; the vaccine has so far been tested in healthy subjects in countries where typhoid is not endemic, but it is known that the safety and immunogenicity profiles of vaccines, particularly live vaccines given orally, can be different in subjects where the disease is endemic and where the socio-economic conditions are very different. The proposed project will therefore highlight any differences between the different populations and will provide new scientific data on this issue that will be useful for the development of other vaccines.

The other major objective will be to identify and prepare a site in the Mekong Delta where a large field study can be performed to establish the efficacy of the vaccine. The site development will be carried out in parallel to the Phase II programme described above.

In order to achieve the overall objective the key objectives of the project are as follows:

Initiation of a Phase II programme in Viet Nam in healthy adult volunteers and children:

- · Identification of site
- · Clinical protocol development
- · Regulatory approval from Vietnamese and US authorities
- · Assay transfer
- · Manufacture and release of clinical material
- · Screening and recruitment of subjects

Demonstration of safety, tolerability and immunogenicity in Vietnamese adults and children

- Dosing
- Monitoring of study (safety and GCP)
- · Evaluation of safety
- · Completion of immunoassays
- · Management and validation of data

Preparation of field site for Phase III study

- · Identification of site
- · Establishment of infrastructure
- Perform Census
- · Establishment and provide training in diagnostic tools
- Disease surveillance

Name of applicant: [\*\*]

(b) Describe how this proposal will ultimately lead to healthcare benefit

The proposal could lead to considerable healthcare benefits for both the developing and developed world. The activities outlined in the proposal are the first steps in a clinical evaluation of the vaccine critical for moving to an efficacy study in an endemic area. Such a study will be required for approval of the vaccine in any country since there are no accepted correlates of immunity. All other typhoid vaccines have been approved on efficacy data generated in endemic areas. Typhoid fever remains a very significant global health problem with an estimated 17 to 33 million cases occurring worldwide annually resulting in 600,000 deaths, virtually all these cases occur in the developing world. In the last few years there has been the worrying development and global spread of bacteria that are resistant to all affordable antibiotics. Over 90% of isolates in Southern Viet Nam are resistant to all first line antibiotics making the need for an effective and affordable vaccine more urgent. There are licensed vaccines available to prevent typhoid fever but these are less than ideal for control of typhoid fever in developing countries. The currently licensed oral typhoid vaccine achieves protection in 60-70% of recipients but requires four doses resulting in compliance issues and difficulty in maintaining the cold chain. The single dose injectable vaccine based on the surface polysaccharide Vi is also not ideal as it's administration requires the use of needles and being a polysaccharide, it is poorly immunogenic in young children. The incidence of typhoid fever is highest in school age and pre-school age children in developing countries.

A single dose vaccine that is immunogenic in young children and does not require a needle for administration would therefore bring enormous healthcare benefits to developing countries where it is difficult to maintain the cold chain that is required for multi-dose vaccines. Furthermore, because S. *typhi* is a human restricted pathogen, has no animal reservoirs and does not persist in the environment, the vaccine also offers a new opportunity for the control and possibly the future eradication of typhoid from the wild.

Additional healthcare benefits will be derived from setting up of a field site for testing efficacy. Establishing the infrastructure and expertise at a potential field site will also provide information on the general disease burden of the population making it possible to derive other healthcare strategies to address other disease targets.

Finally, the proposal could also lead to the approval of the vaccine for the prevention of typhoid fever in travelers to endemic areas.

#### Give relevant technical background information (maximum 1½ pages)

Modern molecular biology techniques and increasing knowledge of *Salmonella* pathogenesis have led to the identification of several genes that are essential for *in vivo* growth and survival of these organisms. (1) This has provided new gene targets for attenuation, leading to the concept that future live vaccine strains can be rationally attenuated by introducing defined mutations into selected genes that are known to be involved in virulence. This will facilitate the development of improved vaccines, particularly in terms of the immunogenicity and therefore the number of doses that have to be given.

Microscience has constructed a Salmonella typhi vaccine strain S. typhi (Ty2 aroC ssaV) ZH9 that contains defined (independently attenuating) deletions in two genes, aroC and ssaV. (2) The aroC gene encodes chorismate synthase, an enzyme involved in the biosynthesis of aromatic compounds. Aro mutations are well described as being attenuating for Salmonella in humans, (2) and the basis is presumed to be that two aromatic compounds, para-aminobenzoic acid and 2,3-dihydroxyaminobenzoic acid are limiting for growth in mammalian tissue. The ssaV gene is encoded on SPI-2, Salmonella Pathogenicity Island 2, SPI-2 encodes a type III secretion system and ssaV is believed to encode a structural component of the secretory apparatus. SPI-2 mutations have previously been shown to be attenuating in mice, (3) and there is evidence that this is because SPI-2 is required for growth within macrophages, the mechanism by which S. typhi is thought to be spread systemically. Therefore, a mutation in this gene will prevent systemic spread of the vaccine strain.

S. typhi (Ty2 aroC ssaV) ZH9 is derived from the virulent S. typhi strain Ty2. This strain has been used as a background strain for constructing candidate typhoid vaccines previously evaluated in volunteers. The currently licensed live Salmonella vaccine is derived from this strain.

S. typhi (Ty2 aroC ssaV) ZH9 is being developed as a single dose, orally delivered vaccine that will protect against typhoid fever. (4)

The attenuation of S. typhi (Ty2 aroC ssaV) ZH9 has been demonstrated directly by comparing the replication of S. typhi (Ty2 aroC ssaV) ZH9 with S. typhi (Ty2 aroC DTY8, which harbours a single aro mutation, in human macrophage-like cells in the presence and absence of aromatic compound supplements. S. typhi (Ty2 aroC ssaV) ZH9 was highly attenuated for growth in macrophages since it failed to replicate and bacterial killing was observed, even in the presence of aromatic compounds. (5) This is an important finding, demonstrating the utility of mutations in SPI-2 as an attenuation strategy for Salmonella. This adds an additional level of safety to the strain.

The attenuation of vaccine strain S. *typhi* (Ty2 *aroC* ssaV) ZH9 has also been demonstrated indirectly by comparing the attenuation of *Salmonella typhimurium* (S. *typhimurium*) strains harboring similar mutations in mice. S. *typhi* does not infect mice. However, genetically-susceptible mice infected with S. *typhimurium* develop a systemic "typhoid-like" disease and this mouse typhoid model has been used to predict the usefulness of attenuating mutations in S. *typhi*. This model has been used to demonstrate a safety advantage of a mutation in SPI-2 (such as *ssaV*) in combination with an *aro* mutation, over that of an *aro* mutation alone. (5)

Both IFN-y and IL-12 are required for control of Salmonella infection in mouse and man, therefore, mice deficient in either IL-12 or IFN-y are useful models of immunocompromised humans. The attenuation of a SPI-2 (ssaJ) transposon insertion mutant and an aro (aroA) transposon insertion mutant of S. typhimurium were compared in both IFN-y KO mice and in mice treated with IL-12 specific antibodies. No clinical symptoms of disease were observed with the SPI-2 mutant in either class of immunocompromised mouse and clearance from the tissues was observed. In contrast, the aro mutant replicated to high levels in the tissues and caused death of both the IFN- KO and anti-IL 12-treated mice. Further studies sought to assess the attenuation of S. typhimurium harboring defined deletions in aroC and ssaV identical to those present in S. typhi (Ty2 aroC ssaV) ZH9. The aroC ssaV double mutant strain S. typhimurium (TML aroC ssaV) WTO5 was completely attenuated in IFN — KO mice (100% survival) whereas the single aroC mutant caused up to 100% mortality. (5) Further studies in conventional mice showed that the aroC ssaV double mutant colonized the mouse tissues at lower levels than a single aroC mutant and was cleared more rapidly from the tissues. These data generated in the mouse typhoid model further demonstrate the utility of mutations in SPI-2 in combination with an aro mutation as an attenuation strategy for Salmonella and provide confidence that S. typhi (Ty2 aroC ssaV) ZH9 will be highly attenuated in humans with an increased attenuation over single aro mutants.

Give relevant technical background information (continued)

To date S. typhi (Ty2 aroC ssaV) ZH9 has been administered to over 80 healthy adult volunteers in three studies. Full details and results of these studies are provided in Appendix A in the form of a published paper and two clinical trial study reports. A summary of the design of the studies and results is provided below:

In the first study (Study MS01.01) 9 subjects (3 per cohort) received doses of either 107, 108 or 109 CFU of a frozen formulation of the vaccine. (4) In the second study (Study MS01.03) 48 subjects (16 per cohort) received doses of 5 x 107, 5 x 108 or 5 x 109 CFU of a freeze-dried formulation of the S. *typhi* (Ty2 *aroC ssaV* ) ZH9 vaccine. In the third study (Study MS01.04) 32 subjects received 5 x109 CFU of freeze-dried S. *typhi* (Ty2 *aroC ssaV* ) ZH9 in one of two different Presentation solutions (16 per group). These studies indicate that the vaccine is highly immunogenic at a single dose with a good safety profile. The immunogenicity achieved with one dose is comparable to that obtained after 4 doses of the currently licensed oral typhoid vaccine.

Study MS01.03 was a placebo controlled, double blind, out-patient, single dose, dose escalating study conducted under an Investigational New Drug (IND). The study was designed to determine the safety, tolerability and immunogenicity of three dose levels of the vaccine which consisted of a freeze-dried formulation of the live attenuated vaccine strain S. typhi (Ty2 aroC ssaV) ZH9 and excipients. A total of 60 healthy adult volunteers were recruited in 3 cohorts of 20. In each cohort, 16 subjects were randomized to receive vaccine and 4 to receive placebo. The cohorts were dosed sequentially such that the first cohort received a single dose of 5x107 CFU of S. typhi (Ty2 aroC ssaV) ZH9 or placebo, the second cohort received 5x108 CFU of S. typhi (Ty2 aroC ssaV) ZH9 or placebo and the third cohort received 5x109 CFU of S. typhi (Ty2 aroC ssaV) ZH9 or placebo. The vaccine or placebo was administered in 50ml 2% bicarbonate following the prior ingestion of a volume of 2% bicarbonate to neutralise stomach acid.

The important consideration for safety of a live, attenuated strain of S. *typhi* is that following ingestion the strain is not able to disseminate throughout the body and give rise to bacteraemia or shed persistently from the gut. The safety monitoring was designed to show that this did not occur with MICRO-TY.

The S. typhi (Ty2 aroC ssaV) ZH9 vaccine exhibited an excellent safety profile and was found to be well tolerated by all of the subjects dosed. None of the blood or urine cultures taken during the study were positive for S. typhi (Ty2 aroC ssaV) ZH9. Shedding of S. typhi (Ty2 aroC ssaV) ZH9 in the stools of the subjects did not continue beyond 6 days for any subject, at any of the three dose levels. The number of subjects shedding increased with increasing dose level.

There were no serious adverse events (SAEs) related to study medication and there was no statistically significant difference in the incidence of adverse events (AEs) between subjects receiving the vaccine and those who received placebo.

The immune responses measured were the ability to elicit serum IgG antibody against LPS (humoral immune response), and the presence of gut derived anti-LPS IgA antibody secreting cells in the blood, which be indicative of the priming of the gut mucosa (mucosal immune response). The correlates of protection for typoid are not clearly understood, hence the need to carry out an efficacy study in order to demonstrate protection. However, for the currently licensed oral typhoid vaccine (Vivotif, Bema vaccines) which requires four doses, results of the two immunological assays used in assessing this vaccine have been found to putatively correlate with the protection conferred by different formulations and immunisation schedules of Vivotif in field trials (6,7). The identification of these measurements as putative immunological correlates of protection provides an invaluable tool for use in early clinical trials evaluating new live oral typhoid vaccines. (2,4).

In study MS01.03 all three dose levels of S. typhi (Ty2  $aroC^-ssaV^-$ ) ZH9 were shown to be immunogenic, with the highest dose level being immunogenic in all subjects. In both the 5 x 10<sup>7</sup> and 5 x 10<sup>8</sup> CFU dose groups 9 (56%) subjects in each group mounted an immune response detected by either an anti-LPS ELISPOT response on Day 7 or an anti-LPS serum IgG response on Day 28. This number increased to 16 (100%) in the 5 x 10<sup>9</sup> CFU dose group. None of the subjects that received placebo mounted an immunological response against S. typhi (Ty2  $aroC^-ssaV^-$ ) ZH9.

The vaccine presentation used in this study requires preparation in non-chlorinated water and involve pre-dosing with a volume of buffer prior to vaccine administration; this is not a convenient method of preparation and administration. The purpose of study MS01.04 was to assess safety and immunogenicity following administration using a presentation that will be more convenient to prepare and administer; it can be prepared in any water and pre-dosing with a volume of buffer will not be required. This presentation will be suitable for commercialisation. Study MS01.04 was performed in the US under the IND. It was an open label, single oral dose (5 x 109 CFU), out patient study involving 32 healthy adult volunteers. 16 subjects were vaccinated using the presentation used for study MS01.03 (Presentation 1) and 16 were vaccinated using the new presentation (Presentation 2).

The database for this study was locked in February 2004 and the data are currently being analysed. Preliminary results are summarised below:

S. typhi (Ty2 aroC ssaV) ZH9 demonstrated an excellent safety profile. There were no serious or severe adverse events reported during the study. No subjects reported a fever considered attributable to the vaccine, there were no bacteraemia, no persistent shedding in stools (no subject shed beyond day 6), and no clinically significant changes in haematological and biochemical profiles.

An immune response was elicited in the majority of subjects following administration of the vaccine and there was no evidence of a difference between the presentation groups in the proportion of subjects showing an immunogenic response detected in either the ELISA or ELISPOT assay; fifteen subjects (94%) who received the vaccine using Presentation 1 showed a response; and fourteen subjects (93%) who received the vaccine using Presentation 2 showed a response.

Microscience is also planning to carry out a clinical trial in South Korean healthy adult volunteers during Q4 of 2004. This will be similar in design to the first study that will be carried out in Vietnam. It is designed to evaluate the safety and immunogenicity of a single dose of the intended commercial dose of the vaccine in 28 healthy Asian volunteers in South Korea. It will be blinded and placebo controlled (16 will receive active and 12 placebo). This study is at an advanced stage of planning and Microscience is now committed to it. It was originally considered that it would be necessary to carry out this study in order to provide comfort to the Vietnamese authorities that safety and immunogenicity had been demonstrated in an Asian population prior to being able to move the programme to Vietnam. However, further discussion with the Wellcome Trust Unit in Vietnam indicates that the initiation of the first study in Vietnam will not be dependent on results from this study. Nevertheless, it is considered that initiating a study in the region ahead of the first Vietnam study will be very helpful in securing regulatory approval in Vietnam and, together with the studies in Vietnam it will also provide valuable information on the uptake of the vaccine in individuals of different genetic backgrounds.

The study will be performed at the Clinical Trial Centre based at Seoul National University (SNU), South Korea. Ethics approval submissions have been made and initial discussions have taken place with the Korean FDA. A submission to Korean FDA is being made on the 30<sup>th</sup> June 2004. It is planned to dose the first subject during the first week of October 2004. Initiation of studies in Viet Nam is not dependant on data from this study in Korea.

In summary, Microscience has developed a novel single dose oral vaccine that has shown to be safe and immunogenic in healthy U.K. and North American volunteers. There is clearly an unmet medical need in the market for a vaccine that can overcome the compliance issues associated with multi-dose vaccines, provide good immunological memory after a single dose and potentially have increased efficacy. Such a vaccine could potentially have a big impact on the control of typhoid in endemic areas and also represent a big improvement for prevention of typhoid to traveller's to those

It is considered that the Microscience product is the lead improved typhoid vaccine in development. It has been developed under a Company sponsored IND and is now in Phase II development in outpatient studies in the US. The clinical studies have used a product manufactured from a process that is capable of being commercialised and it is delivered in a commercial presentation that is acceptable to regulatory authorities.

Name of applicant: [\*\*]

(d) Describe the workplan (this should not be more than four pages, excluding the project timeline)

Cover experimental design and methods to be used in this investigation.

- Identify up to three scientific objectives clearly within the workplan.
- Present the project timescale visually as a Gantt chart or other project timeline profile as a one-page appendix to this application form.

The project timescale is presented as Appendix B.

### Objective 1. Initiation of a Phase II programme in Viet Nam in healthy adult volunteers and children

#### Objectives/key tasks

- Identification of site. Responsibility of the clinical investigators [\*\*]. It is important that phase II safety and immunogenicity data is generated in subjects representative of the target population for the field study. It is therefore intended that a number of the phase II studies will be performed in the endemic region in the Mekong Delta. However, at least the first study, in adult volunteers, will be undertaken under well-controlled conditions at the Oxford University Clinical Research Unit at the Hospital of Tropical Diseases in Ho Chi Minh City. This will ensure that technology is transferred, staff are trained and the regulatory approval process is undertaken as efficiently as possible, prior to moving the programme into the endemic region.

  Once vaccine safety has been adequately demonstrated in this study approval will be sought to perform subsequent studies in the endemic region.
- Clinical protocol development. Individual protocols will be written for each of the studies. The protocols will be owned by Microscience but developed jointly by Microscience and the clinical investigators ([\*\*]).
- Regulatory approval. Microscience will be responsible for obtaining regulatory approval for the clinical studies and for field site development. Approval will be sought from both the
  Vietnamese and US regulatory agencies, as it is intended that the clinical studies will be performed under the US IND that is held for this product by Microscience.
- Local ethics approval. The clinical investigators ([\*\*]) will be responsible for obtaining ethics approval from the local Independent Review Board (IRB). Microscience and the clinical investigators ([\*\*]) will be responsible for preparing the documentation required for submission.
- Assay transfer. Assay transfer from Microscience to the Hospital for Tropical Diseases is the responsibility of both parties and is expected to take 1 month. The immunoassays being used
  for these studies have been standardised at Microscience. Assay transfer will ensure that assay performance is comparable at the Hospital for Tropical Diseases, at Microscience and in
  previous clinical studies. The process involves performing the assays multiple times using reference samples. Transfer will be considered successful once an analyst has performed a predefined number of assays that have each met the validity criteria.
- Manufacture and release of clinical material. Responsibility of Microscience.

The clinical material will be vaccine, placebo and [\*\*], manufactured to cGMP. [\*\*]

Adult study. It is anticipated that existing batches of vaccine, placebo and [\*\*] will be used for the adult study; only packaging and labelling will be required for this study. Following review of packaging and labelling batch records and receipt of regulatory and ethics approval, the material will be released by Microscience for use in the clinic.

Studies in children. New batches of vaccine and placebo will be manufactured in Q1 2005 for the studies in children. Following packaging and labelling, review of manufacturing batch records and receipt of regulatory and ethics approval, the material will be released by Microscience for use in the clinic.

Screening and recruitment of subjects. Responsibility of the clinical investigators ([\*\*]). To begin once regulatory and ethics approval have been obtained. For each subject screening has to occur within 28 days of dosing. All efforts will be put in place to obtain written consent that is informed and given voluntarily as described in Appendix C.

Name of applicant: [\*\*]

(d) Workplan (continued)

# Objective 2. Preparation of field site for Phase III study

# Objectives/key tasks

· Identification of site. [\*\*] will have joint responsibility.

The decision as to which area will be the site for the efficacy study and therefore for surveillance will be based on known levels of incidence as defined by current government statistics, predicted levels of incidence and the ease with which the required infrastructure can be put in place. The site will be in the Mekong Delta region of Viet Nam. This area has been chosen because population based surveillance studies for typhoid fever have previously been carried out in this region in 1995/1996. (8) It was found that the incidence level was high (overall it was 198 per 10<sup>9</sup> of the general population). The highest attack rate was among the 5-9 year olds and lowest in the >30 year olds. It was concluded from these studies that typhoid fever is highly endemic in Viet Nam and is a significant disease in both pre-school and school aged children. A region in the Mekong Delta [\*\*] has been selected for this proposal.

A typhoid surveillance study will be conducted in the proposed field-site and data will be collected for at least one year prior to phase III immunization commencing and will continue throughout the duration of the efficacy study. The end-point of the pre-study surveillance will be a rate of incidence of typhoid fever in the study population. These data will be used to determine the number of subjects to be entered into the phase III efficacy study.

- Establishment of infrastucture. [\*\*] will have joint responsibility.
- Perform Census. [\*\*]will have joint responsibility.

A census will be performed in the study area. [\*\*] Each of these households and each individual residing in the household is given a unique identification number (ID#), which is used for all interactions that occur as part of the study. ID numbers will be allocated based on the serial number of the census form, and the sequential order within each household. The aims of the census will be as follows: To assign a unique study number to each household

- To assign a unique study identification number of each individual resident in the household
- To obtain base-line data on socio-economic status, health seeking behaviour, prior typhoid vaccine usage and potential typhoid risk factors
- To provide the household members with information on the project
- · Establish and provide training in diagnostic tools. [\*\*] will have joint responsibility.
- · Disease surveillance, [\*\*] will have joint responsibility.

The surveillance system will rely on patients attending existing healthcare facilities in the endemic region (government health care facilities and participating private healthcare physicians). This healthcare facility-based passive surveillance system will be aimed at detecting the majority of reported cases of typhoid fever among study participants seeking medical care. Medical personnel will interview, examine, and obtain a venous blood specimen for laboratory investigation from all patients living in the study area with [\*\*]

All relevant clinical information will be recorded using standard procedures and will include: date and time of examination; name; study ID number; age and gender; full address; name of head of household; number of days since disease began; symptoms and signs of the disease. The venous blood sample will be taken to identify the presence of S. *typhi* by blood culture. Serum will also be taken for typhoid fever serological assays.

Typhoid fever proven cases will be given antibiotic treatment as appropriate. It is anticipated that S. typhi resistance patterns will be monitored regularly throughout the study.

A crucial feature of the surveillance programme will be the accurate identification of all patients attending healthcare facilities, who are study participants. To accomplish this, each clinical supervisor will attempt to identify patient ID numbers using a computer search programme (for names, age ranges, dates of birth, sex, names of the head of households).

Additionally, all culture-proven cases and positive serological cases will be visited at home to confirm the identification of the patient; to assess clinical progress; to assess any typhoid fever-related disability; to determine typhoid carrier status and to apply a verbal autopsy when needed. Culture-proven typhoid fever cases will be visited [\*\*] after onset of illness. Follow-up questionnaires will be completed at each visit. Stool samples will also be collected at the end of the post-immunization [\*\*] year follow-up on all typhoid fever cases during a home visit, with the aim of identifying typhoid carriers.

# Objective 3. Demonstration of safety, tolerability and immunogenicity in Vietnamese adults and children

The clinical programme will involve Vietnamese subjects of a broad age range (approximately 30-5 years) and will be run as a series of age-descending studies as it will be important to demonstrate that the vaccine is safe when administered to adults and adolescents prior to administering it to children. Volunteers will be stratified into three different age brackets: adults (18-30 years); older children (10-18 years); young children (5-10 years).

# A. Study to demonstrate safety, tolerability and immunogenicity in healthy Vietnamese adults

The purpose of the study is to evaluate the immunogenicity and safety of [\*\*] *S. typhi (Ty2 aroC ssaV )* ZH9 oral typhoid vaccine in approximately [\*\*] healthy adult volunteers (age 18 – 30 years inclusive) from Viet Nam. The study will be a single centre, single-blind, placebo-controlled, randomised study. The study schedule is show in Table 12.1. The study design will be such that there will be two groups of subjects, Group 1 will receive vaccine and Group 2 will receive placebo.

Table 12.1 Study schedule for study in healthy adult volunteers

Visit	Screen	1	2	3	4	5	6
Day	-28 to -2	0	1	7	10	14	28
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# Objectives/key tasks

Dosing. Responsibility of the clinical investigators ([\*\*]).

Following completion of the screening assessments subjects who satisfy the study entry criteria will be randomised to one of the two treatment groups and will receive medication on Day 0. Subjects will be split into at least [\*\*] cohorts for dosing. The time between dosing each cohort may be at least [\*\*] weeks; it may therefore take [\*\*] weeks to complete dosing of all subjects. The size of the cohorts will be governed by the number of [\*\*] samples that can be processed on one occasion. In each cohort some subjects will receive vaccine and some will receive placebo. The vaccine will be nominal dose of [\*\*] typhoid vaccine administered in [\*\*] of presentation solution. Placebo will also be administered in [\*\*] of presentation solution. Vaccine will be prepared in the pharmacy and administered to the subjects within [\*\*] minutes of preparation.

Subjects will return to the investigative site on study Days [\*\*] for assessment of safety and immunogenicity and to provide blood, urine and stool samples as required. Subjects will record their temperatures on a Diary Card for the first [\*\*] days following dosing and will return to the clinic for additional visits should they develop fever.

Evaluation of safety. Responsibility for the clinical investigators ([\*\*]).

The primary safety endpoints for the study are the proportion of subjects:

reporting adverse events during the study, particularly a fever of more than [\*\*]° C, attributable to the study medication.

The secondary safety endpoints are the proportion of subjects:

- withdrawn from the study due to adverse events, including bacteraemia attributed to study medication
- demonstrating bacteraemia, attributable to the study medication
- demonstrating persistent faecal shedding ([\*\*]) of S. typhi (Ty2 aroC ssaV ) ZH9, in stools
- with changes in laboratory parameters from Day 0 to post treatment which are considered clinically significant
- Completion of immunoassays. Responsibility of the clinical investigators ([\*\*]).

As in previous studies in the UK and US, immunogenicity will be assessed by measuring immune response against *S. typhi* lipopolysaccharide (LPS); using the [\*\*] to measure numbers of circulating antibody secreting cells producing anti-LPS IgA, and an ELISA assay to measure serum IgG response against LPS. Subjects will be considered to have an immune response if they achieve the following: a [\*\*].

[\*\*]. ELISA assays will be performed on frozen serum samples. It is anticipated that data from the pivotal immunoassays, [\*\*] to detect secretory IgA against LPS and ELISA to detect serum IgG against LPS, will be available for review within [\*\*] weeks of dosing the first subject.

- Monitoring of study (safety and GCP). Responsibility of Microscience.
- Management and validation of data. Responsibility of Microscience.

Once a full dataset is available from safety assessments and from the pivotal immunoassays, the data will be evaluated by Microscience, the clinical investigators, the regulatory agencies and by the local ethics committee to establish whether it provides adequate confidence to progress to evaluation of safety and immunogenicity in children.

### B. Study to demonstrate safety, tolerability and immunogenicity in Vietnamese children.

This section of the programme will involve a series of age-descending studies. The purpose is to evaluate safety and immunogenicity of the vaccine in children from 5-18 years. Approximately [\*\*] children will be involved, stratified into 2 age groups: 10-18 years, approximately [\*\*] subjects; 5-10 years, approximately [\*\*] subjects.

The studies will be single centre, single-blind, placebo-controlled, randomised studies. The basic study schedules will be as for the adult study shown in Table 12.1.

# Objectives/key tasks for each study

- Dosing. Responsibility of the clinical investigators ([\*\*]).
  - Group 10-18 years it is anticipated that data from the adult study will support the use of the same dose level, [\*\*] dose, and formulation of vaccine as was administered to adults.
  - Group 5-10 years evaluation of safety data from the study in 10-18 year olds will determine whether dose escalation will be required for this study. Dose escalation will require an additional group of subjects who will receive a lower vaccine dose level (likely to be [\*\*]).
- Evaluation of safety. Responsibility of the clinical investigators ([\*\*]).
   As for adult study.
- Completion of Immunoassays. Responsibility of the clinical investigators ([\*\*]).
  - The assays used will be the same as for the adult study.
- Monitoring of study (safety and GCP). Responsibility of Microscience.
- Management and validation of data. Responsibility of Microscience.

Once a full dataset is available from safety assessments and from the pivotal immunoassays, the data will be evaluated to establish whether it is adequate to support entry of children into the phase II field study.

Name of applicant:	[**]

Q13 Detail the commercial opportunities arising from this proposal:

Please refer to the guidance notes before completing. This section should be completed with input from the technology transfer office/group and address the areas outlined below. This section should be no more than 4½ pages.

- (a) Intellectual property and freedom to operate (suggested 11/2 pages)
- (b) Competitive position (suggested 1 page)
- (c) Managing, monitoring and reporting the project (suggested 1/2 page)
- (d) Commercialization strategy (suggested 11/2 pages)

Following appropriate protection of any arising intellectual property, is it intended to publish the findings of this research? o Yes oNo

#### (a) Intellectual property and freedom to operate

The product is a mutated Salmonella bacterium. The ssaV gene and the aroC genes are deleted. The ssaV gene was identified as part of the Salmonella Pathogenicity Island-2 (SPI-2) using Signature Tagged Mutagenesis (STM). Both the method (STM) and the pathogenicity island, including its genes and attenuated mutants, are claimed in WO96/17951. The particular combination of an ssaV mutation with an aroC mutation is claimed in WO00/68261.

Relevant claims relating to this product and directed to genes of the SPI-2 region and attenuated mutants were initially present in WO 96/17951 and WO 00/68261. The major claims As mentioned above, these claims were subsequently filed in divisional applications which have now proceeded to grant in both the US and the EPO. In Europe, the claims provide coverage for particular DNA sequences from *Salmonella* virulence genes; antisense nucleic acids; bacteria having mutations in one or more particular virulence genes (one of these being *ssaV*); virulence genes; promoters of virulence genes; polypeptides; pharmaceutical compositions and methods of identifying compounds which reduce the ability of a microorganism to adapt to a particular environment involving selecting compounds which interfere with the function of a gene covered by the earlier claim. Similar claims have been granted to Microscience and Imperial in the US.

A further European divisional application has also been filed. This divisional application, no. 01205191.8, is also registered in the joint names of Imperial and Microscience. It is at a relatively early stage of prosecution but could, conceivably, provide useful additional peripheral protein in relation to this product. This divisional application is directed to particular DNA sequences isolated from a Salmonella genome and virulence genes containing such DNA; a method of identifying a compound which reduces the ability of a microorganism to adapt to a particular environment, and compounds identified by the method; the use of such a compound in the manufacture of a medicament for treating infection of a host organism with a particular microorganism; molecules which selectively interact with and inhibit a virulence gene; use of such compounds in manufacturing medicaments for treating hosts which have or are susceptible to an infection with the microorganism; mutant bacteria; vaccines and pharmaceutical compositions; methods of making mutant microorganisms; and methods of making a pharmaceutical formulation of a mutant microorganism. Certain claims, eg relating to DNA sequences or to antisense nucleic acids capable of interacting with and inhibiting virulence genes, have had only 'technolocial background' references cited against them in the EPO search report, indicating that at least some of the claimed subject matter is likely to be patentable.

The typhoid vaccine product is also covered by international application no. PCT/GB00/01749. This application has entered a very wide range of national phases. This reflects the number of territories in which typhoid is endemic.

In summary, Microscience has already obtained effective protection for its typhoid vaccine product. Further related protection can also be expected in many territories.

#### b) Competitive position

The principal vaccines for typhoid are currently an injectable purified capsular polysaccharide vaccine ("Vi vaccine") and a live attenuated oral vaccine (Vivotif)

The Vi vaccine has demonstrated 55-74% efficacy and requires re-vaccination every two to three years. Typically for a polysaccharide vaccine the immune response to Vi is age related and it is poorly immunogenic in young children. It is also a T cell independent antigen and so is not able to boost a primary immune response. A Vi-conjugate vaccine is in early development in which Vi is bound to a non-toxic recombinant protein that is antigenically identical to *Pseudomonas aeruginosa* exotoxin A. This has been tested in a field study in Viet Nam but not in a final formulation. However, this is not expected to be a single dose vaccine.

The live oral vaccine was constructed in the pre-molecular biology era. As a consequence, the basis of the attenuation is not fully understood. The vaccination regimen for the US licensed oral vaccine product consists of four doses, one to be taken every other day, which achieves protection in approximately 60 - 70% of recipients.

There is clearly an unmet medical need in the market for a vaccine that can overcome the compliance issues associated with multi-dose vaccines, provide good immunological memory after a single dose and potentially have increased efficacy. Such a vaccine could potentially have a big impact on the control of typhoid in endemic areas and also represent a big improvement for prevention of typhoid to traveller's to those areas.

In terms of other improved vaccines being developed. Avant Immunotherapeutics Inc. and Acambis plc are developing an oral single dose live attenuated typhoid vaccine. Avant were scheduled to commence a Phase I inpatient study (sponsored by NIAID) in 2H 2003. It is not known whether this study was initiated. Acambis have recently decided, for commercial reasons, not to invest further in their vaccine programme and they are seeking to outlicense the vaccine. This vaccine has been in development for some years and product from a commercially viable process has not yet been tested in the clinic.

The advanced product development package associated with the Microscience vaccine represents a real competitive advantage over other products in development.

Vaccines are biologicals, and as such present particular challenges in development as compared to conventional drug products. Unlike small molecules or defined peptides, they are much more difficult to characterize and control, particularly if the product is a whole cell vaccine or complex protein. Because of this, how the product is derived, characterised and manufactured becomes an important part of the product profile. The introduction of changes in product development, for example in the cell banking or manufacturing process are regarded as changes in the product. Therefore, clinical studies may have to be repeated if changes are introduced, particularly if there is no detailed product characterization data to support comparability of products.

One of the driving philosophies behind Microscience has been 'know your product early and be the experts'. This means that prior to any Phase I study, cell banks are established from which the product will be derived, detailed product characterization data are generated, assays are developed for controlling the process and product release and the basis of a robust manufacturing process capable of being commercialized is in place. This has ensured that the product used in the early pre-clinical and clinical studies has essentially the same characteristics as that intended for marketing and that there will be no delays in moving into the later stages of clinical development

In summary it is considered that the Microscience product is the lead improved typhoid vaccine in development. It has been developed under a Company sponsored IND and is now in Phase II development in outpatient studies in the US. The clinical studies have used a product manufactured from a process that is capable of being commercialised and it is delivered in a commercial presentation that is acceptable to regulatory authorities.

Microscience's current target market is both business and leisure travellers from industrialised countries to typhoid risk regions. The US Centres for Disease Control and Prevention (CDC) states that typhoid vaccination is recommended for travellers to areas where there is a recognised risk of exposure to *S.typhi*. It regards risk as greatest to travellers to the Indian subcontinent and other low-income countries (in Asia, Africa and Central and South America)

Q13 Detail the commercial opportunities arising from this proposal (continued):

The market is driven by the number of travellers to the typhoid risk regions. During 2000, there were a total of approximately 40 million visits from the US, Europe and Japan to destinations with a risk of typhoid in Africa, Asia and Central and South America. However, it must be noted that this number has been negatively impacted by world events since then.

However, the greatest need for the vaccine is in the endemic areas themselves. Typhoid fever remains a very significant global health problem with an estimated 17 to 33 million cases occurring worldwide annually resulting in 600,000 deaths throughout the world, virtually all these cases occur in the developing world. In the last few years there has been the worrying development and global spread of bacteria that are resistant to all affordable antibiotics. Over 90% of isolates in Southern Viet Nam are resistant to all first line antibiotics making the need for an effective and affordable vaccine more urgent. There are licensed vaccines available to prevent typhoid fever but these are less than ideal for control of typhoid fever in developing countries.

The current market for typhoid vaccines is about \$100 million in US and Europe and around \$120 million worldwide. Provided its efficacy is superior to existing vaccines, it is well tolerated and it is an oral single dose, Microscience's vaccine should be competitively positioned to gain share in the travellers' market from the existing typhoid vaccines.

# c) Managing, monitoring and reporting the project

The overall management of the project will be the responsibility of Microscience. Microscience has a full time experienced, project manager who leads the existing project team and has been responsible for the development of the oral typhoid vaccine to date. The project team members include experienced development staff from CMC (chemistry manufacturing and control) pre-clinical, regulatory and clinical. The team is further supported by external specialists such as clinical research organisations that handle monitoring, GCP (good clinical practice) compliance and clinical data bases. It is intended that the scientific co-applicants will be integrated into the existing project team and the tasks coordinated through this structure which already has a proven track record in developing this programme. Regular project meetings will be held which will monitor the progress of the project against the project plan and deal with issues as they arise. Project reports will be issues on a monthly basis to the Wellcome Trust in a format to be agreed.

### d) Planned commercial exit

The commercial market for typhoid vaccines is not large and it is difficult for Microscience to justify funding the whole programme required to gain approval of the product, either as a travellers vaccine, or in developing countries, given that the Company has a number of more commercially attractive vaccines in the portfolio. Acambis, who had a similar product in development, recently announced that they are not going to invest further resources in the project because they do not believe that they will generate the required return on investment.

However, Microscience recognises the importance of this vaccine in providing substantial healthcare benefits in the developing world and would like to ensure that if the vaccine is successful, those benefits are delivered.

The route to commercialisation of the vaccine whether it is for travellers or the developing world will involve carrying out a large efficacy study in a country where typhoid is endemic. The STA proposal is critical for taking the first steps in this process and addressing one of the key issues relating to transfer of vaccines from the developed to the developing world, that is whether the safety and immunogenicity profiles will be similar. It will be difficult to obtain further investment into the project until this key question has been answered.

If the vaccine proves to be successful in the stepping stone studies in Viet Nam it should provide leverage for obtaining additional funding, either from commercial or NGO sources.

It is therefore intended to use these data to facilitate interactions with other NGO funding groups in order to provide funding for the Phase III efficacy study that it is intended to initiate in 2006. All studies in Viet Nam will be carried out under a US IND as well as under the appropriate authority in Viet Nam in order that it is possible to eventually submit a Biologics License Application to the FDA for approval of the product in [\*\*]. In parallel, with appropriate funding and technology transfer activities it should also be possible to get the product manufactured and approved in developing countries such as Vietnam where the vaccine has the potential to deliver considerable health care benefits.

	[**]			
Q13 Detail the commercial o	pportunities arising from this p	roposal (continued):		
				61

Name of applicant:	[**]		

#### O14 References

Please give citations in full including titles of papers and all authors.

- 1. Chatfield, S.N., Roberts, M., Li, J-L., Starns, A. and Dougan, G. 1994. The use of live attenuated Salmonella for oral vaccination. In: Recombinant Vaccines in Vaccine Development: Dev. Biol. Stand. Basel, Karger 82, 35-42.
- 2. Tacket, C.O, Sztein, M.B., Losonsky, G.A., Wasserman, S.S., Nataro, J.P., Edelman R., Pickard, D., Dougan, G., Chatfield, S.N. and Levine, M.M. 1997. Safety of live oral *Salmonella typhi* vaccine strains with deletions in *htr*A and *aroC aroD* and immune response in humans. Infect. Immun. 65, (2) p.452-456.
- 3. Shea, J.E, Buezon, C.R, Gleeson C, Mundy R, Holden, D.W. Influence of the Salmonella typhimurium Pathogencity isaland 2 type III secretion system on bacterial growth in the mouse. Infect. Immun. 1999, 67(1): 213-219.
- 4. Hindle Z, Chatfield SN, Phillimore J, Bentley M, Johnson J, Cosgrove CA, Ghaem-Maghami M, Sexton A, Khan M, Brennan FR, Everest P, Wu T, Pickard D, Holden DW, Dougan G, Griffin GE, House D, Santangelo JD, Khan SA, Shea JE, Feldman RG, Lewis DJ Characterization of Salmonella enterica derivatives harboring defined aroC and Salmonella pathogenicity island 2 type III secretion system (ssaV) mutations by immunization of healthy volunteers. Infect. Immun. 2002 Jul:70(7):3457-67..
- 5. Shahid A Khan, Richard Stratford, Tao Wu, Nicola McKelvie, Trevor Bellaby, Zoe Hindle, Katharine A Sinha, Shayne Eltze, Piero Mastronel, Derek Pickard, Gordon Dougan, Steven N Chatfield, Frank R Brennan Salmonella typhi and S. typhimurium derivatives harbouring deletions in aromatic biosynthesis and Salmonella pathogenicity island-2 (SPI-2) genes as vaccines and vectors Vaccine 21 (2003) 538-548
- 6. Kantele, A. Antibody secreting cells in the evaluation of the immunogencicty of an oral vaccine. Vaccine. 1990 (8) 321-326
- Ferreccio. C, Levine. M.M, Rodriguez, H, Contreras. R, Chilean Typhoid Committee.
   J. Infect. Dis 1989 (159) 4 766-769
- 8. Feng-Ying C. Lin, Vo Anh Ho, Phan Van Bay, Hguyen Thi Thanh Thuy, Dolores Brlyla, Tran Cong Thanh, Ha Ba Khiem, Dang Duc Trach and John B. Robbins. The epidemiology of typhoid fever in the Dong Tap Province, Mekong Delta Region of Vietnam. J. Trop. Med. Hyg. 2000 62 (5), 2000 644-648.

Copies of references provided in Appendix D.

# Q15 Research on human participants or human tissue

(a)	Does your project involve the use of human participants or human tissue?	R Yes	£ No
	Please confirm that appropriate informed consent has been/will be obtained for patenting.	R Yes	£ No
	Please confirm that appropriate informed consent has been/will be obtained for commercial use.		
	If yes, please refer to guidance notes. If the project includes studies on patients being cared for by the NHS, please also answer Q16.	R Yes	£ No
(b)	Does your project involve the use of human participants or other human tissue, outside the UK?	R Yes	£ No
	Please confirm that appropriate informed consent has been/will be obtained for patenting.	R Yes	£ No
	Please confirm that appropriate informed consent has been/will be obtained for commercial use.	R Yes	£ No
	If yes, please refer to guidance notes.		
(c)	Does your project involve the use of human embryos requiring a licence from the Human Fertilisation and Embryology Authority (HFEA)?	£ Yes	R No
	If yes, please refer to guidance notes.		
(d)	Does your proposal involve research on gene therapy which requires regulatory approval?	£ Yes	R No
	If yes, please refer to guidance notes.		
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64

(a) in the course of your project, do you propose to use facilities within the National Health Service and/or does your research involve patients being cared for by the NHS?

If yes, please confirm that your project is in accordance with the principles of the Statement of Partnership on Non-Commercial Research and Development in the NHS in England (or the corresponding statements

in Northern Ireland, Scotland and Wales), distributed with Department of Health EL(97)77, dated 27 November 1997 (a link to this site can be found in the associated guidance notes).

N/A
Which NHS provider(s) has agreed to facilitate this research?
N/A

Q17 Experiments on animals		
Do your proposals involve the use of animals or animal tissue?	£ Yes	R No
(a) If yes, do your proposals include procedures to be carried out on animals in the UK which require a Home Office Licence?	£ Yes	R No
If yes, has the Home Secretary granted a Project Licence under the terms and the Animals (Scientific Procedures) Act 1986, authorising the proposed experiments?	£ Yes	£ No
If yes, state the name and address of the licensee, the Project Licence reference number, date of issue and end date.		
N/A		
Do you, or any other researchers associated with the project, hold a Personal Licence under the Animals (Scientific Procedures) Act 1986, permitting the procedures required for the research to be carried out?	£ Yes	£ No
If yes, state Personal Licence Reference Number and name of licence holder.		
N/A		
If no, has an application been made for such a licence?	£ Yes	£ No
Please give a brief explanation, including the date when an application will be made.		
N/A		
(b) Do your proposals involve the use of animals or animal tissue outside the UK?	£ Yes	R No
If yes, give details of the local ethics committee approval that has been sought, relating this approval to the permission which would be required if the resear in the UK.	rch were to b	e conducted
N/A		

- "	ame of applicant:	[**]							
18 A	Access to radiation sources								
a)		h require access to either the y or the European Synchro			ble?			£ Yes	R No
	If yes, please complete th in whole days only.]	e table below, providing de	etails of beam time req	uested and schedul	ing information (ant	icipated usage in da	ys.) [Beam time is con	unted	
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b) Ple	ease justify the station(s) an $N/A$		more than 500 words)	·	Year I	Year 2	Year 3	f Yes	Year 5
b) Ple	ease justify the station(s) an N/A Will the proposed researc	d beam time requested (no	more than 500 words) on source?	· ).	Year I	Year 2	Year 3		

Name	of applicant:	[**]					
Q19	Related appl	ications					
(a)				ne Trust, you should not submit an application to any third party to fund the online that you agree to give the Wellcome Trust exclusivity to consider thi		☑Yes	o No
		3 11			••	N/A	
						oYes	☑ No
(b)	Has this or a r	elated application already l	been submitted (	elsewhere?	N/A		
	If yes, to which	n organization?		N/A			
	If a decision h	as been given, what was the	e result?				
	If a decision h	as not yet been given, when	is a decision exp	pected? (dd/mm/yy)			
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		this time will the principal plicant(s) spend on this project	et? (%)				
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(d)	Will the resea	rch project be undertaken i	n a Wellcome Ti	rust Clinical Research Facility?		☑Yes	o No
	If yes, please specify:		Clinical Resear Vietnam	ch Unit, Hospital for Tropical Diseases, Ho Chi Minh,			
(e)	Will the resear	ch project be undertaken in a	Wellcome Trust	Centre?		oYes	☑ No
If	yes, this applica	ation should be accompanie	d by a letter of s	upport from the Director of the Centre.			
							67

# Q20 Commercial interactions (a) Do any of the scientific applicants hold any directorships, equity holdings, Scientific Advisory Board memberships or consultancy arrangements in companies or other organizations that may have an interest in the results of the proposed research? If yes, please refer to guidance notes, give brief details and provide copies of relevant agreements. [\*\*] (b) Is the proposed research in whole or in part, subject to any agreements with commercial, academic or other organizations?

68

If yes, give details

A consultancy agreement already exists with the International Vaccine Institute (dated 02-12-03) which relates to the project. This was set up in order for Microscience to receive advice on the development of clinical strategy and to establish the field site in Vietnam. This is attached as Appendix E.	e
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Curriculum vitae of pr	rincipal applicant				
This page should be dup	plicated if there is more than one applica	ant/coapplicant/sponsor.			
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Please deta	nology transfer office/group experi ail relevant project management and ploitation of research arising from o	ience deal-making experience of the technology tran ther Wellcome Trust awards (including Univer-	sfer office/group. Give field-specific exam sity Translation Awards).	uples if available, and details of any other ex	xperience gained
N/A					
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Q23	Curriculum vitae of named research assistant(s)			
	This page may be duplicated if more than one research	h assistant is required.		
(a)	Surname:		Date of	
	Forename		Nationality:	
(b)	Degrees, diplomas etc. (subject, class, univers	ity and dates):		
(-)	,,			
(c)	Current post (if not currently in employment, ple Position and	ase give details of most recent post):		
	Institution:			
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	Current basic salary and incremental			
		m any salary enhancements or other allowance		
	If currently funded by a Wellcome Trust grant, p	please give grant reference number:		
(d)	Previous posts (with dates):			
				74

(e)	Recent publications: (List no more than five publications. Please give citation in full, including title of paper and all authors)	
(f)	Please confirm that you have obtained the research assistant's consent to disclose the information provided above in accordance with the principles set out in the Wellcome Trust Data Protection statement which appears on this form. £	
		75

#### Q24 Reasons for support requested

### Please refer to guidance notes before completing this section.

On this page justify (a) the scientific staff requested

The detailed budget is shown in Appendix F.

#### Phase Two Studies at the Hospital for Tropical Diseases

These studies will build on an existing infrastructure at the Hospital for Tropical Diseases and this will help to limit the costs. However, during the duration of the project there will clearly need to be staff that are dedicated to this work. We have therefore requested salaries for two Clinical Investigators, costs for Nursing staff and two technicians, costs to the Ward where this work will be undertaken and costs for the volunteers.

#### Surveillance Studies in [\*\*] Province

The Hospital for Tropical Diseases and the Oxford University-Wellcome Trust Unit, in Viet Nam and the International Vaccine Institute has extensive experience of organizing surveillance studies similar to this. A full time Clinical Epidemiologist based in Viet Nam will be essential in coordinating all aspects of the Surveillance in [\*\*] Province. This individual will split his (her) time between Ho Chi Minh City and [\*\*] Province and ensure that the data is collected and stored appropriately. They will need to be senior enough to take on a considerable degree of responsibility and autonomy. This is the key appointment for this project.

The data management is a crucial point of all epidemiological studies. The IVI has extensive experience in running such projects and that knowledge will be vital to the success of these population based studies. We have requested support for a Data Manager and Statistician.

From previous experience the request for Health Care Workers, Medical Officers, Clinical Investigators, secretarial support etc is the minimum required to undertake surveillance in a population of this size. The numbers and skills of the individuals have been estimated from previous work in Viet Nam and in the region.

#### Q24 Reasons for support requested (continued)

On this page justify (b) Materials and consumables and (c) Equipment and equipment maintenance requested

### Phase Two Studies at the Hospital for Tropical Diseases

a) Materials and consumables.

This has been estimated from similar previous studies.

b) Equipment

This work will build on an existing infrastructure in Viet Nam and therefore there are no equipment costs for the Phase II studies.

#### Surveillance Studies in [\*\*] Province

c) Materials and consumables

[\*\*] will clearly need support for all the consumables required for this project as outlined in the application. This has been estimated from similar previous studies in Viet Nam.

d) Equipment

The collaboration with [\*\*] is clearly critical to this application and will require regular visits to maintain the links. The project will need regular and reliable transport to [\*\*]. We have requested the support for a 4-wheel drive vehicle plus petrol, insurance and driver costs that will allow regular access.

The only reliable way to get around [\*\*] Province to follow up individuals and families recruited into this project is via motorbike. Many of the subjects will live well off the main roads and there is no access by car. [\*\*] but it is not well equipped. [\*\*]. This investment in basic laboratory infrastructure is essential to ensure the highest yield from the blood culture and hence the success of this project.

The project will need to invest in computers and communications both in [\*\*].

# Q24 Reasons for support requested (continued)

On this page justify (d) Miscellaneous costs requested

### Miscellaneous costs requested

Administrative and office costs are required both in [\*\*].

This is a multiparty project with collaborators in the UK, [\*\*], and two centres in Viet Nam. It is important that there is regular exchange of information by e-mail and the internet but also intermittent face-to-face meetings to ensure full exchange of information.

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### Q24 Reasons for support requested (continued)

On this page justify (e) Use of animals. Address the following:

- (i) Why is animal use necessary? Are there any other possible approaches?
- (ii) Is the species to be used the most appropriate? This is especially important when an animal is being used as a model for a human physiological or pathological condition. Also consider whether the model is an appropriate pharmaceutical industry standard for the investigation.
- (iii) Is the number of animals required to achieve significance in the experimental design appropriate? What are the factors that might affect this? Outline the sample size calculations that have been used to estimate the number of animals required in the proposed experimental design.

N/A

#### Q25 Requests for animal costs

### (a) Animal species

Indicate species of animal used:

 Year 1
 Year 2
 Year 3
 Year 4
 Year 5

Number to be purchased per annum Source of supply and biological quality

Purchase price per animal		Year I	Year 2	Year 3	Year 4	Year 5
(c) Maintenance						
Number of animals to be maintained						
Number of weeks' maintenance required						
Cost per animal per week						
(d) Experimental procedures						
Types of procedure						
Cost per procedure(s)						
Name of applicant:	[**]					
						80

<u>Year 1</u> <u>Year 2</u> <u>Year 3</u> <u>Year 4</u> <u>Year 5</u>

# Q26 Financial details of support requested: Salaries

(a) Non-clinical research assistants (UK only)

POST 1		

Name:							
Level Required (specify on	e, two, three or four):						
Period of funding sought:	From:		to:				
Full-time o Part-time o	If part-time, state percentage of full time:			%			
POST 2							
Name:							
Level Required (specify on	e, two, three or four):						
Period of funding sought:	From:		to:				
Full-time o Part-time o	If part-time, state percentage of full time:		<del></del>	%			
POST 3							
Name:		Grade:			Increme	ntal date:	
Start date:		End date:				ent on grant (%):	
		-					
Commencing salary:	Year 1	Year 2	Year 3		Year 4	Year 5	Total
London Allowance:							
Employer's contributions:							
Sub total							
POST 4							
Name:		Grade:			Increme	ntal date:	
Start date:		End date:				ent on grant (%):	
		-					
Commencing salary:	Year 1	Year 2	Year 3		Year 4	Year 5	Total
London Allowance:							
Employer's contributions:							
%							
Sub total		<del></del>					
(c) Principal investigator(s)	or coapplicant seeking his/her own salary						
POST 5							
Name:			Level (specify	one, two, t	three or four):		
Period of funding sought:		Start date:				End date:	
						<del>-</del>	
Commencing salary:	Year 1	Year 2	Year 3		Year 4	Year 5	Total
London Allowance:							
Employer's contributions:							
%							
Sub total							

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# Q26 Financial details of support requested (continued): Other costs

(d) Research expenses (no inflation allowable for years 2-5)

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Materials and consumables						
(Please give brief description)						
Subtotal						
Animals						
Total purchase price:						
p.a.						
m . 1						
Total maintenance cost:						
Total procedure cost:						
Total procedure cost.						
Subtotal						
Miscellaneous						
Subtotal						
Total						
10tai						
						02
						82

# Q26 Financial details of support requested (continued): Other costs

Equipment and equipment maintenance This page may be duplicated if necessary. Please include costs for access charges and for equipment maintenance for equipment not being requested elsewhere in this grant application. Give contact details for the University's Director of Procurement/Head of Purchasing (or equivalent) Name: Tel: Fax: Address: E-mail: Preferred manufacturer (if known) Cost per Type of equipment Preferred supplier Number Equipment specification Total cost (if known) Total: Signature: Name (in full): (University Head of Procurement) Name of applicant: Wellcome Trust University Translation Award Application 83

[**]	
Q26 FINANCIAL DETAILS OF SUPPORT REQUESTED (CONTINUED):	
(F) REQUEST FOR EQUIPMENT MAINTENANCE AND ACCESS CHARGES (SEE GUIDANCE NOTES)	

Type of equipment/facility for which access, maintenance or upgrade is requested

Original source/duration of funding (provide Trust grant reference number if applicable)

Date of award

Date of purchase

Estimated usage time for applicant and other users

Wellcome Trust University Translation Award Application

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# Q27 SUBJECT CLASSIFICATION

#### (A) SYSTEMS AND PROCESSES

Choose one primary classifier (compulsory) and up to three secondary classifiers

(optional).

Primary: Drug and vaccine Development								
Secondary:	Infection							
	Immune system							

# (B) DISEASE

Choose one primary classifier (compulsory) and up to three secondary classifiers

(optional).

Primary: Bacterial					
Secondary:	Typhoid				

### (C) DISCIPLINE

Choose one primary classifier (compulsory) and up to three secondary classifiers (optional).

Primary: Clinical Research

Secondary: Immunology

Microbiology

# (D) TECHNIQUE

Choose up to three classifiers (optional).

N/A

## (E) OTHER IDENTIFIER

N/A

Choose up to six classifiers (optional).

(f) Check relevant subject classification box
Basic o

Wellcome Trust University Translation Award Application

#### 2.3 Updated Objective Schedule

#### Objective 1

#### Preparation, conduct and completion of a Phase II clinical trial in Viet Nam in healthy adult volunteers

The clinical programme will involve Vietnamese subjects of a broad age range (approximately 30–5 years) and will be run as a series of age-descending studies as it will be important to demonstrate that the vaccine is safe when administered to adults and adolescents prior to administering it to children. Volunteers will be stratified into three different age brackets: adults (18–30 years); older children (10–18 years); young children (5–10 years). The initial clinical trial will focus on healthy adults.

#### Clinical Trial synopsis:

The purpose of the study is to evaluate the immunogenicity and safety of [\*\*]S. typhi (Ty2 aroC ssaV) ZH9 oral typhoid vaccine in approximately [\*\*] healthy adult volunteers (age 18 – 30 years inclusive) from Viet Nam. The study will be a single centre, single-blind, placebo-controlled, randomised study. The study schedule is shown in Table 12.1. The study design will be such that there will be two groups of subjects. Group 1 will receive vaccine and Group 2 will receive placebo.

Table 12.1 Study schedule for study in healthy adult volunteers

Visit	Screen	1	2	3	4	5	6
Day	-28 to -2	0	1	7	10	14	28
Day [**]	[**]						
[**]	[**]	[**]					
[**]	[**]	[**]					
[**]	[**]						
[**]	[**]						[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]						
[**]		[**]					
[**]		[**]		[**]			
[**]			[**]	[**]	[**]	[**]	
[**]		[**]	[**]	[**]	[**]	[**]	[**]
[**]		[**]	[**]	[**]	[**]	[**]	[**]
[**]		[**]					
[**]							
[**]	[**]	[**]		[**]		[**]	[**]
[**]	[**]	[**]					[**]
[**]	[**]	[**]		[**]			
[**]	[**]	[**]		[**]	[**]		
[**]							
[**]		[**]		[**]			
[**]		[**]				[**]	[**]

Following completion of the screening assessment subjects who satisfy the study entry criteria will be randomised to one of the two treatment groups and will receive medication on Day 0. Subjects will be split into at least [\*\*] cohorts for dosing. The time between dosing each cohort may be at least [\*\*] weeks; it may therefore take [\*\*] weeks to complete dosing of all subjects. The size of the cohorts will be governed by the number of [\*\*] samples that can be processed on one occasion. In each cohort some

subjects will receive vaccine and some will receive placebo. The vaccine will be a nominal dose of [\*\*] typhoid vaccine administered in [\*\*] of presentation solution. Placebo will also be administered in [\*\*] of presentation solution. Vaccine will be prepared in the pharmacy and administered to the subjects within [\*\*] minutes of preparation.

Subjects will return to the investigative site on study Days [\*\*] for assessment of safety and immunogenicity and to provide blood, urine and stool samples as required. Subjects will record their temperatures on a Diary Card for the first [\*\*] days following dosing and will return to the clinic for additional visits should they develop fever.

The primary safety endpoints for the study are the proportion of subjects:

• reporting adverse events during the study, particularity a fever of more than [\*\*]° C, attributable to the study medication.

The secondary safety endpoints are the proportion of subjects:

- withdrawn from the study due to adverse events, including bacteraemia attributed to study medication.
- demonstrating bacteraemia, attributable to the study medication
- demonstrating persistent faecal shedding ([\*\*]) of S. typhi (Ty2 aroC ssaV) ZH9, in stools
- with changes in laboratory parameters from Day 0 to post treatment which are considered clinically significant

As in previous studies in the UK and US, immunogenicity will be assessed by measuring immune responses against *S. typhi* lipopolysaccharide (LPS); using the [\*\*] to measure numbers of circulating antibody secreting cells producing anti-LPS IgA, and an ELISA assay to measure serum IgG response against LPS. Subjects will be considered to have an immune response if they achieve the following: a [\*\*]. ELISA assays will be performed on frozen serum samples. It is anticipated that data from the pivotal immunoassays, [\*\*] to detect secretory IgA against LPS and ELISA to detect serum IgG against LPS, will be available for review within [\*\*] weeks of dosing the first subject.

Once a full dataset is available from safety assessments and from the pivotal immunoassays, the data will be evaluated by Microscience, the clinical investigators, the regulatory agencies and by the local ethics committee to establish whether it provides adequate confidence to progress to evaluation of safety and immunogenicity in children.

### Objectives/key tasks/responsibilities:

- Identification of site: Responsibility of the clinical investigators [\*\*]. It is important that phase II safety and immunogenicity data is generated in subjects representative of the target population for the field study. It is therefore intended that a number of the phase II studies will be performed in the endemic region in the Mekong Delta. However, at least the first study, in adult volunteers, will be undertaken under well-controlled conditions at the Oxford University Clinical Research Unit at the Hospital of Tropical Diseases in Ho Chi Minh City. This will ensure that technology is transferred, staff are trained and the regulatory approval process is undertaken as efficiently as possible, prior to moving the programme into the endemic region. Once vaccine safety has been adequately demonstrated in this study approval will be sought to perform subsequent studies in the endemic region.
- Clinical protocol development: The protocol will be owned by Microscience but developed jointly by Microscience and the clinical investigators ([\*\*]).
- Regulatory approval: Microscience will be responsible for obtaining regulatory approval for the clinical study. Approval will be sought from both the Vietnamese and US regulatory
  agencies, as it is intended that the clinical programme will be performed under the existing US IND that is held for this product by Microscience.
- Local ethics approval: The clinical investigators ([\*\*]) will be responsible for obtaining ethics approval from the local Independent Review Board (IRB). Microscience and the clinical investigators ([\*\*]) will be responsible for preparing the documentation required for submission.
- Assay transfer: Assay transfer from Microscience to the Hospital for Tropical Diseases is the responsibility of both parties and is expected to take 1 month. The immunoassays being
  used for these studies have been standardised at Microscience. Assay transfer will ensure that assay performance is comparable at the Hospital for Tropical Diseases, at Microscience
  and in previous clinical studies. The process involves performing the assays multiple times using reference samples. Transfer will be considered successful once an analyst has
  performed a pre-defined number of assays that have each met the validity criteria.
- Manufacture and release of clinical material: Responsibility of Microscience. The clinical material will be vaccine, placebo and [\*\*], manufactured to cGMP. [\*\*]

It is anticipated that existing batches of vaccine, placebo and [\*\*] will be used for the adult study; only packaging and labelling will be required for this study. Following review of packaging and labelling batch records and receipt of regulatory and ethics approval, the material will be released by Microscience for use in the clinic.

- Screening and recruitment of subjects: Responsibility of the clinical investigators ([\*\*]). To begin once regulatory and ethics approval have been obtained. For each subject screening has to occur within 28 days of dosing. All efforts will be put in place to obtain written consent that is informed and given voluntarily as described in Appendix C.
- Dosing: Responsibility of the clinical investigators ([\*\*])
- Evaluation of safety: Responsibility of the clinical investigators ([\*\*]).
- Completion of immunoassays: Responsibility of the clinical investigators ([\*\*]).
- Monitoring of study (safety and GCP): Responsibility of Microscience.
- Management and validation of data: Responsibility of Microscience.

#### Objective 2

Preparation, conduct and completion of two Phase II clinical trials to demonstrate safety, tolerability and immunogenicity in Vietnamese adolescents and children living in an endemic region

Following completion of the adult study in a non-endemic region, this section of the programme will involve a series of age-descending studies. The purpose is to evaluate safety and immunogenicity of the vaccine in children and adolescents from 5-18 years. Approximately [\*\*] children will be involved, stratified into two age groups: 10–18 years, approximately [\*\*] subjects; 5–10 years, approximately [\*\*] subjects. The vaccine will be administered initially to adolescents and then to children. These studies will be conducted in the endemic area that will be selected as a potential site for the phase III efficacy study.

The studies will be single centre, single-blind, placebo-controlled, randomised studies. The basic study schedules will be as for the adult study shown in Table 12.1.

#### Objectives/key tasks for each study

- New batches of vaccine and placebo will be manufactured in 2005 for the studies in children. Following packaging and labelling, review of the manufacturing batch records and receipt of regulatory and ethics approval, the material will be released by Microscience for use in the clinic.
- Dosing. Responsibility of the clinical investigators ([\*\*]). Group 10–18 years it is anticipated that data from the adult study will support the use of the same dose level, [\*\*] nominal dose, and formulation of vaccine as was administered to adults.
  - Group 5-10 years evaluation of safety data from the study in 10-18 year olds will determine whether dose escalation will be required for this study. Dose escalation will require and additional group of subjects who will receive a lower vaccine dose level (likely to be [\*\*]).
- Evaluation of safety. Responsibility of the clinical investigators ([\*\*]). As for adult study.
- Completion of immunoassays. Responsibility of the clinical investigators ([\*\*]). The assays used will be the same as for the adult study.
- Monitoring of study (safety and GCP). Responsibility of Microscience.
- Management and validation of data. Responsibility of Microscience.

Once a full dataset is available from safety assessments and from the pivotal immunoassays, the data will be evaluated to establish whether it is adequate to support entry of children into the phase III field study.

#### Objective 3

#### Preparation of field site for Phase III study

The activities listed below, necessary for the completion of Objective 3, will not commence until adequate funding of the phase III clinical development programme has been secured, likely either through a commercial collaboration with a pharmaceutical partner or through an NGO collaboration.

#### Objectives/key tasks

• Identification of site. [\*\*] will have joint responsibility. The decision as to which area will be the site for the efficacy study and therefore for surveillance will be based on known levels of incidence as defined by current government statistics, predicted levels of incidence and the ease with which the required infrastructure can be put in place. The site will be in the Mekong Delta region of Viet Nam. This area has been chosen because population based surveillance studies for typhoid fever have previously been carried out in this region in 1995/1996. (8) It was found that the incidence level was high (overall it was 198 per 105 of the general population). The highest attack rate was among the 5-9 year olds and lowest in the >30 year olds. It was concluded from these studies that typhoid fever is highly endemic in Viet Nam and is a significant disease in both pre-school and school aged children. A region in the Mekong Delta ([\*\*]) has been selected for this proposal.

A typhoid surveillance study will be conducted in the proposed field-site and data will be collected for at least one year prior to phase III immunication commencing and will continue throughout the duration of the efficacy study. The end-point of the pre-study surveillance will be a rate of incidence of typhoid fever in the study population. These data will be used to determine the number of subjects to be entered into the phase III efficacy study.

- Establishment of infrastructure. [\*\*] will have joint responsibility.
- Perform Census. [\*\*] will have joint responsibility.

A census will be performed in the study area. [\*\*]. Each of these households and each individual residing in the household is given a unique identification number (ID#), which is used for all interactions that occur as part of the study. ID numbers will be allocated based on the serial number of the census form, and the sequential order within each household. The aims of the census will be as follows:

- To assign a unique study number to each household
- To assign a unique study identification number to each individual resident in the household
- To obtain base-line data on socio-economic status, health seeking behaviour, prior typhoid vaccine usage and potential typhoid risk factors
- To provide the household members with information on the project
- Establish and provide training in diagnostic tools. [\*\*] will have joint responsibility.

• Disease surveillance. [\*\*] will have joint responsibility.

The surveillance system will rely on patients attending existing healthcare facilities in the endemic region (government health care facilities and participating private healthcare physicians). This healthcare facility-basedpassive surveillance system will be aimed at detecting the majority of reported cases of typhoid fever among study participants seeking medical care. Medical personnel will interview, examine, and obtain a venous blood specimen for laboratory investigation from all patients living in the study area with [\*\*].

All relevant clinical information will be recorded using standard procedures and will include; date and time of examination; name; study ID number; age and gender; full address; name of head of household; number of days since disease began; symptoms and signs of the disease. The venous blood sample will be taken to identify the presence of S. *typhi* by blood culture. Serum will also be taken for typhoid fever serological assays.

Typhoid fever proven cases will be given antibiotic treatment as appropriate. It is anticipated that S. typhi resistance patterns will be monitored regularly throughout the study.

A crucial feature of the surveillance programme will be the accurate identification of all patients attending healthcare facilities, who are study participants. To accomplish this, each clinical supervisor will attempt to identify patient ID numbers using a computer search programme (for names, age ranges, dates of birth, sex, names of the head of households).

Additionally, all culture-proven cases and positive serological cases will be visited at home to confirm the identification of the patient; to assess clinical progress; to assess any typhoid fever-related disability; to determine typhoid carrier status and to apply a verbal autopsy when needed.

Culture-proven typhoid fever cases will be visited [\*\*] after onset of illness. Follow-up questionnaires will be completed at each visit. Stool samples will also be collected at the end of the post-immunization [\*\*] year follow-up on all typhoid fever cases during a home visit, with the aim of identifying typhoid carriers.

# 2.4 Updated Budget

Appendix F Summary of Costs

	US \$	GB £∗
Phase II clinical studies Viet Nam	[**]	[**]
Personnel costs (research fellow, data manager)	[**]	[**]
Manufacturing costs	[**]	[**]
Surveillance	[**]	[**]
Microscience resource costs	[**]	[**]
*Exchange Rate 1GBP = 1.65US\$		
TOTAL	[**]	[**]

### Objective 1:

Preparation, conduct and completion of phase II adult study in Ho Chi Minh City

# Objective 2:

Preparation, conduct and completion of phase II adolescent and children's studies in endemic area Manufacturing additional phase II clinical trial material for adolescent and children's studies

# Objective 3:

Preparation of field site for phase III study

Start of objective 3 activities flexible, dependent on partnering / further NGO funding

#### Schedule 3

### **Background Intellectual Property**

Background Intellectual Property – some of the Background Intellectual Property is jointly owned with Imperial College Innovations Limited but, as between Imperial College Innovations Limited and Microscience Limited, Microscience Limited has the sole right to grant further licences of such Background Intellectual Property

"Identification of Genes"
 Patent application WO 96/17951

2. "Attenuated Microorganisms for the Treatment of Infection" Patent Application WO 00/68261

The Background Intellectual Property is subject to the following Encumbrances:

- 1. A loan note facility dated 6th October 2004 provided by the existing investment syndicate to Microscience to fund the working capital requirements of the group pending agreement of a series C financing round; and
- 2. Fixed and floating charges over all Microscience assets, including the rights and benefits of this Agreement, in favour of the holders of loan notes to secure loan notes provided under a loan note agreement dated 6th October 2004.

#### Schedule 4 Microscience Territory

Australia

New Zealand

Canada

European Union (including any new member states that join the European Union while this Agreement is in force, provided that if any such new member state of the European Union has become part of the Trust Territory by virtue of the provisions of Clause 10 before it becomes part of the European Union, that member state shall not become part of the Microscience Territory)

European Free Trade Area (EFTA)

Japan

Norway

United States of America

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# Schedule 5

# **Microscience Option Territory**

All countries, dominions, protectorates, colonies and other territories of the world not set out in Schedule 4.

# Schedule 6 Press Release and Statement

# **Microscience Press Release**

### Microscience PLC

# Wellcome Trust makes £1.95 Million Programme Related Investment to Advance Microscience's Phase II Typhoid Vaccine Programme in South East Asia

Wokingham, UK, [Date]: Microscience PLC announces that it has been awarded a Wellcome Trust Strategic Translation Award (STA) of £1.95 million to advance the clinical development of Microscience's drinkable typhoid vaccine programme. This is the largest single STA ever made by the Wellcome Trust.

Wellcome Trust STAs aim to provide vital financial bridging for important healthcare programmes and are awarded to researchers in fields of strategic importance to the Wellcome Trust and that address major unmet healthcare needs. The Microscience single-dose drinkable vaccine targets a significant medical need for both travellers to typhoid-endemic areas and the endemic population in large areas of the developing world.

Beginning in early 2005, Microscience, with this financial support from the Wellcome Trust, will undertake the next stage of the Phase II clinical development programme of its oral typhoid vaccine, set up a surveillance programme to determine demographics and disease prevalence in the region and prepare the field-site for the Phase III efficacy study. As the incidence of disease in typhoid endemic regions tends to be the most prevalent in children, this population will form a key element of the Phase III efficacy study.

The programme will be undertaken in conjunction with the Hospital for Tropical Diseases in Ho Chi Minh City, Viet Nam and Oxford University, UK. This long-standing collaboration focusing on infectious diseases important in Viet Nam has been funded by the Wellcome Trust since 1991.

The first study will evaluate safety and immunogenicity in adult volunteers in a controlled setting in Ho Chi Minh City and is planned to commence during the first half of 2005. Following the completion of this study, a series of age-descending Phase II studies will be carried out prior to the large-scale Phase III field study.

Previous trials with this drinkable vaccine in over 100 subjects in the US and UK showed it to be highly immunogenic at a single dose with a good safety profile.

Rod Richards, Chief Executive Officer of Microscience, commented:

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"The sizeable grant awarded to Microscience by the Wellcome Trust is a clear recognition of the need for a new and effective typhoid vaccine and a significant endorsement of our proprietary approach. The STA investment and collaboration gives us the momentum needed to move into large-scale field studies. It will enable us to pursue a clear path to commercialisation for our typhoid vaccine, with the potential to address healthcare needs to both tourists and business travellers from Europe and North America as well as the needs of the developing world."

Dr. Jeremy Farrar, Director of the Oxford University-Wellcome Trust Clinical Research Unit in Viet Nam, said: "Typhoid is almost untreatable in parts of Viet Nam because of drug resistance. Therefore an easy-to-use vaccine like this could be of tremendous value in preventing infection in parts of the world where typhoid remains such an important disease."

Dr Ted Bianco, Director of the Wellcome Trust's Technology Transfer Division said: "Our ultimate goal is to translate research into better healthcare and to facilitate the dissemination of new technologies to maximise the benefit to society globally. This vaccine trial is an excellent example of how we can assist in the development of a promising new product with a view to exploring its usefulness in areas beyond the main commercial markets but where the disease is a particular problem."

- Ends -

**Enquiries:** 

Microscience + 44 (0)118 944 3300

Rod Richards, Chief Executive Officer

Weber Shandwick Square Mile + 44 (0)20 7067 0700

Sarah MacLeod / Yvonne Alexander

Notes to Editors

About Typhoid

Typhoid is caused by the Salmonella typhi bacterium and is transmitted via contaminated drinking water or food. Infection typically causes sustained fever, headache, constipation,

malaise, stomach pains, anorexia and myalgia. In severe cases, patients experience confusion, delirium and intestinal perforation, leading to death in some cases.

According to World Health Organisation estimates, between 17 to 33 million cases of typhoid fever occur annually worldwide. The infection results in approximately 400 travellers returning to the US each year having contracted the disease abroad and in approximately 600,000 deaths annually worldwide, of which 70% occur in Asia.

#### **Current Treatment**

Antibiotics are used to treat the disease and usually lead to recovery commencing within four days. Without antibiotic therapy, the mortality rate is up to 30 per cent. In recent years, strains exhibiting resistance to some of the antibiotics have emerged, driving demand for an effective prophylactic vaccine for travellers to "high-risk" areas. There are currently injectible vaccines available however, there is an unmet need and significant opportunity for an efficacious oral, single dose vaccine that would prevent the need for injection.

### Microscience Drinkable Typhoid Vaccine

The advent of modern molecular biology techniques has led to the identification of several genes that are essential for the *in vivo* growth and survival of the organism. This has provided new gene targets for attenuation, leading to the concept that introducing defined non-reverting mutations into selected genes known to be involved in virulence can 'rationally' attenuate future vaccine strains. This has facilitated the development of improved vaccines, particularly in terms of increasing the immunogenicity and therefore reducing the number of doses that have to be administered.

Microscience's new single-dose, drinkable, typhoid vaccine contains independently attenuating deletions in two genes, *aro*C and *ssa*V. The *aro*C gene encodes chorismate synthase, an enzyme involved in the biosynthesis of aromatic compounds, *aro* mutations are well described as being attenuating for Salmonella in humans. The *ssa*V gene is encoded on Salmonella Pathogenicity Island 2 (SPI-2). SPI-2 encodes a type III secretion system and *ssa*V is a structural gene encoding part of the secretion apparatus. The deletion of the *ssa*V gene prevents the bacteria replicating inside the antigen presenting cell.

The Microscience vaccine stimulates not only a systemic antibody response but also unlike injectible typhoid vaccines stimulates an immune response at the mucosal surface in the gut. This is important as this is the first line of defence following exposure to typhoid.

### Clinical Development to Date

To date, three clinical studies involving over 100 healthy adult volunteers have been conducted. These studies showed the vaccine to be highly immunogenic, generating both systemic and mucosal responses, at a single dose with a good safety profile. In trials it has been administered in a presentation suitable for commercialisation.

# Strategic Translation Awards (STAs)

The WT seek collaborations with industry or academia that can achieve commercialization of new technologies and products. Technology Transfer at the Wellcome Trust proactively seek applications from development scientists conducting research in strategic areas who wish to work in partnership with the Trust to achieve the commercial translation of targeted technologies. Collaborating researchers benefit from access to the Wellcome Trust's considerable expertise and networks.

# B Trust Statement

The safety and immunogenicity of a single dose oral typhoid vaccine in Vietnamese healthy adults and children and identification and preparation of a field site for a Phase III efficacy study.

Typhoid fever remains a major disease of the developing world. There is currently no available affordable vaccine that offers long-term protection after a single dose. Microscience aims to clinically evaluate their vaccine, already tested in studies in the UK and US, in healthy Vietnamese adults and children. In conjunction with the Wellcome Trust programme led by Dr Jeremy Farrar in Vietnam, it is also planned to set up a field site in the Mekong Delta region where future phase II and III studies can be carried out to assess whether the vaccine protects against typhoid fever following natural exposure.

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# <u>DATED June 24, 2005</u>

# THE WELLCOME TRUST LIMITED MICROSCIENCE HOLDINGS PLC

and

# MICROSCIENCE LIMITED

DEED OF ASSIGNMENT AND NOVATION relating to INVESTMENT AGREEMENT RELATING TO MICROSCIENCE HOLDINGS PLC

(logo) Pinsent Masons

### THIS DEED OF NOVATION is made on June 24 2005

### BETWEEN

- 1. **THE WELLCOME TRUST LIMITED** a company incorporated in England and Wales under registration number 2711000 whose registered office is at 215 Euston Road, London NW1 2BE, as trustee of the Wellcome Trust, a charity registered in England under number 210813 (the "**Trust**");
- 2. MICROSCIENCE HOLDINGS PLC a company incorporated in England and Wales under registration number 5106930 whose registered office is at 545 Eskdale Road, Winnersh, Wokingham, Berkshire RG41 5TU ("MS Holdings"); and
- 3. **MICROSCIENCE LIMITED** a company incorporated in England and Wales under registration number 3270465 whose registered office is at 545 Eskdale Road, Winnersh, Wokingham, Berkshire RG41 5TU ("MS Limited");

together the "Parties".

#### WHEREAS:

- A. By an agreement (the "Agreement") dated 18 March 2005 between the Parties, the Trust agreed, inter alia, to make a Programme Related Investment (as defined in the Agreement) by way of subscribing for ordinary shares in MS Holdings and providing further funding to MS Holdings to undertake research and development of MS Holdings' single-dose, oral type typhoid
- B. MS Holdings has agreed to sell its shareholding in MS Limited to a subsidiary of Emergent Biosolutions, Inc. which will mean that MS Holdings is unable to perform its obligations under the Agreement.
- C. In contemplation of the completion of the transaction set out in recital B, MS Holdings has agreed to assign to MS Limited the benefit of the Agreement, subject to the consent of such assignment by the Trust.
- D. Following the completion of the sale of the shares in MS Limited by MS Holdings ("Completion"), MS Limited wishes to perform the Agreement and (subject to this Deed) MS Limited and the Trust have agreed to release MS Holdings from its obligations under the Agreement on and with effect from Completion and the Parties have agreed that with effect from such date the rights and obligations of MS Holdings in relation to the Agreement shall be novated to and assumed by MS Limited in its own right and on its own behalf in substitution for MS Holdings.

### NOW THIS DEED witnesses as follows:

- Assignment by MS Holdings
- .1 MS Holdings assigns to MS Limited with full title guarantee the rights, claims, liberties and full benefit of the Agreement to hold the same unto MS Limited absolutely.
- 1.2 At the request and cost of MS Limited, MS Holdings shall, at all times after the date of this deed, do all acts and execute all documents as may be reasonably necessary or desirable to secure the vesting in MS Limited of the benefit of the Agreement.
- 1.3 The Trust hereby consents to the assignment of the Agreement pursuant to this Clause, and the restriction on assignment contained in clause 20.1 of the Agreement is hereby waived in respect of such assignment.

# 2. Undertaking by MS Limited

Subject to Clause 6, on and with effect from the date of Completion, MS Limited undertakes with the Trust and MS Holdings to perform and accept all obligations and liabilities arising under the Agreement on and with effect from Completion and to be bound by the terms of the Agreement in every way as if MS Limited were named therein in place of MS Holdings.

#### . Release of MS Holdings

Subject to Clause 6, on and with effect from the date of Completion, the Trust releases and discharges MS Holdings from all obligations, claims, liabilities and demands whatever arising under the Agreement on or after the date of Completion and accepts the liability of MS Limited under the Agreement in place of the liability of MS Holdings and agrees to be bound by the terms of the Agreement in every way as if MS Limited was named therein in place of MS Holdings.

#### 4. Intellectual Property Assignment

On and with effect from the date of Completion, MS Holdings hereby assigns with full title guarantee all its rights title and interest in the Project Intellectual Property (as defined in the Agreement) and the Background Intellectual Property (as defined in the Agreement) to MS Limited.

#### . Consequential Amendment

Subject to Clause 6, on and with effect from the date of Completion, as between the Trust and MS Limited and to the extent relevant for the purposes of carrying out their obligations under the Agreement all references in the Agreement to MS Holdings shall with respect to the rights and obligations arising on or after the date of this novation be deemed to be references to MS Limited and all other necessary amendments consequent upon the change of identity of the parties shall be deemed to be made in the Agreement.

### 6. Variation of clause 8 of the Agreement

- 6.1 The amount of £[\*\*] of the First Instalment paid to MS Holdings by the Trust shall be treated as a subscription by the Trust for an additional [\*\*] A ordinary shares in the capital of MS Holdings and accordingly the figure in clause 8.1 of the Agreement of "[\*\*]" shall be and is hereby deleted and replaced with the figure of "[\*\*]" and clause 8.2 of the Agreement shall be deleted and left blank.
- 6.2 MS Holdings will immediately issue and allot to the Trust fully paid an additional [\*\*] A ordinary shares.

# Extent of Novation

Nothing in this deed:

- (a) shall impose on MS Limited any obligations other than those contained in the Agreement or any liability to issue equity to the Trust; or
- (b) relieve MS Holdings from any obligations other than those contained in the Agreement.

# 8. Governing law and jurisdiction

- 8.1 This deed and any disputes or claims arising out or in connection with its subject matter are governed by and construed in accordance with the laws of England.
- 8.2 The parties irrevocably agree that the courts of England have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this deed.

IN WITNESS WHEREOF the Parties hereto have executed and delivered this document as a deed the day and year first above written.

EXECUTED AS A DEED by THE WELLCOME TRUST LIMITED as trustee of the WELLCOME TRUST acting by	) )	/s/ [Illegible] Authorised Signatory	/s/ [Illegible] Authorised Signatory
<b>EXECUTED AS A DEED</b> by <b>MICROSCIENCE HOLDINGS PLC</b> acting by:	)	/s/ [Illegible] Director/Secretary	/s/ [Illegible] Director
EXECUTED AS A DEED by MICROSCIENCE LIMITED acting by:	)	/s/ [Illegible] Director/Secretary	/s/ [Illegible] Director

# STANDARD EMPLOYMENT CONTRACT

This statement sets out the Terms & Conditions of employment between Emergent Europe Limited of 540~545 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire RG41 5TU, UK And Steven N. Chatfield residing at 31 Kenwood Drive, Beckenham, Kent, England BR3 6QX ('the Employee').

#### 1 Position

1.1 President of Emergent Europe Limited reporting to the Chief Executive Officer of Emergent BioSolutions Inc., a Delaware corporation with its offices located at 300 Professional Drive, Gaithersburg, MD, USA, or to such other person as the Chief Executive Officer of Emergent BioSolutions may from time to time appoint.

#### 2. Preconditions

2.1 Your employment with the Company is conditional on (a) your producing at least two references to the Company which the Company considers satisfactory, which has been satisfied, and (b) such documentation as the Company may require to establish your right to work lawfully in the United Kingdom and (c) the company receiving a medical report from its Occupational Health Advisers which the Company considers satisfactory. (Please complete the enclosed pre-employment health questionnaire and return to the Occupational Health Department in the pre-paid envelope provided, your answers will be treated as strictly confidential and you may be required to attend a health interview/ examination) Should you fail to produce to the Company the required documentation, or should the medical report not prove satisfactory to the Company, then any offer of employment by the Company may be withdrawn and if already accepted, the Company may terminate your employment without notice or a payment in lieu of notice (or on statutory minimum notice if applicable).

# 3. Responsibilities

- 3.1 Your normal responsibilities are set out in your written job description but you may be required to perform other reasonable tasks from time to time. (The job description does not have contractual force, but is intended as a guide to your main duties). You may be required to carry out your duties for the benefit of associated companies of the Company, without payment of additional remuneration.
- 3.2 You are required to devote the whole of your time, attention and ability to the Company (or any associated companies for whom you are required to work) and to use your best endeavours to promote, develop and expand the business of the Company and its interests generally. You agree not to have any outside business or other interests which conflict or may conflict with the interests of the Company or any associated Company or which may otherwise interfere with or impede your ability to carry out your responsibilities for the Company, without specific written approval of the Company given in advance.

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- 3.3 You must not act in any way that may be harmful to the Company's interests and/or damages the reputation of the Company.
- 3.4 You are expected to comply with the Company's policies and procedures (as issued and/or amended from time to time), even though these do not form part of your contract of employment. The policies and procedures are available electronically on the Company's systems or from the Administration Office. Failure to comply, may lead to disciplinary action. In the event of a conflict between the terms of this contract and any Company policy, the terms of this contract will apply
- 3.5 You shall not at any time, (including during any period spent on garden leave), make any disparaging, untrue or misleading oral or written statements concerning the business and affairs of the Company or any associated company.

### 4. Duratio

- 4.1 Your employment with the Company commenced as of June 24, 2005 in accordance with the letter agreement between you and Emergent BioSolutions dated September 16, 2005. Your prior period of employment with Emergent BioSolutions counts towards your period of continuous employment.
- 4.2 Subject to clause 19 below, the period of notice required by either party to terminate your employment is six (6) months, or the statutory minimum whichever is the greater. Notice under this sub-clause must be given in writing
- 4.3 Subject to any contrary provision of law, your employment will end automatically without the need for notice of termination to be served, at the end of the month in which you reach the age of 65, which is the Company's normal retirement age.

# 5. Salary

- 5.1 Your gross salary ("Salary") will be One Hundred Forty Nine Thousand Nine Hundred Fourteen Pounds (£149,914) per annum payable by equal monthly instalments directly to your bank or building society account. It is our normal practice to pay Salary on approximately the 24th day of each calendar month. Salary through December 31, 2005 has been paid through Emergent BioSolutions Inc. in U.S. dollars. The above payment schedule for Salary will commence on January 1, 2006. Salary will be accrued on a daily basis. The Company's policy is to calculate daily pay on the basis of a 260 working day year (or in a leap year a 261 working day year).
- 5.2 Salaries are generally reviewed annually each year in the Company's discretion commencing in 2007. Any changes will be notified to you in writing.
- 5.3 The Company reserves the right to deduct from your Salary or from any severance pay due to you on the termination of your employment, any sums owing from you to the Company or any associated company, including but not limited to loans, debts and sums paid to you by mistake or through misrepresentation and you agree to the making of these deductions.

5.4 The Company shall make such Income Tax and National Insurance deductions from your remuneration as shall be required by law

#### Expenses

6.1 You will be reimbursed all out-of-pocket expenses necessarily and properly incurred by you on the business of the Company or any associated company provided you produce to the Company such evidence of actual payment of the expenses concerned as the Company reasonably requires.

#### Hours of Worl

7.1 Your normal hours of work are 09.00 — 17.00 (exclusive of lunch intervals and other breaks) Monday to Friday inclusive, making a total of 35 hours per week. Times of attendance will be agreed with your Manager. You will however be expected to work such extra hours as may be reasonably required for the purpose of completing your tasks efficiently and on time. You agree that the limits on average weekly working time set out in paragraph 4(1) of the Working Time Regulations 1998 will not apply to you. However you may withdraw your consent on giving the Company not less than 3 months' prior written notice. Overtime is only paid in exceptional circumstances and with the written agreement of your Line Manager.

### 8. Mobility and Travel

- 8.1 While the Company's offices in Winnersh, (wherever located there), will be your normal place of work, the Company reserves the right to relocate its operations or open additional sites elsewhere in the UK. If so requested by the Company on not less than one month's notice, you agree to move to a new place of work or the place of work of an associated company, within a radius of 30 miles from Winnersh.
- 8.2 You will undertake any travel either in the UK or overseas as may be necessary to carry out your responsibilities.

#### 9. Holida

- 9.1 Our holiday year runs from 1st January to 31st December. In addition to the normal English Public and Bank Holidays you are entitled to 25 days paid holiday in each holiday year, which accrues at the rate of 25/52 days for each complete calendar week of employment. The Company reserves the right to require you to take up to 3 days of your annual entitlement during the Christmas period.
- 9.2 Your holiday entitlement for the year in which you start or end your employment will be calculated on a pro-rata basis.
- 9.3 Where you have not taken your full accrued holiday entitlement on leaving you will be paid in lieu for your untaken entitlement calculated on a pro-rata basis up to the date of termination of your employment. If you have taken more holiday than your accrued holiday entitlement for that year, you agree that the Company is authorised to deduct the

- value of the excess days from your Salary or from any severance pay due to you on the termination of your employment. The Company reserves the right to require you to take any outstanding holiday leave during a period of notice.
- 9.4 You are entitled to carry forward into the next holiday year a maximum of 5 days holiday which have accrued but which have not been taken before the end of the holiday year. These 5 days must be taken by 31st March of the next holiday year. Any carried forward holiday remaining at this date will lapse. You may not take more than 30 days holiday in any one year.

#### 10. Notification of Absence

- 10.1 If you cannot attend for work you should telephone the Company or arrange for someone to telephone or otherwise deliver a message on your behalf as soon as possible on your first day of absence and indicate when you expect to return to work. If your return to work is delayed you should contact the Company again in the same way on each following day of absence.
- 10.2 If you are prevented by illness or accident from working for seven or more consecutive days you must provide a medical practitioner's statement on the eighth day and weekly thereafter. A self-certification form must be completed and produced to the Company immediately following your return to work for shorter periods of absence.

### 11. Sick Pay

- 11.1 If you are entitled to Statutory Sick Pay ("SSP") the Company will pay it to you.
- 11.2 During absence due to sickness or injury, Company Sick Pay equivalent to your normal Salary, may be paid at the Company's discretion. Statutory Sick Pay will be paid in accordance with the then prevailing rules of the Statutory Sick Pay Scheme.
- 11.3 Full details of the Company Sickness/Absence Policy and Procedure are available electronically on the Company's systems and from the Administration Office.
- 11.4 The Company provides permanent health insurance cover. Full details of this cover (including conditions of eligibility, the rules and benefits to which cover is subject) are available from the Administration Office. The Company reserves the right to arrange equivalent cover through an alternative insurer.

### 12. Pension Scheme

12.1 The Company agrees to contribute 10% of your Salary in equal monthly instalments to an appropriate and qualified personal pension plan nominated by you. This contribution is conditional upon your making monthly contributions equal to 2.5% of your Salary to the said plan. You agree that your contributions to the plan may be made by the Company making the relevant deductions from your Salary and paying the required amount into the plan on your behalf. The said contributions are subject to the rules of the plan as amended

from time to time and will be capped at Inland Revenue limits. No Contracting Out certificate is in force in respect of employment with the Company.

#### 13. Bonus Scheme

13.1 You will be eligible to participate in any bonus scheme the Company establishes from time to time (if at all), for employees of your level, subject to the rules of the scheme. For 2005 you shall be eligible for a bonus (hereinafter, the "Bonus"), which shall be capped at thirty percent (30%) of the portion your salary earned by you during that year, inclusive any salary paid by Emergent BioSolutions. Notwithstanding anything to the contrary contained herein, the determination as to whether any Bonus shall be awarded, and the amount of the Bonus, if any, shall be made in the sole and absolute discretion of the Board of Directors of the Company or Emergent BioSolutions, or such other person or committees as may be delegated that responsibility. The Committee's criteria for awarding any Bonus shall be based on its assessment your job performance and the Company's financial performance during the applicable Period. The relative weight to be given to each such factor shall also be within the Company's sole and absolute discretion. The Company reserves the right to amend, replace or withdraw any such bonus scheme from time to time. Further details are available from the Administration Office. The fact that a bonus is paid in one or more years is no guarantee that bonuses will be paid in subsequent years. As the bonus is also intended to incentivise employees to remain in the employment of the Company, payment of any bonus is conditional on your remaining in the employment of the Company and not being under, or having given, notice to terminate your employment at the date bonus is payable.

#### 14. Life Assurance

14.1 You will become a member of the Company's Life Assurance Scheme when you commence permanent employment subject to meeting any conditions of eligibility and the rules of the Scheme from time to time. (These may require you to pass a medical examination to the satisfaction of the benefit providers as a condition of cover). In the event of death during your employment the sum of four times Salary, subject to the Inland Revenue Earnings Cap from time to time, will be payable.

### 15. Private Medical Cover

15.1 You may join the Company's Private Medical Insurance Scheme at the Company's expense and you may pay for dependants (as defined in the scheme) to be included. The Company reserves the right at any time to arrange equivalent cover through an alternative insurer. The provision of cover (including alternative cover) is conditional on your satisfying any conditions (such as passing a medical examination) and accepting any restriction imposed by the insurer. Details of the scheme in operation are available from the Administration office.

#### 16. Medical Examination

16.1 The Company may reasonably require you to be examined by a Company appointed doctor at its own expense. The doctor may report to the Company and its professional advisers, on your fitness to do your job or other appropriate work. The Company may also require verification from your own GP that you are fit to return to work after a period of absence or sickness incapacity.

### 17. Grievance and Disciplinary Procedures

17.1 The Company's Grievance and Disciplinary procedures can be viewed electronically on the Company's systems and are also available from the Administration Office. It is the Company's policy to deal fairly with disciplinary issues and grievances, which arise, in accordance with these procedures. The Grievance and Disciplinary Procedures do not form part of your contract or otherwise have contractual effect As can be seen if you have a grievance relating to your employment or wish to appeal against disciplinary action or decisions, you should, in the first instance, notify your line manager in writing making it clear that you are raising it formally. If the grievance is against your line manager personally, you should notify your grievance or appeal in writing to a member of the Executive Committee.

# 18 Company Systems

18.1 The Company's e-mail and Internet system must be used for Company and only essential personal use in accordance with the Office Systems Policy which is available electronically on the Company's system and from the Administration office.

### 19 Termination

- 19.1 The Company can dismiss you without prior notice or pay in lieu (and you will not be entitled to damages) for conduct amounting to gross misconduct or any other conduct or performance issues of equivalent seriousness. A non-exhaustive list of the grounds for summary dismissal is contained in the Company's Disciplinary Procedure.
- 19.2 The Company reserves the right to pay you your base Salary in lieu of any unexpired period of notice less income tax and employee NI contributions.
- 19.3 Once notice of termination has been given by either party.
  - (a) the Company may send you on paid leave of absence, suspend you from performing your job and/or exclude you from entering our premises. During your suspension you will continue to receive your Salary and contractual benefits. During your employment or any notice period, the Company may, in its absolute discretion, assign you to different tasks consistent with your position or require you to perform no tasks at all. This may include requiring you to stay at home and to have no contact with the Company's clients, suppliers or employees for part or all of your suspension period. You will continue to receive your Salary and all your contractual benefits during the suspension period Your implied duties of

loyalty and good faith will continue to apply whether or not you are actually working and you may not be engaged or employed by or take up any office or partnership in any other company, firm or business, or trade on your own account without the Company's written permission.

- (b) you must not make any public statements in relation to the Company or your employment or its termination .
- 19.4 At the end of your employment, or earlier if the Company requests, for whatever reason you must return all Company property, including all equipment, documents, computer disks or tapes and all other tangible items in your possession or control belonging to, or containing any confidential information of, the Company or an associated employer.
- 19.5 In the event that as a result of incapacity you became eligible to receive benefits under the Company's permanent health insurance scheme, the Company may, in its discretion, a) continue your employment only to the extent necessary and solely to ensure that you continue to be treated as an employee for the purposes of the permanent health insurance scheme or b) terminate your employment. During such time, you will not be entitled to any remuneration or other benefit from the Company and the Company will have no obligation to continue your employment or provide any work or payment to you, if you recover from the incapacity

### 20 Confidentiality/Inventions

- 20.1 You will, in fulfilling your responsibilities, have access to confidential information relating to the Company or any associated employers and develop knowledge and influence over the Company's suppliers and/or customers and/or be involved in making inventions or creating copyright material. You will be asked to sign a separate Non-Disclosure and Invention Assignment Agreement, which seeks to protect the Company's interests both during and after the termination of your employment.
- 20.2 You shall not, either during or after your employment for whatever reason, divulge or communicate to any person or persons, except authorised members of the Company, or make use of yourself; any Confidential Information relating to the business of the Company or any associated company which may have been disclosed to you or which may otherwise have come to your attention
- 20.3 This restriction shall cease to apply to information or knowledge which comes into the public domain, otherwise than by reason of your default, or which is required to be disclosed by law or by a court or tribunal of competent jurisdiction. Nothing in this Agreement will prevent you making a "protected disclosure" under the Employment Rights Act 1996.
- 'Confidential Information' includes but is not limited to business and marketing plans, customer and price lists, the requirements of customers and potential customers for products and services, management accounts, budgets and other sales or financial data, the terms on which the Company or any associated Companies do business with third parties, details of any pending or threatened litigation, details of confidential and

proprietary computer technology (including source and object codes), any confidential information relating to scientific data, formulae or processes, (including unpublished research and development reports and details of products and services in the course of development).

20.5 In the case of inventions employees must sign a separate claim to inventorship, which is then ratified by the R & D Management Committee or any other similar committee of the Company.

### 21 Statutory Particulars

- 21.1 This contract includes your statutory particulars of employment.
- 21.2 No collective agreements affect your terms and conditions of employment.

### 22 Health & Safety

22.1 You have a legal duty to take reasonable care for the health and safety of yourself and of other persons who may be affected by your acts or omissions at work. You must also cooperate with the Company so that the Company can discharge its statutory obligations. No employee or other person shall intentionally or recklessly interfere with, or misuse, anything that is provided in the interests of health, safety or welfare.

### 23 Miscellaneous

23.1 Any notice to be given pursuant to these terms and conditions must be given in writing and delivered either by courier, by hand, by first class post or by facsimile. Any notice to you will be sent to your last known address or facsimile number or given to you at your place of work and any notice to the Company should be sent to its registered office from time to time. A notice will be deemed to have been served at the time of delivery if sent by courier or by hand, on completion of transmission by the sender if sent by facsimile and 2 clear days after the date of posting if sent by first class post.

### 24 Employee Data

You consent to the Company holding and processing both personal data and sensitive personal data (the latter includes your religious beliefs, your ethnic or racial origin, information relating to your physical or mental health and any unspent criminal convictions), for all purposes relating to your employment. In particular you agree that the Company can hold and process personal and sensitive personal data to: (a) pay and review your remuneration and other benefits; (b) provide and administer any such benefits; (c) determine your fitness to work for the Company or your entitlement to sick pay or maternity or other leave of absence; (d) provide information to the Inland Revenue (or other taxation authorities), the police, other regulatory bodies, the Company's legal advisers and potential purchasers of the Company or any business area in which you work and to any investors or potential investors in the Company; (e) administer and maintain personnel records (including sickness and other absence records); (f) carry out performance reviews, disciplinary or grievance procedures; (g)

give references to future employers; and (h) transfer personal and sensitive personal data concerning you to a country outside the EEA (and, in particular, to the HR department of any associated employer based overseas including in the US, particularly for the purposes of HR administration) and you understand that such countries outside the EEA may not have laws to protect your personal information.

### 25 Choice of Law

25.1 The terms and conditions of your employment are governed and will be construed in accordance with English law and all claims, disputes and proceedings are subject to the exclusive jurisdiction of the English courts

### 26 Definitions

"associated company" or "associated employer" means any company which from time to time is a subsidiary or a holding company of the Company or a subsidiary of such holding company and "subsidiary" and "holding company" have the meanings attributed to them by section 736 of the Companies Act 1985.

any Act or delegated legislation includes any statutory modification or re-enactment of it or the provision referred to.

# 27 Additional Provisions

You acknowledge and agree that the Employment Agreement dated January 3, 2005 between you and Emergent BioSolutions be and it hereby is terminated and superseded by this agreement; provided however, that the obligations, rights and agreements contained in Section 8 (Protection of the Company), Section 9 (Inventions, Improvements and Copyrightable Materials) and Section 12 (Additional Obligations) shall survive and inure to the benefit of Emergent BioSolutions and the Company.

The letter agreement between you and Emergent BioSolutions dated September 16, 2005 shall continue to apply as it relates to the rights, obligations and agreements to serve as Chief Scientific Officer of Emergent BioSolutions during the Transition Period.

You acknowledge and agree that effective November 12, 2005, you resigned as Chief Executive Officer of Emergent ImmunoSolutions Inc.

Please confirm that you accept this appointment on the above Terms and Conditions, by signing the duplicate of this letter and returning it to me as soon as possible

For and on behalf of

Emergent Europe Limited

Signed: /s/ Fuad El-Hibri

Fuad El-Hibri, Chairman of the Board

Date: December 22, 2005

I have read and understood the above terms and accept them.

Signed: /s/ Steven N. Chatfield

Steven N. Chatfield

Date: December 22, 2005

December 2005

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July 11, 2006

Emergent BioSolutions Inc. 300 Professional Drive, Suite 250 Gaithersburg. MD 20879

**t** 301 944 0290 f 301 944 0173 www.emergentbiosolutions.com

Dr. Steven Chatfield 31, Kenwood Drive Beckingham, Kent UNITED KINGDOM

RE: Role of Chief Scientific Officer

Dear Dr. Chatfield:

As you know, your duties as President, Emergent Product Development-UK (formerly Emergent Europe Limited) are and remain as set forth in your employment agreement dated December 22, 2005. However, in addition to your serving as President, Emergent Product Development-UK, you have been appointed as the Chief Scientific Officer (CSO) of Emergent Biosolutions Inc. As of March 1, 2006, the CSO role changed such that the CSO does not have direct management responsibility for any department or group.

In light of the foregoing, you agree in performing your responsibilities as CSO of EBSI that:

- 1. You will spend one week per month in the US and the Maryland corporate offices attending to the duties related to performing your responsibilities as CSO of Emergent BioSolutions Inc.

  These duties and responsibilities are set forth in Attachment 1.
- 2. You will be flexible regarding travel to the US in excess of one week a month on an as-needed basis.
- 3. You will not renew your lease for your Gaithersburg apartment which expires on August 31, 2006 and will no longer receive the monthly \$1,900.00 stipend.
- 4. While you are in the US or elsewhere in the world performing your duties, you will submit business expenses (e.g., hotel, car rental, business meals, etc.) in accordance with the Company's reimbursement policies as they may exist from time to time.

In addition, it is mutually agreed upon that:

- 1. You are not required to relocate your residence to the US.
- 2. You will not be required to repay the first portion of the relocation stipend in the amount of US\$15,000.
- 3. You will no longer receive a per diem payment of \$100.00 for each day that you are in the US on business in fulfilling your CSO responsibilities.
- 4. You have received reimbursement from the Company of all amounts related to the US\$3,000 payment referenced in the penultimate paragraph on page 2 of the September 16, 2005, Letter Agreement.

This letter memorializes the full understanding of the parties relating to your performance of your duties as CSO for Emergent BioSolutions Inc. and supersedes and replaces any and all prior letters, representations, or understandings, oral or written, express or implied with respect thereto, including, without limitation, your September 16, 2006, Letter Agreement. This Letter Agreement shall not modify or amend your Employment Agreement with Emergent Product Development-UK, except it is agreed that the second paragraph of Section 27 is deleted.

Sincerely,

/s/ Paula M. Lazarich

Paula M. Lazarich Vice President, Human Resources

Attachment

Accepted and agreed

This 11th day of July 2006

/s/ S. N. Chatfield

Steven N. Chatfield, Ph.D.

# Chief Scientific Officer Duties and Responsibilities

- 1. Present at scientific conferences and meetings
- 2. Advise CEO, EMC, and Board of Directors on scientific matters and issues
- 3. Assist Business Development in identifying opportunities and assessing them as they arise
- 4. Support corporate interactions in connection with financing and acquisition activities
- 5. Assist scientific advisory panel in achieving their agreed upon objectives
- 6. Assist in patent prosecution matters and other actions to advance intellectual property estate of the Company

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

#### CONSULTING SERVICES AGREEMENT

This Recruiting Services Agreement ("Agreement") is made effective the 1st day of March 2006, by and between EMERGENT BIOSOLUTIONS INC., with offices at 300 Professional Drive, Gaithersburg, Maryland 20879 ("EMERGENT"), and The Hauer Group with offices at 7850 Southdown Road, Alexandria, VA 22308 ("Consultant") (sometimes referred to in the singular as "Party" and collectively as the "Parties").

WHEREAS, EMERGENT is engaged in the production and sale of biopharmaceutical products; and

WHEREAS, Consultant is engaged in the business of providing consulting services as described in this Agreement; and

WHEREAS, EMERGENT desires to engage Consultant directly to provide the services described in this Agreement and Consultant desires to be so engaged.

NOW, THEREFORE, in consideration of the mutual covenants herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be bound, agree as follows:

- 1. **Engagement**. EMERGENT hereby engages Consultant to provide the services specified below as and when requested by EMERGENT, under the terms and conditions of this Agreement and Consultant hereby accepts the engagement to perform such services under such terms and conditions. Without limiting the generality of the foregoing, Consultant shall provide those services as are described more fully in the Scope of Work attached hereto as <u>Exhibit A</u> (the "Services").
- 2. Payment for Services. In payment for the Services, EMERGENT shall pay Consultant as described in the Scope of Work attached hereto as Exhibit A. Invoices for payment shall be submitted to EMERGENT in the month following the month in which the Services are satisfactorily rendered, with such supporting documentation as is acceptable to EMERGENT in its reasonable discretion. In order for invoices to be processed and paid, they must refer to the EMERGENT Accounting Code designated in the Scope of Work attached hereto as Exhibit A. Such payments shall be in full compensation for the Services performed by Consultant unless expressly agreed otherwise in writing by the Parties. Invoices shall be payable within thirty (30) days of receipt by EMERGENT. In the capacity as an independent contractor, representatives of Consultant performing Services hereunder will not receive employee benefits from EMERGENT, including but not limited to paid vacation, sick leave or any insurance benefits, even if such representatives are physically situated at EMERGENT's offices.
- 3. **Expenses**. EMERGENT shall pay for or reimburse Consultant for its out of pocket expenses reasonably incurred in the performance of Services hereunder; provided, however, that expenses shall only be paid for or reimbursed if in compliance with EMERGENT's Travel Policy (attached as <u>Exhibit B</u>) or otherwise expressly authorized in <u>Exhibit A</u> or otherwise in writing by EMERGENT. Consultant shall submit monthly invoices detailing expenses incurred during the immediately preceding month by appropriate category and

shall provide supporting documentation as is acceptable to EMERGENT in its reasonable discretion. It is agreed that expenses shall not be marked up. This Agreement relates to the provision of Services only. In the event Consultant deems it necessary to purchase equipment, goods, software or other tangible or intangible property for which he will seek reimbursement from EMERGENT, no such purchase shall be made and EMERGENT shall not be responsible for reimbursement to Consultant unless Consultant has received EMERGENT's express, prior written authorization.

4. Confidentiality of Information. Consultant acknowledges that this Agreement creates a confidential relationship between Consultant and EMERGENT. Consultant and EMERGENT acknowledge that, in order to perform the Services, it will be necessary for EMERGENT to allow Consultant to have access to certain commercially valuable, proprietary, and confidential information of EMERGENT and its affiliates. Consultant agrees to keep confidential and not, without the prior written consent of EMERGENT, to publish, disclose to any third party or use (except for purposes of performance under this Agreement) any confidential information, in either written, electronic or oral form whether or not marked as "confidential" or "proprietary", and without limitation, any and all information relating to the business, prospective business, technical processes, finances, price lists, customer lists, information relating to the licensing or approval of any of the products, business plans, business prospects, employee information, information regarding facilities, operations and financial condition and results, inventions, improvements, trade secrets, know-how, processes, formulas, methods, assays, data, instrumentation, sales and marketing information, standard operating procedures, clinical trial, clinical trial data, clinical specimens, study protocols, investigators' brochures and instructions or other scientific or technical information, and any documentation and materials specifically developed or prepared for or by Consultant in performance of Services under this Agreement (collectively, the "Confidential Information"). The obligations of this paragraph do not pertain to information which is generally known or hereafter becomes generally known to the public through no fault of Consultant or is disclosed by Consultant with the written approval of EMERGENT. Consultant shall return all such Confidential Information to EMERGENT upon completion of the Services hereunder or upon EMERGENT's request.

If confidential information is sought by any source, including any governmental organization, Consultant must immediately notify EMERGENT of such request and refuse to divulge any such information at least until a representative of EMERGENT is permitted to address the situation and, either consents to the disclosure or has the opportunity to engage legal means to protect the disclosure of such information.

- 5. Authorized Contacts. With respect to the performance of Services, Consultant shall report to Daniel Abdun-Nabi, Senior Vice President, Legal & Corporate Affairs (or such other person that may hold the same position at a later date) or such other person(s) as he may designate from time to time in writing.
  - 6. Reports. Consultant shall make weekly reports together with such reports as EMERGENT may from time to time request.

7. **Ownership of Work**. All right, title, and interest in and to all information which relate to Services provided under this Agreement, shall belong to and be the property of EMERGENT. Consultant agrees, without further payment by EMERGENT, to make any assignments and execute documents as are necessary to effect EMERGENT's title thereto in all countries of the world. Furthermore, all documents and materials prepared by Consultant in the performance of its duties hereunder will constitute works-made-for-hire and shall belong to and be the exclusive property of EMERGENT and shall be surrendered by Consultant to EMERGENT upon request at the termination of this Agreement. Consultant hereby assigns to EMERGENT all rights of copyrights that Consultant has to such documents and materials referred to in this paragraph.

# 8. Term and Termination.

- (a) This Agreement shall become effective as of the date set forth above and shall continue in effect until March 31, 2007 (the "Term") or until this Agreement otherwise terminates under this Section 8.
  - (b) This Agreement shall terminate upon the expiration of the Term or the first to occur of the following events:
    - (i) On the date EMERGENT provides Consultant with written notice (setting out with particularity) that this Agreement is being terminated for "cause". For purposes of this Agreement, Consultant shall be deemed terminated for cause if EMERGENT terminates Consultant after Consultant:
      - (a) shall have committed any act or acts of embezzlement, theft or fraud against EMERGENT;
      - (b) shall have been convicted of a felony or any crime involving moral turpitude, whether or not related to Consultant' Services;
      - (c) shall have committed any act or acts of gross negligence or willful misconduct; or
      - (d) shall have committed a breach of the representations, warranties or covenants contained in Sections 4, 7, 9, 11 or 14 herein.
    - (ii) On the date EMERGENT terminates Consultant's Services for convenience on not less than ten (10) days prior written notice.
    - (iii) On the date Consultant terminates the Services for any reason, provided that Consultant shall give EMERGENT ten (10) days prior written notice.
- (c) Upon termination of this Agreement, EMERGENT shall have no further liability other than for payment in accordance with the terms of this Agreement for Services provided prior to the termination date. If this Agreement is terminated by EMERGENT under Section 8(b)(i)(d), in addition to any other rights or remedies available at law or in equity, Consultant

will surrender any claim for payment under the Agreement and will refund any payments received under this Agreement.

- (d) The provisions of Sections 2, 3, 4, 7, 8, 11(c) (only for twelve months following termination or expiration), 12, 13, 14, and 16 shall survive the expiration or termination of this Agreement for any reason.
  - 9. Representations and Warranties Consultant represents and warrants that:
  - (a) the Services performed hereunder will be performed in a competent, diligent and workmanlike manner consistent with the highest standards of professional conduct;
- (b) all of its personnel that will perform the Services for EMERGENT hereunder shall have been screened for, and shown to be free of, any prior use of illegal drugs or other controlled substances and have been subjected to detailed background checks and shown to be free of any criminal record, other than minor traffic violations and otherwise meet the requirements set form in EXHIBIT C;
- (c) all of its personnel that will perform the Services for EMERGENT hereunder shall be advised of the restrictions and obligations set forth in this Agreement, including without limitation, the requirements of confidentiality (Section 4), compliance with laws (Section 11) and non-solicitation (Section 14); and
- (d) it has full power to enter into and fully perform this Agreement and has the full and unrestricted right to disclose to EMERGENT any information Consultant makes available to EMERGENT under this Agreement.
- 10. **Relationship of Parties**. With respect to the subject matter of this Agreement, the Parties are and remain independent contractors. This Agreement shall not be deemed to create an employer/employee relationship, joint venture, partnership, association, or agency between the Parties. Consultant is not authorized to incur or create any obligation express or implied on behalf of EMERGENT or to bind EMERGENT in any manner whatsoever.
- 11. **Compliance with Laws**. In performing the Services, Consultant shall comply with all applicable existing and future laws, rules and regulations. Consultant covenants and agrees to perform its duties and responsibilities under this Agreement in accordance with the highest standards of ethical business conduct and will not engage in any acts or activities that are illegal or that may adversely affect or reflect upon the business, integrity or goodwill of EMERGENT. Without limiting the generality of the foregoing, Consultant represents, warrants and agrees that:
- (a) Consultant will comply with all applicable existing and future international, federal, state and local laws, rules and regulations, including but not limited to those governing employment practices (including those governing employee recruiting and hiring), anti-bribery and anti-gratuities laws or other similar laws.

- (b) Consultant will comply with all EMERGENT stated policies and procedures applicable to employees operating at EMERGENT's offices, including without limitation, those governing safety, health, harassment, and discrimination.
- (c) At such times as may be requested by EMERGENT, Consultant will certify to EMERGENT in writing that (1) Consultant has complied with all applicable laws, regulations, and EMERGENT's policies and procedures; (2) Consultant does not know or have any reason to believe that any employee, agent, representative or other person retained by Consultant has violated any of the foregoing undertakings; and (3) Consultant will immediately advise EMERGENT if Consultant should learn or have reason to believe that there has been a violation of any of the foregoing undertakings.
- (d) In the event that EMERGENT becomes a publicly traded company on the New York Stock Exchange or NASDAQ, Consultant represents that he may have access to certain material nonpublic information of EMERGENT and will not disclose such information to any third parties as outlined in the Security Exchange Commission ("SEC") regulations. Consultant acknowledges that violation of this provision is called insider trading and is in violation of the SEC laws. "Insider trading" is defined as the purchasing or selling of securities of a company while in the possession of material information that has not been generally disclosed in the marketplace.
- 12. **Indemnification**. Consultant shall hold harmless and indemnify EMERGENT, its employees, agents and representatives, from and against any and all suits, demands, losses, damages, judgments, claims, costs, (including reasonable attorneys' fees and costs) or other liability (including, without limitation personal injury or death) (collectively "Liability"), to the extent that such Liability arises from or is related to the performance of Services under this Agreement or the negligence, act or omission of Consultant or any of its agents or representatives.
- 13. **Arbitration**. All disputes or claims arising under this Agreement which cannot be settled amicably shall be finally resolved by binding arbitration in Bethesda, Maryland before a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association then in effect, and any judgment or arbitral award thereon may be entered and enforced in any court of competent jurisdiction. Each Party shall bear its own costs of arbitration or litigation thereon, including attorneys' fees.
- 14. **Non-Solicitation**. Consultant agrees that, during the term of this Agreement, and for a period of twelve (12) consecutive months after termination of such Agreement, Consultant will not knowingly (i) directly induce or attempt to induce or otherwise counsel, advise, solicit or encourage any employee to leave the employ of EMERGENT or accept employment with Consultant or any other person or entity, (ii) directly induce or attempt to induce or otherwise counsel, advise, solicit or encourage any person who at the time of such inducement, counseling, advice, solicitation or encouragement had left the employ of EMERGENT within the previous six (6) months to accept employment with any person or entity besides EMERGENT or (iii) solicit, interfere with, or endeavor to cause any customer, client, or business partner of EMERGENT to cease or reduce its relationship with EMERGENT or induce or attempt to

induce any such customer, client, or business partner to breach any agreement that such customer, client, or business partner may have with EMERGENT.

15. Force Majeure. Neither Party shall be liable for delay or failure in the performance of any of its obligations under this Agreement if and to the extent such delay or failure is due to circumstances beyond the reasonable control of such Party, including but not limited to fires, floods, explosions, accidents, acts of God, war, riot, strike, lockout or other concerted acts of workers, acts of government and shortages of materials. The Party claiming force majeure shall use its best efforts to eliminate or prevent the cause so as to continue performing its obligations under this Agreement. During such time that the event of force majeure causes such a delay or failure of performance, this Agreement and the Parties' obligations and responsibilities under it shall be deemed suspended until the event of force majeure ceases.

### 16. Miscellaneous Provisions

- (a) Governing Law. This Agreement and its interpretation shall be governed by the laws of the State of Delaware, USA without reference to its conflict of law or choice of law provisions.
- (b) Non-Waiver. No delay by or omission of any Party in exercising any right, power, privilege, or remedy shall impair such right, power, privilege, or remedy or be construed as a waiver thereof.
- (c) Remedies. The rights and remedies provided in this Agreement are cumulative and are not exclusive of other rights or remedies provided by law. Consultant acknowledges that the injury to EMERGENT resulting from any violation by Consultant of any of the covenants contained in this Agreement shall be of such a character that EMERGENT cannot be adequately compensated by money damages and, accordingly, EMERGENT may, in addition to pursuing its other remedies, obtain an injunction from any such violation; and no bond or other security shall be required in connection with such injunction.
- (d) <u>Taxes</u>. Consultant shall be fully responsible for payment of all state and federal income taxes, social security taxes, and for any other taxes or payment which may be due and owing by Consultant as the result of fees or amounts paid to it by EMERGENT under this Agreement, and Consultant shall indemnify and hold harmless EMERGENT from and against any such tax or payment.
- (e) <u>Notices</u>. Any notice hereunder shall be given by first class or express mail, or by facsimile followed by confirmation, addressed to the Parties at the addresses given in the preamble of this Agreement, or to such other address as a Party may later designate in writing to the other Party. Notice given by Consultant to EMERGENT shall be directed to the Vice President, Legal Affairs. Notice given by EMERGENT to Consultant shall be directed to the President of Consultant.

- (f) <u>Use of Name</u>. Neither Party shall use the name, tradename or trademark of the other Party in a press release, advertising, publicity or promotional activity without the prior written consent of the other Party.
- (g) Severability. In the event that any section or any part of a section of this Agreement should be declared void, invalid, or unenforceable by any court of law, for any reason, such a determination shall not render void, invalid, or unenforceable any other section or any part of any other section of this Agreement and the remainder of this Agreement shall remain in full force and effect.
  - (h) Headings. Headings and titles of parts and sections are for convenience only and have no interpretative significance.
  - (i) Successors. This Agreement and the covenants hereof are binding on the Parties and their respective heirs, executors, representatives, trustees, permitted assigns, and successors in interest.
- (j) <u>Assignability</u>. As this is a personal service contract, this Agreement may not be assigned by Consultant without the prior, express written consent of EMERGENT. This Agreement may not be assigned by EMERGENT without the prior, express written consent of Consultant; provided, however, that this Agreement may, without Consultant' written consent, be assigned and transferred to any affiliate of EMERGENT upon such assignee assuming EMERGENT's obligations hereunder, in which event Consultant agrees to continue to perform the duties and obligations according to the terms hereof to or for such assignee or transferee of this Agreement.
- (k) Counterparts. This Agreement may be signed in two identical copies, each of which shall be deemed to be an original copy, and a facsimile copy shall constitute a legally binding, enforceable document
- (l) Integration. This Agreement along with the corresponding Scope of Work constitutes the entire agreement of the Parties, supercedes all prior discussions, negotiations and understandings verbal and written, if any, and may only be amended or modified by a written agreement signed by both Parties. In the event of a conflict between the terms of this Agreement and the terms of any Exhibit or attachment hereto, an EMERGENT purchase order or any Consultant documentation, the terms of this Agreement shall prevail.

(Remainder of page intentionally left blank. Signature page to follow)

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date set forth in the preamble.

C. N.	ALC D	CENT	DIOCOL	LITIONS INC	

THE HAUER GROUP

/s/ Daniel J. Abdun-Nabi

Printed Name: Daniel J. Abdun-Nabi Title: Senior Vice President Legal and Corporate Affairs and General Counsel

/s/ Traci Brown-Hauer

Printed Name: Title: President

# EXHIBIT A

# Scope of Work and Compensation

The Services shall include, without limitation, the following in which Consultant will:

### **Contract Objective:**

To assist Emergent BioSolutions to expand opportunities for BioThrax and its pipeline product candidates.

### Summary of expected activities:

# Strategic Support of Corporate Objectives

- Consultation to CEO and Senior Management on corporate strategic issues
- · General consultation and directed project support to Marketing and Communications Group in the area of public relations including but not limited to:

PRelationship management with targeted media outlets and reporters

PIntroductions to relevant government officials

PIntroductions to potential commercial partners

Other projects as may be directed by the CEO and Senior Management

### Domestic Marketing

- Target audiences:
  - P Senior Leadership and Decision Makers in First Responders Communities in Major Cities in the US (see list below of target cities). [\*\*]
  - P Senior Leadership and Decision Makers in Health Departments in major cities in the US to help support decision makers in the first responder community when making a medical decision surrounding the use of BioThrax,
- Specific activities targeted at these markets include the following:
  - P Contacting individuals within the target audiences, prioritizing and arranging initial meetings/teleconferences with senior leadership and decision makers within the first responder and health department community
  - P As needed and appropriate, attend meetings with member of the sales and marketing team when meeting with these key officials.
  - Þ Provide input and information on senior leadership and decision makers prior to meetings to ensure meeting materials are appropriate and targeted for the individuals
  - Þ 2 to 4 meetings will be arranged per month with target audiences within the target geographic areas.
- Target Cities/Metro Areas (based on geography)

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All Services shall be performed on-site at EMERGENT's offices (as specified in the preamble to this Agreement), unless otherwise directed by EMERGENT.

Compensation: In exchange for the services provided above, EMERGENT shall compensate Consultant at the rate of \$15,000.00 per month.

Agreement Start Date: March 1, 2006

Agreement End Date: March 1, 2007 (unless extended by mutual agreement)

Travel: Parties agree that Consultant may book his own air travel for reservations in business class longer than 2.5 hours of flight time. All other travel will be pursuant to Emergent's Travel Policy (attached as Exhibit B) and all necessary lodging, rental car and other travel reservations shall be made by a Emergent Administrative Assistant and MAY NOT be made directly by Consultant. Emergent will not reimburse for expenses that fail to comply with this process. If airline, lodging, rental car or other travel reservations are to be made in connection with Services provided under this Agreement, it is Consultant's responsibility to contact the Emergent Authorized Contact identified in Section 5 of this Agreement to request that such arrangements be made.

# EXHIBIT B Travel Policy



# EMERGENT BIOSOLUTIONS INC. TRAVEL POLICY AND GUIDELINES FOR NON-EMPLOYEES

The following guidelines apply to Emergent consultants, contractors and other Non-Employees (hereinafter "Non-Employees) seeking payment for or reimbursement of travel expenses. Failure to comply with this policy may result in non-reimbursement of expenses or a delay in reimbursement. Questions regarding this Policy or any travel matter should be directed to the Emergent Travel Administrator, Dee Weller at 301 944 0166.



### 1. TRAVEL APPROVAL

Authorization to travel must be obtained from Emergent Travel Administrator prior to each trip. Authorization to make changes to any existing travel arrangements must be obtained from the Emergent Travel Administrator prior to making the change.

# 2. AIRLINE, HOTEL AND TRAVEL ARRANGEMENTS

Except as noted below, all necessary airline, railroad, lodging, rental car and other travel reservations shall be made by the relevant Emergent Administrative Assistant and may not be made directly by the Non-Employee. Any exception to this requires the approval of the CFO. Emergent will not reimburse for expenses that fail to comply with this process. All changes that need to be made to ticketed reservations must be approved by the Emergent Travel Administrator. Change fees assessed to changes not approved by the Emergent Travel Administrator will not be reimbursed. Any exception to this requires the approval of the CFO.

Non-Employees should notify and immediately return any unused tickets to Emergent's Travel Administrator.

Non-Employees should advise the appropriate Emergent Administrative Assistant of travel priorities to ensure that travel requirements are met at the lowest cost. Please specify all possible times and days of travel as well as alternate airports that may be considered.

Non-Employees should arrange for any necessary car rentals through the Emergent travel management company contract rate in effect at the time.

The Emergent travel management company contract rate for hotel and car rental reservations is meant to be a ceiling price. Weekly, weekend and other unadvertised promotional prices may be in effect at the time of use. Always check for a lower special rate at check in.

# **Airline Reservations**

- Non-Employees will be booked at the lowest air fare, coach class. Upgrading to a higher class of service at the departure airport or before will not be allowed.
- Frequent flyer awards that Non-Employees accrue while on business travel for Emergent belong to Non-Employees provided there is no additional direct or indirect expense to the company.



· Chartering or renting an airplane or private helicopter is not permitted. Personal, leased or rented aircraft may not be used for company business.

# Car rental

- Consultants from the same company and/or consultants visiting Emergent on the same day must share vehicles whenever feasible.
- A car may be rented when business conditions warrant. Rental is limited to midsize vehicles.
- Cars should be returned with a **full tank of gas** to avoid inflated fuel charges unless given other instructions by the rental company. Emergent will not pay for fuel charges resulting from a failure to return a car with a full tank of gas.
- Rental cars should always be inspected for damage before driving them.
- The cost of any insurance covering a rental car or any damage to a rental car is the responsibility of the Non-Employee.
- The company does not expect the use of personal cars for business travel. However, when appropriate, mileage at the effective rate \* (rate is adjusted per IRS guidelines), parking and tolls are reimbursed. Personal cars should only be used for business travel when using a rental car creates unnecessary inconvenience to the employee.
- Damage to a personal car used for company business will be reimbursed if the use was required for business. Reimbursement is limited to the person's personal automobile collision insurance deductible up to \$500, or up to \$500 if no collision insurance is in force. This must be reported to and approved by the CFO.

### **Hotel Reservations**

- Emergent has arranged for special rates at certain hotels. The relevant Emergent Administrative Assistant will reserve rooms for Non-Employees at these hotels. Any exception to this (other than for unavailability) requires the approval of the CFO.
- · Standard rooms will normally be used unless special contract arrangements permit the use of other rooms at minimal or no extra charge.
- All reservations are guaranteed for late arrival. Hotel reservations must be canceled by 4:00 PM on the scheduled day of arrival to avoid a no-show charge being made. Non-Employees are responsible for contacting the hotel by 4:00 PM if cancellation of the room is necessary. Emergent will not pay for no-show charges.
- Hotel shuttle services should be used to/from airports whenever possible. Emergent's travel management team will verify this service. Travel by taxi is permitted where public transportation is unavailable or inappropriate. The



fare and method of payment should always be verified before entering a taxi.

# 3. FOOD & BEVERAGE EXPENSES

- Reasonable expenses for food and beverages consumed while traveling will be reimbursed. Detailed receipts must be turned in on everything. Food and beverage expenses should be directly related to fulfilling business objectives.
- Tear tab receipts are not acceptable.
- A separate receipt for alcohol must be turned in if alcoholic beverages are consumed.
- As a general guideline, meal expenses should generally average out to no more than \$43/day, with certain exceptions based on pricing differences between different geographic regions.
- If a Non-Employee incurs a meal expense for other persons and seeks reimbursement for such additional expense, the business reason for the meal and the list of attendees must be submitted in order for reimbursement to be processed.

# 4. REIMBURSABLE EXPENSES

Listed below are examples of business travel expenses that are reimbursable:

- · Parking fees
- · Toll charges
- Travelers check fees for international travel only
- Business telephone calls
- Reasonable (one per day) personal telephone calls, with a cap of \$5.00 for domestic and \$25.00 for international travel
- Business-related FAX
- Taxi and airport shuttle transportation
- Tips will be reimbursed, up to the amount specified, as follows: 20% for meals, 10% for drivers, \$10.00 per week for maid service, \$3.00 for valet parking, \$5.00 for luggage handling. Anything over these amounts will not be reimbursed.

Listed below are examples of business travel expenses that are not reimbursable:

- Personal charge/credit card annual fees
- Normal dependent-care expenses
- Club membership fees



- Auto repairs on personal cars
- Personal amenities
- · Gifts, flowers, contributions/awards and prizes
- Pet care
- Traffic fines
- Hotel movies
- Clothing

# 5. EXPENSE REPORTING

Requests for expense reimbursement must accompany the Non-Employee's invoice for services. In order for invoices to be processed, they must refer to the applicable EMERGENT Accounting Code, which shall be designated by Emergent.

# 6. RECEIPTS

Receipts are required to support all expenses incurred during travel, other than expenses billed directly to Emergent. Documentation of expenses — such as receipts, paid bills or similar verification sufficient to support an expenditure — is required for all non-direct billed travel expenses. Alcoholic beverages consumed are to be itemized separately.

Examples of acceptable documentation include:

Leased Car

Air Travel
Hotel
Car
Food and Beverage
Entertainment
Other Transportation

Original passenger coupon or invoice
Hotel bill plus proof of payment
Original rental agreement or express return receipt
Itemized receipt only (tear tab receipts are not acceptable)
Itemized receipt only (tear tab receipts are not acceptable)
Taxi/shuttle receipts are required.
All receipts for gas and oil are required, regardless of the amount

If receipts are missing, the Non-Employee must prepare a memo specifying the amount requested for reimbursement and the details. Such memos must be approved by the functional vice president and the CFO. Repeated failure to submit receipts may result in Emergent's refusal to reimburse such expenses.

Receipts for direct-billed expenses must not be submitted to Emergent.



## 7. FOREIGN CURRENCY

Foreign currency expenditures should be converted and shown on each invoice in

U.S. dollars. The exchange rate given at the time the currency was exchanged should be used. If the exact U.S. dollar amount is not available, use the Wall Street Journal exchange rate or the rate of the Currency Exchange Bulletin Board closest to the date(s) of the business event and add a one percent conversion cost.

### 8. TRAVEL ACCIDENT INSURANCE

Non-Employees are not covered by travel accident insurance while they are traveling on behalf of Emergent. Non-Employees must make their own arrangements for travel insurance, which will not be reimbursed by Emergent.

## 9. PASSPORTS, VISAS AND VACCINATIONS

Non-Employees are responsible for determining the proper documentation required whenever traveling outside their country of residence. Attempting to enter another country without proper documentation can result in immediate deportation or imprisonment.

Non-Employees are responsible for determining and obtaining any necessary innoculations required whenever traveling outside the United States.

## 10. EMERGENCY MEDICAL SERVICE

The cost of any emergency medical care is the responsibility of the Non-Employee.

A list of the Emergent Administrative Assistants may be obtained from the Emergent Travel Administrator. Any questions about which Administrative Assistant should assist in making travel arrangements should be directed to the Emergent Travel Administrator.

## **EXHIBIT C**

Background Checks. Company shall perform conviction checks (felonies and misdemeanors) BEFORE the Company employee is sent to EBS's facility if the employee of the Company is assigned to EBS for more than ten (10) consecutive work days or more than thirty (30) work days in any twelve (12) month period. Company shall perform conviction checks every two (2) years for all individuals referred to EBS and for those currently on assignment at EBS's facility. The following guidelines should be used to determine if Company's employee may be sent to work on EBS's

A. Company must exclude an individual from EBS's premises if he/she has ever been convicted of the following types of crime:

Any type of Murder Voluntary Manslaughter Aggravated Assault Assault with a Deadly Weapon Kidnapping

Rape

Sexual Battery or Gross Sexual Imposition

Arson

Robbery

Trafficking in Drugs

B. If Company's employee will deal directly with cash on behalf of EBS or with the authorization of any type of payment, Company must exclude any individual who has ever received a misdemeanor or felony conviction for:

Theft

Embezzlement

Fraud of any kind

- Other than the specific felonies listed in paragraph "A" (which excludes an individual from EBS's premises), Company must exclude any individual convicted of a felony, e.g. Burglary, Unauthorized Criminal Access to Computer Systems, etc., within the last five (5) years.
- D. Company must exclude any individual convicted of a misdemeanor within the last two (2) years. Individuals with convictions for traffic violations do not fall into the exclusion category. Individuals with DUI convictions do not fall into the exclusion category unless he/she will be driving a Company vehicle, or multiple charges exist. Company should contact EBS for clarification if uncertainties exist.

Company must exclude any individual from EBS's premises if he/she meets any of the above guidelines.

Note: Different states may have different names for the above types of crime. For example, some states may refer to "assault with a deadly weapon" as "battery with a dangerous ordnance."

Conviction checks should consist of the following:

DC, MD, VA Residents: Check in the city and county of residence and the city and county of employment.

New to area (resident less than two years): Check in the city and county of former residence. If the individual has moved several times in the past two (2) years, contact EBS for clarification around required checks.

All other locations: Check in the county of residence and the county where individual will be working, via the county Clerk of Courts.

Company shall check all references provided by applicants before sending to EBS and shall not refer anyone who has poor references. EBS is to be made aware of any person being referred who has worked for a company that makes products like EBS's every time this person is referred to EBS, and must agree before the person is sent to EBS's facility.

<u>Prohibition on Controlled Substance Use.</u> EBS prohibits the use, possession, or distribution of any controlled substance or alcoholic beverage by a Company or an employee of the Company on any of EBS's premises. A controlled substance is any drug or drug-like substance whose sale, use, or possession is unlawful, or any prescribed substance used without a prescription. Violators of this policy will be banned from EBS's premises.

The Company shall not permit users of controlled substances to work on EBS's premises. Any employee of the Company who is assigned to EBS for more than thirty (30) work days in any twelve (12) month period or is assigned to EBS for more than ten (10) consecutive work days must be tested before being sent to EBS for the presence of amphetamines, barbiturates, benzodiazepines, cannabinoids (marijuana, THC, hashish), cocaine, opiates (codeine, morphine, oxycodone, hydrocodone), methadone, and phencyclidine (PCP) by a qualified laboratory using initial screening and confirmation of any positive results. A qualified laboratory must follow the standards of the College of American Pathologists, meet any federal, state, and local laws and regulations, and use a cutoff limit within the detection ranges specified in this contract. Any individual who has been tested once but has not worked on EBS's premises for more than the six (6) previous months must be retested in accordance with this paragraph. Company shall retest every two (2) years all individuals referred to EBS and those currently on assignment at EBS's facility.

Anyone who confirms positive for a controlled substance without a legitimate medical reason will not be assigned to work on EBS's premises. Furthermore, the Company will control the work assignments of anyone taking a prescription drug for a legitimate medical reason so the person does not present a safety risk to himself/herself, other personnel, or EBS's property.

A Company must have a written policy on substance abuse to assure compliance with the above criteria.

A qualified laboratory must use a cutoff limit within the detection ranges specified in the table below:

### DRUG DETECTION THRESHOLDS (ng/ml)

Drug, Drug Group or Drug Metabolites	Typical Detection Threshold,ng/ml
Amphetamines	500-1000
Barbiturates	200-300
Benzodiazepines	300
Cannabinoids (marijuana)	15-50
Cocaine metabolites	150-300
Opiates (Codeine, Morphine, Oxycodone, Hydromophone, Hydrocodone)	300
Methadone	300
Phencyclidine (PCP)	25

EBS shall have the right to require confirmation that the conviction checks and drug tests of Paragraphs 16 and 17, above, respectively, have been and are being conducted pursuant to this Agreement. Said confirmation may take the form of an audit which EBS may conduct of Company's records. However, any such audit shall be done at a reasonable time and place and shall not be unduly burdensome on the Company's business operations. Furthermore, any information regarding any of Company's employees or applicants which may be revealed during such audit shall remain confidential.

Working with Bloodborne Pathogen(s). If the Company's employees covered by this agreement are to have assignments in which they could be exposed to bloodborne pathogens, Company acknowledges that EBS requires Company to provide for any training at Company's expense under requirements in Federal Regulation 29 CFR 1910.1030. Furthermore, Company agrees to offer to any such employees who could be exposed to bloodborne pathogens at Company's expense any and all inoculations as may be required under Federal Regulation 29 CFR 1910.1030 and to follow any and all other requirements under said Federal Regulation.

## Health, Safety and Environmental.

- (A) Company shall immediately inform EBS of any credible threat made against anyone on EBS's premises and/or against EBS's property by any of Company's employees. Company is required to communicate any such information of a credible threat to EBS.
- (B) Company agrees that when on EBS's premises, Company and its employees will conform to the requirements of the Plant's/Site's work and safety rules.

The following is also required regarding Health, Safety and Environmental (HS&E) expectations prior to Company's employees or sub-contracted employees beginning work. Company is expected to:

- § Abide by applicable governmental and internal health, safety and environmental requirements.
- § Has a documented and written Health, Safety and Environmental policy and management system (that is reviewed by EBS), and is consistent with the potential risk and scope of work to meet the performance criteria of that system.

- § Employ or cause to be employed only persons who are skilled in the work to be performed and trained in applicable HS&E policies and procedures.
- § Use or provide equipment that is safe to operate and meet governmental requirements.
- § Record work hours and HS&E incidents and report to EBS as requested by EBS. Follow-up to prevent recurrence of incidents.
- § Monitor and evaluate Company's HS&E performance and take corrective action as needed.
- § Provide authorized EBS representatives access to Company's work area(s).

## AMENDED AND RESTATED MARKETING AGREEMENT

THIS AMENDED AND RESTATED MARKETING AGREEMENT (the "Agreement") is made effective this 1st day of January 2000 (the "Effective Date"), by and between BioPort Corporation, a Michigan corporation having its principal office at 3500 N. Martin Luther King, Jr., Blvd., Lansing Michigan 48906 ("BIOPORT") and INTERGEN N.V., a corporation of the Netherlands Antilles, its address being c/o Tarma Trust Management, Castorweg 22-24, Curacao, Netherlands Antilles ("INTERGEN") (BIOPORT and INTERGEN being sometimes referred to in the singular as "Party" and collectively as "Parties").

#### RECITALS

WHEREAS, INTERGEN and Michigan Biologic Products, Inc. ("MBP") entered into a Marketing Agreement, effective November 28, 1997 (the "Marketing Agreement"), whereby INTERGEN agreed to serve as the sole and exclusive marketing agent for certain products in defined territories;

WHEREAS, INTERGEN paid \$60,000 to MBP in consideration of its appointment as an exclusive representative pursuant to the Marketing Agreement;

WHEREAS, INTERGEN and MBP entered into a Consulting Agreement, effective November 28, 1997 (the "Consulting Agreement"), whereby INTERGEN agreed to serve as a consultant to MBP for the sale and promotion of certain products in defined territories;

WHEREAS, INTERGEN paid \$40,000 to MBP in consideration of its appointment as an exclusive representative pursuant to the Consulting Agreement;

WHEREAS, BIOPORT acquired certain assets from the State of Michigan pursuant to Public Act 522 of 1996;

WHEREAS, INTERGEN, MBP and BIOPORT agreed to assign the benefits and obligations of MBP under the Marketing Agreement and the Consulting Agreement to BIOPORT, and INTERGEN received notice of the assignment, and gave consent thereto;

WHEREAS, the Parties deem it desirable and in their mutual interest to restructure their contractual relationships, to terminate the Consulting Agreement, and to amend and restate the Marketing Agreement in its entirety; and

WHEREAS, the Parties have entered into a Termination and Settlement Agreement on even date herewith.

THEREFORE, in consideration of the mutual covenants herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby amend and restate the Marketing Agreement in its entirety as follows:

### AGREEMENT

- For purposes of this Agreement, the terms listed below shall have the meaning ascribed to them in this Section.
  - "Affiliates" when used with respect to any Person shall mean any Person which, directly or indirectly, controls or is controlled by or is under common control with another Person. For purposes of this definition, "control" (including the correlative meanings of the terms "controlled by" and "under common control with"), with respect to any Person, shall mean possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of another Person, whether through the ownership of voting securities or by contract or otherwise
  - "AVA" shall mean anthrax vaccine adsorbed.
  - "Availabilty Date" shall mean the date on which BIOPORT has 100,000 doses of AVA or PBT Vaccine that have (i) been released for distribution by the Food and Drug Administration and the Quality Assurance Department of BIOPORT and (ii) been made available by the U.S. Department of Defense for sale.
  - "BIOPORT" shall mean, for purpose of this Agreement, BIOPORT and any Affiliate or joint venture in which BIOPORT is a participant.
  - "Confidential Information" shall mean information relating to the buss ness, prospective business, technical processes, finances, price lists or lists of customers and suppliers of a Party which is provided to the other Party in connection with this Agreement and is designated as "confidential" or "proprietary" by such Party. Notwithstanding the above, "Confidential Information" shall not include information which (i) was known to the Party receiving the information prior to the date of this Agreement, (ii) has been generally known to others in the trade or business of the Parties, (iii) has been part of public knowledge or the literature otherwise than as a result of any breach of confidence by the Party receiving the information, (iv) has become available to the Party receiving the information from a third party not representing either of the Parties, or (v) has been independently acquired by the Party receiving the information as a result of work carried out by an employee of such Party to whom no disclosure of such information shall have been made.
  - "Dollars" and \$" shall mean dollars in the legal tender of the United States of America.
  - "PBT Vaccine" shall mean the pentavalent botulinum toxoids vaccine
  - "Person" shall mean and includes natural persons, corporations, limited liability companies, limited partnerships, general partnerships, joint stock companies, joint ventures, associations, companies, trusts, lenders, trust companies, -land trusts, business trusts, or other organizations, irrespective of whether they are legal entities, and governments and agencies and political subdivisions thereof
  - "Products" shall mean AVA, the PBT Vaccine, and such other vaccines against any biological warfare threat agent for which BIOPORT may be duly licensed to manufacture or sell, currently or in the future.

"Territory" shall mean all countries of the Middle East and North Africa, except Israel and those countries to which export of AVA or PBT vaccine is prohibited by the U.S. government; provided, however, if such prohibition is subsequently eliminated, then any such country for which the prohibition has been eliminated shall be deemed to be included within the definition of Territory.

"Total Contract Value" shall mean the gross amount promised to be paid to BIOPORT from any Person in the Territory for the purchase of the Products.

### APPOINTMENT

- 2.1 BIOPORT appoints INTERGEN to be its sole and exclusive marketing representative with regard to the sale and promotion of the Products in the Territory. The Parties agree that BIOPORT has the right to retain other representatives for the sale and promotion of the Products in the Territory; provided, however, that such retention shall not limit or relieve the obligation of BIOPORT to pay fees to INTERGEN that may otherwise be due under this Agreement. INTERGEN shall provide services to BIOPORT in accordance with the terms and conditions set out in this Agreement.
- 2.2 The Parties acknowledge and agree that INTERGEN shall have the right to, in its sole discretion, hire such employees, engage such consultants and appoint such agents as it deems appropriate to perform its obligations hereunder. INTERGEN further agrees that such consultants, employees or agents shall be bound by the restrictions of Paragraphs 3.2 and 12 herein.

## 3. DUTIES OF INTERGEN

- .1 Throughout the term of this Agreement, INTERGEN shall perform a variety of marketing and other activities as follows:
  - 3.1.1 Assist BIOPORT with the promotion and sale of the Products throughout the Territory and assist with inquiries or orders received for Products;
  - 3.1.2 Advise BIOPORT on advantageous pricing structures for the Products, from time to time;
  - 3.1.3 Safeguard the property, rights, and interests of BIOPORT and assist BIOPORT in taking all steps to defend the rights of BIOPORT;
  - 3.1.4 Assist BioPort with promptly obtaining and maintaining all licenses, permits and authorizations as may be required from time to time in connection with the supply of the Products to the Territory;
  - 3.1.5 Supply customers and potential customers with (i) such literature as may be commercially prudent for the purpose of promoting sales of the Products within the Territory and (ii) catalogs and such other information that are necessary for proper presentation and solicitation of Product sales;

- 3.1.6 Promptly forward to BIOPORT a duplicate copy of every invoice, communication, letter or opportunity relating to the supply of the Products (directly or indirectly) to Persons in the Territory;
- 3.1.7 Keep BIOPORT informed from time to time as to the market for the Products in the Territory, the prices at which customers and potential customers are prepared to buy the Products, and use its best efforts to give BIOPORT notice of any change in the market price structure for the Products;
- 3.1.8 Take, particularly in light of the preferred customer status to be granted to the U.S. Government in terms of pricing and the Products supplied, all reasonable and necessary steps to ensure that sales of Products to Persons in the Territory will be used for the internal requirements of the Persons acquiring the Products from BIOPORT and such Products are not acquired for purposes of resale or other transfer into the private or foreign public sectors;
- 3.1.9 Take all reasonable and necessary steps to ensure that its sales of Products to Persons inside of the Territory are under terms and conditions that do not undermine other existing or potential sales of Products outside the Territory; and
- 3.1.10 Use its best efforts to sell, at a minimum, 100,000 doses of AVA, in the aggregate, to Persons in the Territory per year, pursuant to orders received by BIOPORT.
- 3.2. INTERGEN shall perform the above-described in accordance with the highest business standards and with its best efforts, and will not perform any acts which will or may reflect adversely upon the business, integrity, or goodwill of BIOPORT. INTERGEN shall not, and shall ensure that its officers, employees and agents do not, make any representation or give any warranty in relation to the Products other than those which are contained in BIOPORT's current printed literature or packaging or which have been specifically previously authorized in writing by BIOPORT. It is understood by the Parties that INTERGEN shall not accept orders or make contracts on behalf of BIOPORT other than subject to confirmation and acceptance in writing by BIOPORT, nor shall INTERGEN incur any liability of whatever nature on behalf of BIOPORT or pledge BIOPORT's credit.

## 4. DUTIES OF BIOPORT

## BIOPORT shall:

- 4.1 Use its best efforts to promptly obtain and maintain all licenses, permits and authorizations as may be required from time to time in connection with the supply of the Products to the Territory;
- 4.2 Supply INTERGEN, at the expense of BIOPORT, with (i) such literature as INTERGEN shall reasonably request from time to time for the purpose of promoting sales of the Products within the Territory and (ii) catalogs and such other information as, in BIOPORT's opinion, are necessary for proper presentation and solicitation of Product sales;

- 4.3 Promptly forward to INTERGEN a duplicate copy of every invoice, communication, letter or opportunity relating to the supply of the Products (directly or indirectly) to Persons in the Territory;
- 4.4 Keep INTERGEN informed as to the Products it has available for sale in the Territory, the prices at which it is prepared to sell the Products, and use its best efforts to give INTERGEN at least three (3) months' advance notice of any proposed change in its price structure;
- 4.5 Permit INTERGEN by nameplate at its office and/or in its letter heading to indicate that INTERGEN is the marketing representative of BIOPORT for the Products in the Territory subject to such indication having been previously approved in writing by BIOPORT (such approval not to be unreasonably withheld or delayed) and provided that such indication shall cease on the expiration or earlier termination of the Agreement (for any cause);
- 4.6 Allow INTERGEN to have access to the relevant books and accounts and records of BIOPORT at all reasonable times so as to ensure that all invoices relating to the supply of the Products to the Territory have been properly recorded;
- 4.7 Take, particularly in light of the preferred customer status to be granted to the U. S. Government in terms of pricing and the Products supplied, all reasonable and necessary steps to ensure that sales of Products to Persons in the Territory will be used for the internal requirements of the Persons acquiring the Products from BIOPORT and such Products are not acquired for purposes of resale or other transfer into the private or foreign public sectors;
- 4.8 Take all reasonable and necessary steps to ensure that its sales of Products to Persons outside of the Territory are under terms and conditions that do not undermine other existing or potential sales of Products within the Territory.
- 4.9 Use its best efforts to supply, at a minimum, 100,000 doses of Anthrax, in the aggregate, to Persons in the Territory per year, pursuant to orders received by BIOPORT; and
- 4.10 Advise INTERGEN, in writing, of all established policies and procedures of BIOPORT by which INTERGEN shall be expected to abide and shall promptly notify INTERGEN, in writing, of any changes to such policies and procedures.

# INDEMNIFICATION

BIOPORT shall unconditionally and irrevocably indemnify and hold harmless INTERGEN, its officers, employees and representatives from all losses (except indirect, incidental or consequential losses), liabilities, claims, demands, expenses, and costs which INTERGEN, its officers, and/or employees may suffer or incur as a direct result of any claim or demand by any third party relating to the Products or any of them-, provided, however, that the indemnity contained in this Subparagraph shall not apply to the extent that any losses, liabilities, claims, demands, expenses, and costs should arise from the gross negligence or willful misconduct of

 $INTERGEN\ its\ officers,\ employees\ or\ representatives,\ and\ provided,\ further,\ that\ INTERGEN\ shall:$ 

- 5.1 At the expense of BIOPORT, render such reasonable assistance to BIOPORT as BIOPORT may require in respect of such claim or demand;
- 5.2 Not make any admissions in respect of such claim or demand or otherwise prejudice the position of BIOPORT in respect of such claim or demand; and
- 5.3 The provisions of this Section shall survive the expiration or earlier termination of this Agreement;

#### 6. COMPENSATION

- 6.1 In compensation for the marketing services provided by INTERGEN and any and all of its subagents under this Agreement, BIOPORT shall pay to INTERGEN a fee for sales of the Products supplied by or on behalf of BIOPORT to any Person in the Territory, regardless of whether the sale was instigated by INTERGEN at forty percent (40%) of Total Contract Value
- 6.2 The fee herein in respect of any Products shall be paid to INTERGEN in Dollars. Upon the payment of any fee, INTERGEN shall deliver to BIOPORT an acknowledgement of receipt therefor.
- 6.3 The fee due hereunder shall be paid to INTERGEN within seven (7) banking days (excluding Saturdays and Sundays and days in which banks in Michigan are authorized or obligated by law to be closed) after payment for the Products has been received by or on behalf of BIOPORT. In the case of BIOPORT's receipt of any partial payment hereunder, BIOPORT's shall pay INTERGEN the fee on a pro rata basis.
- As regards orders for the supply of the Products to Persons within the Territory which are received by BIOPORT during the term of this Agreement but in respect of which payment has not been made to BIOPORT at the expiration or earlier termination of this Agreement, BIOPORT shall pay to INTERGEN (or as INTERGEN shall reasonably direct in writing) fees in accordance herewith in respect of each such order as and when payment has been received by BIOPORT for the Products that are the subject of such order. For any sale of the Products for which contracts are concluded for the benefit of BIOPORT with Persons in the Territory resulting from standing orders, follow-on orders, extensions, or renewals of orders generated by INTERGEN during the term of this Agreement, such sales shall be deemed sales under this Agreement for which INTERGEN shall be paid fees in accordance with the provisions of this Agreement.
- 6.5 In the event that BIOPORT fails to make any payment due under this Agreement to INTERGEN by the due date for such payment, interest shall accrue and be payable on the unpaid amount at the annual rate of five percent (5%) above the prime rate published by <a href="https://doi.org/10.1081/j.com/received-such-payment">The Wall Street Journal (New York edition)</a>) as of the date on which INTERGEN should have received such payment until payment, in full, is received by INTERGEN.

- 6.6 INTERGEN shall be responsible for all out-of-pocket expenses incurred by it in the performance of its duties hereunder.
- 6.7 The Parties agree that INTERGEN may present additional sales opportunities to BIOPORT outside of the Territory on a non-exclusive basis. The Parties, in such an instance, shall negotiate in good faith the compensation due INTERGEN, if any.

### DURATION AND TERMINATION

- 7.1 The term of this Agreement shall commence on the Effective Date and unless previously terminated in accordance with its provisions, this Agreement shall terminate at midnight on the last day of the third (3rd) year from the Availability Date.
- 7.2 This Agreement shall be automatically extended for an additional five (5) year term upon the same terms and conditions if BIOPORT achieves \$5,000,000 of sales in the Territory during the initial three (3) year term of the Agreement. As used in this Section, "sales" means the Total Contract Value of completed orders, orders received but not completed and sales contracts entered into but not fully performed as of the expiration of the three (3) year initial term of this Agreement.
- 7.3 Either Party may terminate this Agreement at any time by notice in writing to the other Party if the other Party commits a material breach of any of the material provisions of this Agreement and falls to remedy the breach within a reasonable time and in any event not less than sixty (60) days from the date of the notice requiring it to do so. If a non-financial breach cannot reasonably be cured, the Parties shall negotiate in good faith for an additional sixty (60) days to attempt to agree upon an alternative performance by the breaching Party or the payment of damages to the non-breaching Party that will constitute a cure and will be deemed to terminate the breach, it being acknowledged that if no such agreement is reached within the additional sixty (60) days. The breach at issue shall be deemed a default and the non-breaching Party may thereafter terminate this Agreement by written notice to the other Party with immediate effect.
- 7.4 In the event that BIOPORT shall not have at least 100,000 doses reasonably available for sale by INTERGEN, the Parties shall negotiate an extension of the term of this Agreement as provided in paragraphs 7.1 and 7.2. The Parties shall not unreasonably withhold consent to such extension.
- 7.5 The termination of this Agreement shall not affect any accrued rights or liabilities of either Party nor shall it affect the coming into force or continuance in force of, any provision of this Agreement which is expressly or impliedly intended to come into or remain in force on or after such termination.

#### 8. DISPUTE RESOLUTION AND GOVERNING LAW

All disputes arising between the Parties shall be finally settled by binding arbitration before a single arbitrator in Lansing, Michigan, in accordance with the Commercial Arbitration Rules of the American Arbitration Association. Any award rendered by the arbitrator shall be final and may be enforced by any court of competent jurisdiction. This Agreement shall be governed by

and construed in accordance with laws of the State of Michigan, excluding any conflicts of law rules that would refer the choice of law to another jurisdiction.

#### 9 NON-SOLICITATION

INTERGEN agrees that during the term of this Agreement, and for a period of twelve (12) consecutive months after termination of such Agreement INTERGEN will not i) directly or indirectly induce or attempt to induce or otherwise counsel, advise, solicit or encourage any employee to leave the employ of BIOPORT or accept employment with any other person or entity, ii) directly or indirectly induce or attempt to induce or otherwise counsel, advise, solicit or encourage any person who at the time of such inducement, counseling, advice, solicitation or encouragement had left the employ of BIOPORT within the previous six (6) months to accept employment with any person or entity besides BIOPORT; and iii) solicit, interfere with, or endeavor to cause any customer, client, or business partner of BIOPORT to cease or reduce its relationship with BIOPORT or induce or attempt to induce any such customer, client, or business partner to breach any agreement that such customer, client, or business partner may have with BIOPORT.

## 10. BIOPORT REPRESENTATIVE

INTERGEN shall take direction and guidance in performing its services hereunder from Robert Bidlingmeyer, Vice President, Marketing of BIOPORT, or such other persons as may be designated from time to time in writing.

#### 11. INDEPENDENT CONTRACTORS

With respect to the subject matter of this Agreement, the Parties are and remain independent contractors. This Agreement shall not be deemed to create a joint venture, partnership, association, or agency between the Parties. INTERGEN is not authorized to incur or create any obligation express or implied on behalf of BIOPORT or to bind BIOPORT in any manner whatsoever. The Parties understand and agree that this Agreement is not a contract of employment, or an offer to enter into a contract of employment. The Parties further agree that INTERGEN shall have sole control of the manner and means of performing the services. BIOPORT shall not have the right to require that INTERGEN or its employees do anything that would jeopardize the relationship of independent contractor between the Parties. INTERGEN shall have the right to appoint and shall be solely responsible for its own workforce, who shall be its own employees.

### 12. COMPLIANCE WITH FOREIGN CORRUPT PRACTICES ACT

INTERGEN, on its own behalf and on behalf of its owners, managers, affiliates, agents and related entities, warrants, represents, and agrees that (i) neither it nor its owners, managers, affiliates, agents or related entities are officials or candidates of any government, governmental agency or instrumentality, or political party, (ii) it is aware of the requirements of applicable law including the U.S. Foreign Corrupt Practices Act ("FCPA") and the legal prohibitions on direct or indirect improper payments or gifts to foreign officials or candidates, (iii) it will comply with all applicable laws including the FCPA, and use no part of the above commissions to make any improper or illegal payments, (iv) it will, upon the Company's request, annually certify such

compliance to the Company, and notify the Company of any relevant change in the status of its owners, managers, affiliates, agents or related entities, (v) it will indemnify the Company and its officers, directors, employees, agents and affiliates for any violation of such laws, (vi) in the event of any such violation, this Agreement will immediately terminate without the need for notice, and (vii) in such event INTERGEN will forfeit any right to any accrued and unpaid commissions and compensation under this Agreement.

#### 13. CONFIDENTIALITY

- 13.1. During the term of this Agreement and for a period of two (2) years following its termination (for whatever cause) or expiration, each Party will keep confidential the terms and conditions of this Agreement (but may acknowledge the existence of the relationship between the Parties) and all Confidential Information received from the other Party and will not use the same but, to the extent necessary to implement the provisions of this Agreement, each Party may disclose the Confidential Information to such of its customers, officers, or employees as may be reasonably necessary or desirable provided that before any such disclosures each Party shall make such persons aware of its obligations of confidentiality under this Agreement and shall at all times use its best efforts to procure compliance by such persons therewith.
- 13.2. Notwithstanding the provisions of Section 11.1, the Parties agree that the terms and conditions of this Agreement may be disclosed to the U.S. Government, including any division of the military, in connection with the negotiation or sale of any of the Products to such entity. In such cases, the Parties shall agree as to the best means of disclosure in order to assure the continued protection of Confidential Information.
- 13.3. Either Party may demand the return of the Confidential Information at any time by notice in writing given to the other Party. On the giving of such notice, the Party served with such notice shall deliver or procure the delivery to the other Party or to its order of each and every original and copy document and thing reproducing, containing, or embodying any Confidential Information

#### 14 FORCE MAJEURI

- 14.1. The obligations of a Party under this Agreement shall be suspended during the period and to the extent that such Party is prevented or hindered from complying therewith by any cause beyond its reasonable control including (insofar as beyond such control but without prejudice to the generality of the foregoing expression) strikes, lock-outs, labor disputes, act of God, war, riot, civil commotion, malicious damage, compliance with any law or governmental order, rule, regulation or direction, accident, breakdown of plant or machinery, fire, flood or storm
- 14.2. In the event of either Party being so hindered or prevented such Party shall give notice of suspension as soon as reasonably practicable to the other Party stating the date and extent of such suspension and the cause thereof and the omission to give such notice shall forfeit the rights of such Party to claim such suspension. Any Party whose obligations have been suspended as aforesaid shall resume the performance of such obligations as soon as reasonably practicable after the removal of the cause and shall so notify the other Party. In the event that such cause continues for more than six (6) months, either Party

may terminate this Agreement upon giving to the other Party not less than sixty (60) days' notice.

### 15. ENTIRE AGREEMENT

This Agreement constitutes the entire understanding between the Parties with respect to the subject matter of this Agreement and supersedes all prior agreements, negotiations and discussions between the Parties relating thereto, with the exception of the Termination and Settlement Agreement entered into of even date herewith.

# 16. AMENDMENTS

No amendment or variation of this Agreement shall be effective unless in writing and signed by a duly authorized representative of each of the Parties.

## 17. HEADINGS

Section headings shall not form part of this Agreement for the purposes of its interpretation.

## 18. ASSIGNMENT

Neither Party shall without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed, assign, transfer, sub-contract, charge, delegate or deal in any other manner with this Agreement or its rights or duties hereunder or part thereof, or purport to do any of the same, except, however, it is agreed that INTERGEN may assign, in whole or in part, its rights and obligations under this Agreement to an Affiliate without obtaining the consent of the Company. In the event that INTERGEN assigns any of its rights and interests to an Affiliate in accordance with this provision, it shall provide the Company with notice of such assignment within a reasonable period of time of such assignment

#### 19 WAIVER

The failure of a Party to exercise or enforce any rights under this Agreement shall not be deemed to be a waiver thereof nor operate so as to bar the exercise or enforcement thereof at any time or times thereafter.

### 20. COUNTERPARTS

This Agreement may be signed in two counterparts, both of which taken together shall constitute one and the same Agreement. Either Party may enter into the Agreement by signing either such counterpart.

## 21. NOTICES

Any notice given under this Agreement shall be in writing and shall be given by delivering the same by hand at, or by sending the same by prepaid first class post (airmail if to an address outside the country of posting) or confirmed facsimile to the address of the relevant Party set out in this Agreement or such other address as either Party may notify to the other from time to time. Notices delivered in accordance with this provision shall be deemed delivered on the day delivered by hand or confirmed facsimile and three (3) days after delivery by prepaid first-class post.

## 22. REMEDIES NOT EXCLUSIVE

No remedy conferred by any of the provisions of this Agreement is intended to be exclusive of any other remedy and each and every remedy shall be cumulative and shall be in addition to every other remedy given under this Agreement or now or hereafter existing in law or in equity or by statute or otherwise.

#### 23 SEVERABILITY

If any court of competent jurisdiction finds any provision of this Agreement to be unenforceable or invalid, then such provision shall be ineffective to the extent of the court's finding without affecting the enforceability or validity of the remaining provisions of this Agreement.

WHEREFORE, the Parties have executed and delivered this Agreement in two identical copies, each of which is deemed to be an original, effective as of the date first written above.

BIOPORT CORPORATION		INTERGEN N.V.	
Ву	/s/ Robert G. Kramer	Ву	/s/ Ibrahim El Hibri Ibrahim El Hibri
Its	Chief Financial Officer	Its	Chairman

**LEASE** 

BY AND BETWEEN

ARE-QRS, CORP.

as Landlord

and

ANTEX BIOLOGICS INC.

as Tenant

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#### LEASE

THIS LEASE is made as of December 1, 1998 ("Effective Date"), by and between ARE-QRS CORP., a Maryland corporation ("Landlord") and ANTEX BIOLOGICS INC., a Delaware ("Tenant").

### RECITALS

- A. On January 13, 1989, BioCarb AB, predecessor in interest to Tenant, executed that certain Lease ("Existing Lease") for the "Existing Space" (defined below) with Crown Pointe Center Venture, a Maryland single purpose partnership, as landlord ("Prior Landlord") pursuant to which Tenant leases the Existing Space.
- B. Landlord is the owner of the "Building" (defined below) and has succeeded to the interest of Prior Landlord under the Existing Lease.
- C. On the Effective Date, Tenant and Landlord executed that certain Lease Termination providing for the termination of the Existing Lease on the Effective Date.

## 1. Lease of Premises

Landlord hereby leases to Tenant and Tenant hereby leases from Landlord upon the terms and conditions hereof, those certain premises including the "Existing Space" and the "Expansion Space" (both as defined below, collectively the "Demised Premises") within the building located at the address set forth below (the "Building"). The Demised Premises are comprised of approximately 15,054 rentable square feet of space on the first floor of the Building (the "Existing Space") and approximately 4,461 rentable square feet of adjacent and contiguous space on the first floor of the Building (the "Block A Space") and approximately 4,649 rentable square feet of adjacent and contiguous space on the first floor of the Building (the "Block B Space") and approximately 4,649 rentable square feet of adjacent and contiguous space on the first floor of the Building (the "Block B Space") and approximately 4,649 rentable square feet of adjacent and contiguous space on the first floor of the Building (the "Block B Space") and approximately 4,649 rentable square feet of adjacent and contiguous space on the first floor of the Building (the "Block B Space") and approximately 4,640 rentable square feet of adjacent and contiguous space on the first floor of the Building (the "Block B Space") and approximately 4,640 rentable square feet of adjacent and contiguous space on the first floor of the Building (the "Block B Space") and approximately 4,640 rentable square feet of adjacent and contiguous space on the first floor of the Building (the "Block B Space") and approximately 4,640 rentable square feet of adjacent and contiguous space on the first floor of the Building (the "Block B Space") and approximately 4,640 rentable square feet of adjacent and contiguous space on the first floor of the Building (the "Block B Space") and approximately 4,640 rentable square feet of adjacent and contiguous space on the first floor of the Building (the "Block B Space") and approximately 4,640 rentable square feet of adjacent and contiguous space on the f

## 2. Basic Lease Provisions

- 2.1. For convenience of the parties, certain basic provisions of this Lease are set forth herein. The provisions set forth herein are subject to the remaining terms and conditions of this Lease and are to be interpreted in light of such remaining terms and conditions.
  - 2.1.1 Address of the Building: 300 Professional Drive, Gaithersburg, Maryland 20879
  - 2.1.2 Designation of the Demised Premises: Suite(s): 100 Floor(s): first
  - 2.1.3 (a) Rentable Area of Demised Premises: 24,164 sq. ft.
    - (b) Rentable Area of Building: 47,558 sq. ft.
  - 2.1.4 Initial Basic Annual Rent for the Demised Premises: (24,164 sq.ft.) x (\$1.4275 per sq.ft.) x (12 months) = \$413,929.32
    - (a) Initial Basic Annual Rent for Existing Space:
    - $(15,054 \text{ sq.ft.}) \times (\$1.4275 \text{ per sq.ft.}) \times (12 \text{ months}) = \$257,875.02$
    - (b) Initial Basic Annual Rent for Block A Space:
    - $(4,461 \text{ sq.ft.}) \times (\$1.4275 \text{ per sq.ft.}) \times (12 \text{ months}) = \$76,416.93$
    - (c) Initial Basic Annual Rent for Block B Space:
    - $(4,649 \text{ sq.ft.}) \times (\$1.4275 \text{ per sq.ft.}) \times (12 \text{ months}) = \$79,637.37$
  - 2.1.5 Initial Monthly Rental Installments of Basic Annual Rent for the Demised Premises: (24,164 sq.ft.) x (\$17.13 per sq.ft.) /12 = \$34,494.11
  - 2.1.6 Tenant's Pro Rata Share: 50.81%
  - 2.1.7 (a) Term Commencement Date: As defined in Section 4.2 hereof.
    - (b) Rent Commencement Date: As defined in Section 4.2 hereof.
    - (c) Term Expiration Date: 120 calendar months from the Term Commencement Date, subject to extension or earlier termination as provided herein.

- 2.1.8 Security Deposit: \$173,888.98 (i.e. 6 x (.1722 x 24,164 x \$67/12) + 34,494.11) subject to adjustment in accordance with Section 9 hereof; provided that the security deposit held by Landlord under the Existing Lease in the amount of \$16,935.15, plus interest in the amount of \$10,355.35 shall be retained by Landlord and applied toward this amount.
- 2.1.9 Permitted Use: Scientific research and development, including facilities for animals and bio-hazard level 3 ("BL3") and other types of laboratories and related office, conference, library, computer and storage uses consistent with Section 10 hereof.
- 2.1.10 Address for Rent Payment (rent checks shall be made payable to Landlord):

135 N. Los Robles Avenue, Suite 250 Pasadena, CA 91101 Attention: Accounts Receivable

Address for Notices to Landlord:

135 N. Los Robles Avenue, Suite 250 Pasadena, CA 91101 Attention: General Counsel

2.1.11 Address for Notices to Tenant: 300 Professional Drive, Suite 100 Gaithersburg, MD 20879 Attention: Greg Zakarian

With a copy to:

300 Professional Drive, Suite 100 Gaithersburg, MD 20879 Attention: V.M. Esposito

With a copy to:

Covington & Burling 1201 Pennsylvania Ave. P.O. Box 1566 Washington, DC 20044 Attn: Alfred H. Moses, Esq.

2.1.12 Guarantor of Lease: None.

2.1.13 The following Exhibits are attached hereto and incorporated herein:

Exhibit "A" Demised Premises
Exhibit "B" Land
Exhibit "C" Work Letter
Exhibit "D-1" Commencement Date

Exhibit "D-2" Commencement Date

Exhibit "D-2" Improvement Rent Commencement Date

Exhibit "E" Rules and Regulations
Exhibit "F" Existing Tenant Fixtures
Exhibit "G" Estoppel Certificate

## 3. Term

- 3.1. This Lease shall take effect upon the Effective Date and, except as specifically otherwise provided within this Lease, each of the provisions hereof shall be binding upon and inure to the benefit of Landlord and Tenant, and each of their respective successors and permitted assigns, from the Effective Date.
- 3.2. The term of this Lease (the "Term") will be that period from the Term Commencement Date as defined in Section 4.2 below through the Term Expiration Date, as such may be terminated or extended as provided herein.

### 4. Possession and Commencement Date

4.1. Tenant is currently in possession of the Existing Space pursuant to the Existing Lease and Tenant shall remain in possession of the Existing Space on the Effective Date. Landlord shall tender possession of the Expansion Space which includes both the Block A Space and the Block B Space, to Tenant vacant and broom clean on or before the date which is 30 days after the Effective Date (the date on which Landlord actually delivers the Expansion Space to Tenant being referred to herein as the "Expansion Commencement Date"), it being understood that Tenant's obligation to pay rent on the Expansion Space shall not commence until the Block A Rent Commencement Date (as defined below) and the Block B Rent Commencement Date (as defined below), as the case may be. Tenant agrees that in the event Landlord fails to tender possession of the Expansion Space with Landlord's Work Substantially Completed on or before the Expansion Completion Date, Landlord shall not be liable to

Tenant for any loss or damage resulting therefrom, and this Lease shall not be void or voidable except as specifically provided in this Section 4.1. If Landlord has not tendered possession of the Expansion Space with Landlord's Work Substantially Completed on or before the date which is ninety (90) days after the Expansion Commencement Date, then Tenant may, by written notice to Landlord delivered within ten (10) days thereafter, elect to terminate this Lease. In the event this Lease is terminated pursuant to this Section 4.1, the Security Deposit shall be returned to Tenant and neither Landlord nor Tenant shall have any further rights, duties or obligations under this Lease, except with respect to provisions which, by their terms, survive termination of this Lease

- 4.2. The "Term Commencement Date" shall be the Effective Date. Tenant's obligation to pay rent on the Existing Space shall commence on the Effective Date (the "Existing Space Rent Commencement Date"). Tenant's obligation to pay rent on the Block A Space shall commence 60 days after the Expansion Commencement Date (the "Block A Rent Commencement Date"). Tenant's obligation to pay rent on the Block B Space shall commence 180 days after the Expansion Commencement Date (the "Block B Rent Commencement Date"). Landlord and Tenant shall each execute and deliver to the other written acknowledgment of the Term Commencement Date, the Block A Rent Commencement Date, and the Term Expiration Date when each such date is established and shall attach the acknowledgment to this Lease as part of Exhibit "D-1"; provided, however, failure to execute and deliver such acknowledgments shall not affect Landlord or Tenant's rights or liabilities hereunder. The Existing Space Rent Commencement Date, the Block A Rent Commencement Date and the Block B Rent Commencement Date, as applicable, are sometimes referred to herein as the "Rent Commencement Date."
- 4.3. Tenant shall have the right to enter upon the Expansion Space at any time following the Expansion Commencement Date (or earlier if available) for the purpose of completing Tenant's Work (as defined in the Work Letter); provided, however, that Tenant shall first furnish to Landlord evidence satisfactory to Landlord that insurance coverages required of Tenant under the provisions of Article 21 are in effect, and provided further that such entry shall be subject to all the terms and conditions of this Lease other than the payment of Basic Annual Rent or Tenant's Pro Rata Share of Operating Expense.
- 4.4. Tenant may, at the option of Tenant, cause to be constructed one or more projects of tenant improvements to the Demised Premises (collectively, the "Tenant Improvements"). The Tenant Improvements shall be subject to the terms of Section 16 of this Lease and shall be completed in accordance with the Work Letter. Tenant shall be reimbursed, in accordance with the terms of the Work Letter, for the cost to construct the Tenant Improvements in an aggregate amount for the Tenant Improvements not to exceed the sum of the "Basic Allowance" (as defined below) plus the "Additional Allowance" (as defined below) (the Basic Allowance plus the Additional Allowance being collectively referred to in this lease as the "Tenant Improvement Allowance"). The "Basic Allowance" means the product of (a) Twenty Dollars (\$20.00) multiplied by (b) the rentable square footage of the

Expansion Space. The "Additional Allowance" means the product of (a) Sixty Seven Dollars (\$67.00) multiplied by (b) the rentable square footage of the entire Demised Premises. The Tenant Improvement Allowance shall include the amount of eighteen thousand dollars (\$18,000) (which amount shall constitute Additional Rent) for the cost of construction, project management by Landlord, cost of space planning, architect, engineering and other related services, building permits and other planning and inspection fees. If Landlord reasonably determines that the total cost of the Tenant Improvements will exceed the Tenant Improvement Allowance, then Tenant shall immediately, and as a condition to Landlord's obligation to expend or disburse any portion of the Tenant Improvement Allowance, deposit with Landlord an amount sufficient to pay such excess costs ("Tenant Excess Cost Deposit") in cash or a Letter of Credit (as defined in Section 43.14). Tenant shall have until the date which is twelve (12) months after the Block A Rent Commencement Date to expend the unused portion of the Tenant Improvement Allowance, after which date Landlord's obligation to fund the Tenant Improvement Allowance shall expire.

#### 5. Rent

- 5.1. Basic Annual Rent. Tenant shall pay annual rent as follows ("Basic Annual Rent"):
- 5.1.1. Commencing on the Term Commencement Date, Tenant shall pay to Landlord as Basic Annual Rent for the Existing Space, the sum set forth in Section 2.1.4(a) subject to the rental increases provided in Section 6 hereof;
- 5.1.2. Commencing on the Block A Rent Commencement Date, Tenant shall pay to Landlord as Basic Annual Rent for the Block A Space, the sum set forth in Section 2.1.4(b) subject to the rental increases provided in Section 6 hereof.
- 5.1.3. Commencing on the Block B Rent Commencement Date, Tenant shall pay to Landlord as Basic Annual Rent for the Block B Space, the sum set forth in Section 2.1.4(c) subject to the rental increases provided in Section 6 hereof.

Basic Annual Rent shall be paid in the equal monthly installments set forth in Section 2.1.5, subject to the rental increases provided in Section 6 hereof, each in advance on the first day of each and every calendar month during the Term. Notwithstanding anything to the contrary set forth herein, Tenant shall have no obligation to pay Basic Annual Rent for any period prior to the Term

5.2. <u>Additional Rent.</u> In addition to Basic Annual Rent, Tenant agrees to pay to Landlord as additional rent ("<u>Additional Rent</u>") at times hereinafter specified in this Lease (i) Tenant's pro rata share, as set forth in Section 2.1.6. ("<u>Tenant's Pro Rata Share</u>") of Operating Expenses as provided in Section 7 and (ii) any other amounts that Tenant assumes or agrees to pay under the provisions of this Lease that are owed to Landlord, including, without

limitation, any and all other sums that may become due by reason of any default of Tenant or failure on Tenant's part to comply with the agreements, terms, covenants and conditions of this Lease to be performed by Tenant, after notice and lapse of applicable cure period.

#### 5.3. Improvement Rent

- 5.3.1. In the event and to the extent that Tenant elects to receive any portion of the Tenant Improvement Allowance pursuant to Section 4.4, in addition to the Basic Annual Rent, Tenant further agrees to pay to Landlord as additional rent the "Improvement Rent" (defined below), calculated in accordance with this Section 5.3.
- 5.3.2. The "Improvement Rent" for each year during the Lease Term shall be equal to the product of (a) Seventeen and twenty-two one-hundredths percent (17.22%) multiplied by (b) the aggregate amount of the Additional Allowance actually distributed to or on behalf of Tenant as of the Improvement Rent Commencement Date (as defined below). The Improvement Rent shall commence on the Improvement Rent Commencement Date.
- 5.3.3. The "Improvement Rent Commencement Date" shall be the earliest of (i) the date Tenant has Substantially Completed the Tenant Improvements; (ii) the date Tenant is open for business in both the Block A Space and Block B Space; (iii) the date the certificates of occupancy (either temporary or permanent) have been issued for both the Block A Space and Block B Space by the municipal agency having jurisdiction over the Demised Premises; (iv) the date which is twelve (12) months after the Effective Date, or (v) such earlier date as provided in the Work Letter or as the parties hereto may agree. Landlord and Tenant shall each execute and deliver to the other written acknowledgment of the Improvement Rent Commencement Date when such is established and shall attach the acknowledgment to this Lease as part of Exhibit "D-2"; provided, however, failure to execute and deliver such acknowledgment shall not affect Landlord or Tenant's rights or liabilities hereunder.
- 5.3.4. The Improvement Rent shall be paid in equal monthly installments, each in advance on the first day of each and every calendar month during the Term subsequent to the Improvement Rent Commencement Date.
- 5.3.5. Prior to the Improvement Rent Commencement Date, Tenant shall pay Landlord, as Additional Rent, a monthly amount equal to one percent (1.00%) of the average aggregate amount of the Additional Allowance theretofore distributed to or on behalf of Tenant and outstanding during such month (the "Additional Allowance Charge"). The Additional Allowance Charge shall be payable monthly in arrears commencing with the first day of the month following the first date upon which a distribution of the Additional Allowance is made, and ending on the Improvement Rent Commencement Date (the "Construction Period"). Landlord shall deduct the Additional Allowance Charge from the Additional Allowance on a monthly basis during the Construction Period. In the event the full amount of the Additional

Allowance has been distributed, Tenant shall pay the Additional Allowance Charge due for the preceding month in cash on the first day of each month during the Construction Period.

- 5.4. Rent Credit. So long as no default exists or is continuing hereunder, Tenant shall be entitled to a credit against Basic Annual Rent an amount equal to Two Thousand Three Hundred Thirty-Five Dollars (\$2,335.00) per month for each of the 120 calendar months after the Term Commencement Date.
- 5.5. Rent. Basic Annual Rent, Improvement Rent and Additional Rent shall together be denominated "Rent". Except as provided in Section 5.4, Rent shall be paid to Landlord, without abatement, deduction, or offset, in lawful money of the United States of America, at the office of Landlord as set forth in Section 2.1.10 or to such other person or at such other place as Landlord may from time designate in writing. In the event the Term commences or ends on a day other than the first day of a calendar month, then the Rent for such fraction of a month shall be prorated for such period on the basis of the actual number of days in such month and shall be paid at the then current rate for such fractional month.

#### 6. Rent Adjustments

6.1. Basic Annual Rent shall be adjusted upward on the first day of the calendar month following the expiration of the first twelve (12) full calendar months following the Term Commencement Date, and on such date every year thereafter during the Term (each, a "Rent Adjustment Date") in an amount equal to three percent (3.0%) of the prior year's Basic Annual Rent as the same may be adjusted upward from time to time.

## 7. Operating Expenses

- 7.1. As used herein, the term "Operating Expenses" shall include:
- 7.1.1 Government impositions including, without limitation, property tax costs consisting of real and personal property taxes and assessments including amounts due under any improvement bond upon the Building or the Land, including the parcel or parcels of real property upon which the Building are located or assessments levied in lieu thereof imposed by any governmental authority or agency; any tax on or measured by gross rentals received from the rental of space in the Building (unless such tax is a tax on Landlord's income from the Building or a tax in lieu thereof), or tax based on the square footage of the Demised Premises or the Building as well as any parking charges, utilities surcharges, or any other costs levied, assessed or imposed by, or at the direction of, or resulting from statutes or regulations, or interpretations thereof, promulgated by any federal, state, regional, municipal or local government authority in connection with the use or occupancy of the Building or the parking facilities serving the Building; any tax on this transaction or any document to which Tenant is a party creating or transferring an interest in the Demised Premises; any fee for a business license to operate an office building; and any expenses, including the reasonable cost of

attorneys or experts, reasonably incurred by Landlord in seeking reduction by the taxing authority of the applicable taxes, less tax refunds obtained as a result of an application for review thereof. Operating Expenses shall not include any net income, franchise, capital stock, estate or inheritance taxes or taxes which are the personal obligation of Tenant or of another tenant of the Building.

7.1.2 All other costs of any kind paid or incurred by Landlord in connection with the operation and maintenance of the Building and Land including, by way of examples and not as a limitation upon the generality of the foregoing, costs of repairs and replacements to the Building or the other improvements within the Building or Land as appropriate to maintain the Building and Land as required hereunder including cost of funding such reasonable reserves as Landlord, consistent with good business practice, may establish to provide for future repairs and replacements costs of utilities furnished to the Common Areas; sewer fees; trash collection; cleaning, including windows; heating; ventilation; air-conditioning; maintenance of landscape and grounds; maintenance of drives and parking areas; security services and devices; building supplies; maintenance for and replacement of equipment utilized for operation and maintenance of the Building and Land; license, permit and inspection fees; sales, use and excise taxes on goods and services purchased by Landlord in connection with the operation, maintenance or repair of the Building systems and on-site equipment; telephone, postage, stationary supplies and other expenses incurred in connection with the operation, maintenance, or repair of the Building; accounting, legal and other professional fees and expenses incurred in connection with the operation of the Building; the cost of furniture, draperies, carpeting, landscaping and other customary and ordinary items of personal property provided by Landlord for use in Common Areas; capital expenditures (amortized using a ten percent (10%) interest rate over a period equal to the shorter of (i) the useful life of the item as determined by reference to the vendor's or manufacturer's suggested useful life for such capital improvements or, where such reference does not exist, by reference to generally accepted accounting principles, consistently applied, and (ii) seven years); costs of complying with any applicable laws or hazardous waste remediation rules or regulations which are first enacted after the date hereof or which are incurred in connection with an act or omission of Tenant, its agents, employees, contractors or invitees; insurance premiums, including premiums for public liability, property casualty, earthquake and environmental coverages; portions of insured losses paid by Landlord as part of the deductible portion of such losses by reason of insurance policy terms; service contracts; costs of services of independent contractors retained to do work of nature or type herein referenced; and costs of compensation (including employment taxes and fringe benefits) of all persons at or below the level of property manager who perform regular and recurring duties connected with the day-to-day operation and maintenance of the Building, its equipment, the adjacent walks, landscaped areas, drives, and parking areas, including without limitation, janitors, floor waxers, window-washers, watchmen, gardeners, sweepers, and handymen and costs of management services, which costs of management services shall not exceed three percent (3%) of the Basic Annual Rent (excluding Improvement Rent) due from Tenant.

- 7.1.3 Notwithstanding the foregoing, Operating Expenses shall not include any of the following (but the exclusion of any such items from Operating Expenses shall not prohibit Landlord from charging Tenant therefor as Additional Rent to the extent otherwise expressly provided herein):
  - (1) Payments of principal, interest, or other finance charges made on any debt, or the amortization of funds borrowed by Landlord;
  - (2) Ground rent, master lease rent, or other rental payments made under any ground lease or other underlying lease;
- (3) Costs of leasing commissions, legal, space planning, construction, and other expenses incurred in procuring tenants for the Building or with respect to other individual tenants or occupants of the Building;
  - (4) Costs of painting, redecorating, or other services or work performed for the benefit of another tenant or occupant (other than for Common Areas);
  - (5) Salaries, wages, or other compensation paid to officers or executives of Landlord;
- (6) Management fees in excess of three percent (3%) of the Gross Revenues for all tenants. For the purposes of this subsection, Gross Revenues shall mean: annual base rentals paid by Building tenants; amounts of such tenant's rental abatement; and other income from the use or occupancy of the Building, accrued or collected with respect to the Building, but shall exclude revenue from parking and/or other Building concessions;
- (7) Non-cash items, such as deductions for depreciation and amortization of the Building and the Building equipment, interest on capital invested, and bad debt losses, rent losses and reserves for such losses;
- (8) Any wages, salaries, fees, fringe benefits, or other compensation paid to (i) off-site employees of any property management organization being paid a fee by Landlord for its services, (ii) off-site employees of Landlord who are not assigned to the operation, management, maintenance, or repair of the Building on a full-time or part-time basis, including any accounting or clerical personnel and other overhead expenses of Landlord), or (iii) administrative and executive personnel or officers, partners, members, shareholders, interestholders, or directors of Landlord's managing agent above the grade of building manager; provided, however, that Operating Expenses may include Landlord's reasonable allocation of wages, salaries, fees, fringe benefits or other compensation paid to the individual Building manager or other employees of the property manager, whether on-site or off-site, who are assigned full-time or part-time to the operation, management, maintenance or repair of the Building.

- (9) Costs of advertising and public relations and promotional costs associated with the Building's promotion, leasing, or tenant retention efforts, and costs of signs in or on the Building identifying the owners of the Building or any tenant of the Building;
  - (10) Any costs, fines or penalties incurred due to the violation by Landlord of any governmental rule or authority and not caused or contributed to by Tenant;
- (11) Any other expense for which Landlord actually receives reimbursement from insurance, condemnation awards, other tenants or any other source;
- (12) Costs incurred in connection with negotiations or disputes with other tenants, other occupants, or prospective tenants, or costs and expenses incurred in connection with negotiations or disputes with employees, consultants, management agents, leasing agents, purchasers or mortgagees of the Building;
- (13) Allowances, concessions, permits, licenses, inspections, and other costs and expenses incurred in completing, fixturing, furnishing, renovating or otherwise improving, decorating or redecorating space for tenants (including Tenant), prospective tenants or other occupants or prospective occupants of the Building, or vacant leasable space in the Building, or constructing or finishing demising walls and public corridors with respect to any such space;
- (14) Costs relating to another tenant's or occupant's space which (A) were incurred in rendering any service or benefit to such tenant that Landlord was not required, or was in excess of the service that Landlord was required, to provide Tenant hereunder; and (B) were in excess of the standard services then being provided by Landlord to all tenants or other occupants of the Building, whether or not such other tenant or occupant is actually charged therefor by Landlord;
  - (15) Costs incurred in connection with the sale, financing, refinancing, mortgaging, selling or change of ownership of the Building;
  - (16) Costs, fines, interest, penalties, legal fees or costs of litigation incurred due to Landlord's failure to pay any taxes, utility bills or other costs when due;
- (17) Legal, accounting and other professional fees and costs incurred by Landlord which are associated with the operation of the business of the legal entity which constitutes Landlord as the same is separate and apart from the cost of the operation of the Building, including legal entity formation and legal entity accounting (including the incremental accounting fees relating to the operation of the Building to the extent incurred separately in reporting operating results to the Building's owners or lenders);

- (18) General overhead and general administrative expenses and accounting, record-keeping and clerical support of Landlord or the management agent, except for those cost and expenses attributable to the management of the Building;
- (19) All amounts which would otherwise be included in Operating Expenses which are paid to any affiliate or subsidiary of Landlord, or any representative, employee or agent of same, to the extent the costs of such services exceed the competitive rates for similar services of comparable quality rendered by persons or entities of similar skill, competence and experience;
  - (20) Costs or expenses of utilities directly metered to tenants of the Building and payable separately by such tenants;
  - (21) Moving expense costs of tenants of the Building;
  - (22) Consulting costs and expenses paid by Landlord unless they relate exclusively to the management or operation of the Building;
  - (23) Costs, other than those incurred in ordinary maintenance (for such objects as may be located within the Common Areas) for sculpture, paintings or other objects of art;
  - (24) Costs of overtime HVAC service provided to any other tenant of the Building;
  - (25) Costs incurred in connection with any bankruptcy proceedings of Landlord, Tenant or any other tenant or occupant of the Building;
  - (26) Costs or payments associated with Landlord's obtaining air rights or other development rights;
  - (27) Compensation paid to clerks, attendants or other persons in commercial concessions operated for profit by Landlord or in the parking garage of the Building, if any;
  - (28) Costs incurred to correct violations by Landlord of any law, rule, order or regulation which was in effect as of the date the Building's certificate of occupancy was validly issued;
- (29) Costs arising from the presence of Hazardous Substances in or about or below the Land or the Building, including without limitation, Hazardous Substances in the groundwater or soil (unless introduced into or caused by Tenant) which existed prior to Tenant's occupancy of any portion of the Demised Premises or the Building; and
  - (30) Costs incurred in connection with the operation of retail operations owned, operated or subsidized by Landlord, if any.

- 7.2. Tenant shall pay to Landlord on the first day of each calendar month of the Term, as Additional Rent, Landlord's good faith, reasonable estimate of Tenant's Pro Rata Share of Operating Expenses with respect to the Building for such month which estimate Landlord shall deliver prior to the commencement of each calendar year during the Term and shall be based upon the actual Operating Expenses for the previous calendar year, plus a good faith, reasonable estimate of the increase or decrease in such expenses for the ensuing calendar year.
- 7.2.1 Within ninety (90) days after the conclusion of each calendar year, (or such longer period as may be reasonably required, but in no event more than 120 days) Landlord shall furnish to Tenant a statement showing in reasonable detail the actual Operating Expenses and Tenant's Pro Rata Share of Operating Expenses for the previous calendar year. Any additional sum due from Tenant to Landlord shall be immediately due and payable. If the amounts paid by Tenant pursuant to Section 7.2 exceeds Tenant's Pro Rata Share of Operating Expense for the previous calendar year, Landlord shall, at Landlord's option, either (i) credit the excess amount to the next succeeding installments of estimated Additional Rent, or (ii) pay the excess to Tenant within thirty (30) days after delivery of such statements.
  - 7.2.2 Any amount due under Section 7.2 for any period which is less than a full month shall be prorated (based on the actual number of days in such month) for such fractional month.
- 7.3. Landlord's annual statement shall be final and binding upon Tenant unless Tenant, within ninety (90) days after Tenant's receipt thereof, shall contest any item therein by giving written notice to Landlord, specifying each item contested and the reason therefor. If, during such ninety (90) day period, Tenant reasonably and in good faith questions or contests the correctness of Landlord's statement of Tenant's Pro Rata Share of Operating Expenses, Landlord will provide Tenant with access to such Landlord's books and records and such information as Landlord reasonably determines to be responsive to Tenant questions. In the event that after Tenant's review of such information, Landlord and Tenant cannot agree upon the amount of Tenant's Pro Rata Share of Operating Expenses, then Tenant shall have the right to have an independent public accounting firm selected and hired by Tenant (at Tenant's sole cost and expense) and approved by the Landlord (which approval shall not be unreasonably withheld or delayed) audit and/or review Landlord's books and records for the Building and the Land for the year in question and the immediately preceding year (the "Independent Review"). The results of any such Independent Review shall be binding on Landlord and Tenant. If the Independent Review shows that Tenant's Pro Rata Share of Operating Expenses actually paid for the calendar year in question exceeded Tenant's obligations for such calendar year, Landlord's option either (1) credit the excess amount to the next succeeding installments of estimated Additional Rent or (2) pay the excess to Tenant within thirty (30) days after the completion of such audit and/or review. If the Independent Review shows that Tenant's Pro Rata Share of Operating Expenses for such calendar year were less than Tenant's obligation for the calendar year, Tenant shall pay the

deficiency to the Landlord within thirty (30) days after delivery of such statement. If the Independent Review shows that Tenant's payments of Tenant's Pro Rata Share of Operating Expenses for such calendar year were more than five percent (5%) in excess of Tenant's actual obligation for the calendar year and such excess amount was at least \$1,000, Landlord shall promptly reimburse Tenant for the cost of the Independent Review, not to exceed \$5,000.00.

- 7.4. Tenant shall not be responsible for Operating Expenses applicable to the Expansion Space before the Block A Rent Commencement Date with respect to the Block A Space and the Block B Rent Commencement Date with respect to the Block B Space. The responsibility of Tenant for Tenant's Pro Rata Share of Operating Expenses shall continue to the later of (i) the date of termination of the Lease, (ii) the date Tenant has fully vacated the Demised Premises (including, without limitation, the removal of all items required hereby to be removed and the completion of all procedures necessary to fully release and terminate any permits or licenses restricting the use of the Demised Premises in any manner), or (iii) if termination of the Lease is due to the default of Tenant, the date of rental commencement of a replacement tenant.
- 7.5. Operating Expenses for the calendar year in which Tenant's obligation to share therein commences and in the calendar year in which such obligation ceases, shall be prorated on the basis of the actual number of calendar months (or portion thereof) in such partial calendar year. Expenses such as taxes, assessments and insurance premiums which are incurred for an extended time period shall be prorated based upon time periods to which applicable so that the amounts attributed to the Demised Premises relate in a reasonable manner to the time period wherein Tenant has an obligation to share in Operating Expenses.
- 7.6. Notwithstanding anything set forth herein to the contrary, in the event the Building is not at least ninety-five percent (95%) occupied on average during any year of the Term, an adjustment shall be made by Landlord in computing Tenant' Pro Rata Share of Operating Expenses for such year so that Tenant's Pro Rata Share of Operating Expenses shall be computed for such year as though the Building had been ninety-five percent (95%) occupied on average during such year.
- 7.7. The parties agree that statements in this Lease to the effect that Landlord is to perform certain of its obligations hereunder at its own cost and expense shall not be interpreted as excluding any cost from Operating Expenses if such cost is an Operating Expense pursuant to the terms of this Lease.
- 7.8. Landlord shall cause, during the entire Term of this Lease and as part of the Operating Expenses, an electronic security access system to be installed, maintained and operated for the Building.
- 8. Rentable and Usable Area

- 8.1. As used herein, the terms "Rentable Area" and "Usable Area" shall be calculated in accordance with the 1996 Standard Method for Measuring Floor Area in Office Building as adopted by the Building Owners and Managers Association.
  - 8.2. The Rentable Area of the Building is the total of Rentable Area of all buildings located on the Land.
- 8.3. The term "Rentable Area" when applied to Tenant is that area equal to the Usable Area of the Demised Premises plus an equitable allocation of Rentable Area within the Building which is not then utilized or expected to be utilized as Usable Area, including but not limited to the portion of the Building devoted to corridors, equipment rooms, restrooms, elevator, lobby, atrium and mailroom. In making such allocations, consideration will be given to tenants benefitted by space allocated such that area which primarily serve tenants of only one floor, such as corridors and restrooms upon such floor, shall be allocated to Usable Area of the Building as a whole.
- 8.4. Review of allocations of Rentable Areas as between tenants of the Building may be made as frequently as in Landlord's opinion appears appropriate in order to facilitate an equitable apportionment of Operating Expenses. Such review shall be performed by a licensed architect and the allocations certified as true and correct by such licensed architect Tenant may, at its sole cost and expense and prior to the Effective Date, have an architect of Tenant's choosing verify the calculations and measurements made or performed by Landlord's architect.

#### 9. Security Deposit

9.1. Tenant has deposited with Landlord (in cash or the Letter of Credit, as defined in Section 43.14 hereof) the sum set forth in Section 2.1.8 (the "Security Deposit") which Security Deposit shall be held by Landlord as security for the performance by Tenant of all of the terms, covenants, and conditions of this Lease to be kept and performed by Tenant during the Term. If Tenant defaults with respect to any provision of this Lease, including, but not limited to, any provision relating to the payment of Rent, Landlord may (but shall not be required to) use, apply or retain all or any part of the Security Deposit for the payment of any Rent or any other sum in default, or to compensate Landlord for any other loss or damage which Landlord may suffer by reason of Tenant's default. If any portion of the Security Deposit is so used or applied, Tenant shall, pond demand therefor, deposit cash with Landlord in an amount sufficient to restore the Security Deposit it of this Lease. Landlord shall keep any cash constituting the Security Deposit separate from its general fund in an interest-bearing account. Tenant shall be entitled to any interest on the Security Deposit (to be credited to and added to the Security Deposit) at the rate as may be actually earned thereon by Landlord may reasonably require in order to maintain the Security Deposit in an interest-bearing account.

- 9.2. In the event that upon Landlord's review of the Hazardous Materials List (as defined in Section 40.1.1 hereof) Landlord or any of Landlord's insurers or lenders reasonably determines that Tenant's use of Hazardous Materials at the Demised Premises increases the risk of damage to or contamination of the Demised Premises, the Building or the Land, then upon Tenant's receipt of written notice of such determination from the Landlord, Tenant shall deposit an additional amount with the Landlord as Landlord may reasonably determine, which amount shall be added to and treated as part of the Security Deposit.
- 9.3. So long as no default exists or is continuing, on the first day of the first full calendar month which is forty-eight (48) months after the Term Commencement Date, the Security Deposit shall be reduced to any amount equal to the quotient of (a) the Basic Annual Rent then in effect divided by (b) 12.
- 9.4. In the event of bankruptcy or other debtor-creditor proceedings against Tenant, the Security Deposit shall be deemed to be applied first to the payment of Rent and other charges due Landlord for all periods prior to the filing of such proceedings.
- 9.5. Landlord may deliver the Security Deposit to any purchaser of Landlord's interest in the Demised Premises and thereupon Landlord shall be discharged from any further liability with respect to the Security Deposit. This provision shall also apply to any subsequent transfers.
- 9.6. If Tenant shall fully perform every provision of this Lease to be performed by Tenant, the Security Deposit, or any balance thereof, shall be returned to Tenant (or, at Landlord's option, to the last assignee of Tenant's interest hereunder) within forty-five (45) days after the expiration or earlier termination of this Lease.

#### 10. Use

- 10.1. Tenant shall use the Demised Premises for the purpose set forth in Section 2.1.9 (the "Permitted Use") and shall not use the Demised Premises, or permit or suffer the Demised Premises to be used, for any other purpose without the prior written consent of Landlord which consent shall not be unreasonably withheld or delayed.
- 10.2. Tenant shall not use or occupy the Demised Premises in violation of any federal, state and local laws and regulations, zoning ordinances, or the certificate of occupancy issued for the Demised Premises, and shall, upon five (5) days' written notice from Landlord, discontinue any use of the Demised Premises which is declared by any governmental authority having jurisdiction to be a violation of law, regulation or zoning ordinance or of such certificate of occupancy, or which in the reasonable opinion of Landlord violates law, regulation or zoning ordinance or the certificate of occupancy. Tenant shall comply with any direction of any governmental authority having jurisdiction which shall, by reason of the nature of Tenant's use or occupancy of the Demised Premises, impose any duty upon Tenant

or Landlord with respect to the Demised Premises or with respect to the use or occupation thereof.

- 10.3. Landlord acknowledges that so long as Tenant's intended use of the Demised Premises is consistent with its past use of the Existing Space, to Landlord's actual knowledge, there shall be no invalidation or cost increase of any insurance policy covering the Building. Notwithstanding the above, Tenant shall not do or permit to be done anything which will invalidate or increase the cost of any fire, environmental, extended coverage or any other insurance policy covering the Building and shall comply with all rules, orders, regulations, and requirements of the insurers of the Building and Tenant shall promptly upon demand reimburse Landlord for any additional premium charged for such policy by reason of Tenant's failure to comply with the provisions of this Section 10.3.
  - 10.4. Tenant shall keep all doors opening onto public corridors closed, except when in use for ingress and egress.
- 10.5. No additional locks or bolts of any kind shall be placed upon any of the doors or windows by Tenant nor shall any changes be made in existing locks or the mechanism thereof without the prior written consent of Landlord, which consent shall not be unreasonably withheld, conditioned or delayed. Tenant must, upon termination of this Lease return to Landlord all keys to offices and restrooms, either furnished to, or otherwise procured by Tenant. In the event any key so furnished is lost, Tenant shall pay to Landlord the cost of replacing the same or of changing the lock or locks opened by such lost key if Landlord shall deem it necessary to make such change.
- 10.6. No awnings or other projection shall be attached to any outside wall of the building. No curtains, blinds, shades or screens which are visible from the Common Areas or from outside the Building shall be attached to or hung in, or used in connection with, any window or door of the Demised Premises other than Landlord's standard window coverings, if any. Neither the interior nor exterior of any windows shall be coated or otherwise sunscreened without the express written consent of Landlord, such consent not to be unreasonably withheld, nor shall any bottles, parcels, or other articles be placed on the windowsills. No equipment, furniture or other items of personal property shall be placed on any exterior balcony without the express written consent of Landlord, such consent not to be unreasonably withheld.
- 10.7. No sign, advertisement, or notice shall be exhibited, painted or affixed by Tenant on any part of the Demised Premises or the Building without the prior written consent of Landlord, which consent shall not be unreasonably withheld, conditioned or delayed. Tenant may on a non-exclusive basis place signage on the exterior of the Building and Tenant's logo in the Common Area of the Building on the floor occupied by Tenant; provided that (a) Landlord and Tenant agree upon the size, design and location of such exterior signage and (b) all such signage complies with all applicable laws, ordinances, codes, rules and

regulations of the government authorities with jurisdiction over such matters. Interior signs on doors and the directory tablet shall be inscribed, painted or affixed for Tenant by Landlord at the expense of Tenant, and shall be of a size, color and type reasonably acceptable to Landlord. The directory tablet shall be provided exclusively for the display of the name and location of tenants only. Nothing may be placed on the exterior of corridor walls or corridor doors other than Landlord's standard lettering and Tenant's logo, which may be placed on its corridor walls in a location and in a size, color and type acceptable to Landlord in Landlord's reasonable discretion.

10.8. Tenant shall cause any office equipment or machinery to be installed in the Demised Premises so as to reasonably prevent sounds or vibrations therefrom from extending into Common Areas, or other space in the Building. Further, except for equipment located within the Existing Space on the Effective Date and set forth in Exhibit "F", no equipment weighing five hundred (500) pounds or greater shall be placed upon the Demised Premises without advance notice to and consent by Landlord, which consent shall not be unreasonably withheld, conditioned or delayed. Placement of such equipment, if approved by Landlord, shall be only at a location designed to carry the weight of such equipment.

10.9. Tenant shall not do or permit anything to be done in or about the Demised Premises which shall in any way obstruct or interfere with the rights of other tenants or occupants of the Building, or injure them, or use or allow the Demised Premises to be used for any unlawful purpose. Tenant shall not knowingly cause, maintain or permit any nuisance or waste in, on, or about the Demised Premises, Building or the Land. Tenant may use a portion of the Common Area for an atrium area in accordance with Section 15.

Landlord shall use its reasonable efforts to include a provision similar to the first two sentences of this Section 10.9 in all leases for any other tenants of the Building entered into from and after the Effective Date. Furthermore, Landlord agrees not to lease any space in the Building to a tenant whose primary and principal intended use of such space is any of the following: an employment agency, physician or dentist office, video or amusement arcade, indoor playground, bar, video store, repair shop, bowling alley, fast food restaurant, pawn shop, convenience store, liquor store, gym, fitness center or health club and/or beauty salon or spa.

10.10. Other than costs which shall be included in Operating Expenses pursuant to Article 7 associated with causing the Demised Premises to comply with any retroactively effective law, code, rule or regulation where noncompliance does not result from any use or alterations to the Demised Premises by Tenant, Tenant shall be responsible for all liabilities, costs and expenses arising out of or in connection with the compliance of the Demised Premises (as distinguished from the Common Areas and/or the Building) with the Americans With Disabilities Act, 42 U.S.C. § 12101, et seq. (together with regulations promulgated pursuant thereto, "ADA") which provisions are first enacted after the Effective Date, or the compliance thereof is required as a result of an act or omission of Tenant, its agents.

employees, contractors or invitees or as a result of Tenant's (as opposed to another tenant's) leasing of the Demised Premises; and Tenant shall indemnify, defend and hold Landlord harmless from and against any loss, cost, liability, or expense, (including reasonable attorneys fees and disbursements) arising out of any failure of the Demised Premises (as distinguished from the Common Areas and/or the Building) to comply with the ADA in accordance with this sentence.

#### Brokers.

- 11.1. Tenant and Landlord each represents and warrants to the other that it has had no dealings with any real estate broker or agent in connection with the negotiation of this Lease other than Scheer Partners, Inc. ("Broker"), and that it knows of no other real estate broker or agent who is or might be entitled to a commission in connection with this Lease. If and when the Term Commencement Date has occurred, Landlord shall pay to Broker a brokerage fee pursuant to a separate agreement between Landlord and Broker.
- 11.2. Tenant hereby indemnities and shall defend, hold and save Landlord harmless from and against any and all claims for any commissions or fees in connection with this Lease made by any broker or finder having worked, or claiming to have worked, on behalf Tenant, other than Broker.
- 11.3. Landlord hereby indemnifies and shall defend, hold and save Tenant harmless from and against any and all claims for any commissions or fees in connection with this Lease made by Broker and any other broker or finder having worked, or claiming to have worked, on behalf of Landlord.
- 11.4. Tenant represents and warrants that no broker or agent has made any representation or warranty relied upon by Tenant in Tenant's decision to enter into this Lease other than as contained in this Lease
- 11.5. Tenant acknowledges and agrees that the employment of brokers by Landlord is for the purpose of solicitation of offers of lease from prospective tenants and no authority is granted to any broker to furnish any representation (written or oral) or warranty from Landlord unless expressly contained within this Lease. Landlord in executing this Lease does so in reliance upon Tenant's representations and warranties contained within Sections 11.1 and 11.4 hereof.

#### Holding Over

12.1. If, with Landlord's express written consent, Tenant holds possession of all or any part of the Demised Premises after the expiration or earlier termination of the Term, Tenant shall become a tenant from month-to-month upon the date of such expiration or earlier termination, and in such case Tenant shall continue to pay Basic Annual Rent in the amount

payable upon the date of the expiration or earlier termination of this Lease or such other amount as Landlord may indicate, in Landlord's sole and absolute discretion, in such written consent, and all other provisions, representations, covenants and agreements contained herein, other than with respect to the Term and any extensions thereof, but specifically including, without limitation, the adjustment of Basic Annual Rent pursuant to Section 6 hereof, shall remain in full force and effect.

- 12.2. Notwithstanding the foregoing, if Tenant remains in possession of the Demised Premises after the expiration or earlier termination of the Term without the express written consent of Landlord, Tenant shall become a tenant at sufferance upon the terms of this Lease except that the monthly rental shall (i) for the first thirty (30) days after the expiration of the Term be equal to one hundred twenty-five percent (125%) of the Basic Annual Rent and Additional Rent in effect during the last thirty (30) days of the Term; and (ii) thereafter, be equal to one hundred fifty percent (150%) of the Basic Annual Rent and Additional Rent in effect during the last thirty (30) days of the Term. In addition to the foregoing amounts, from and after the sixtieth (60th) day after the expiration of the Term, Tenant shall also be responsible for all damages suffered by Landlord resulting from or occasioned by Tenant's holding over.
  - 12.3. Acceptance by Landlord of Rent after such expiration or earlier termination shall not result in a renewal or reinstatement of this Lease.
  - 12.4. The foregoing provisions of this Article 12 are in addition to and do not affect Landlord's right to re-entry or any other rights of Landlord hereunder or as otherwise provided by law.

## 13. Taxes on Tenant's Property

- 13.1. Tenant shall pay, prior to delinquency, any and all taxes levied against any personal property or trade fixtures placed by Tenant in or about the Demised Premises.
- 13.2. If any such taxes on Tenant's personal property or trade fixtures are levied against Landlord or Landlord's property or, if the assessed valuation of the Building is increased by the inclusion therein of a value attributable to Tenant's personal property or trade fixtures, and if Landlord, after written notice to Tenant (including a copy of the relevant tax bill), pays the taxes based upon such increase in the assessed valued, then Tenant shall upon demand repay to Landlord the taxes so levied against Landlord.
- 13.3. If any improvements in or alterations to the Demised Premises, whether owned by Landlord or Tenant and whether or not affixed to the real property so as to become a part thereof, are assessed for real property tax purposes at a valuation higher than the valuation at which improvements conforming to Landlord's "Building Standard" improvements in other spaces in the Building are assessed, then the real property taxes and assessments levied against

Landlord or the Building by reason of such excess assessed valuation shall be deemed to be taxes levied against personal property of Tenant and shall be governed by the provisions of Section 13.2 above. Any such excess assessed valuation due to improvements in or alterations to space in the Building leased by other tenants of Landlord shall not be included in the Operating Expenses defined in Section 7.1, but shall be treated, as to such other tenants, as provided in this Section 13.3. If the records of the County Assessor are available and sufficiently detailed to serve as a basis for determining whether said Tenant improvements or alterations are assessed at a higher valuation than Landlord's "Building Standard," such records shall be binding on both Landlord and Tenant. As used herein, "Building Standard" means the quality and standard of improvements (including generic laboratory improvements) provided to a majority of tenants (by square footage) in the Building without payment by such tenants of a premium in excess of their stated basic annual rents.

13.4. Landlord shall cooperate with Tenant in advising the applicable taxing authority as to the distinction between Tenant's personal property and trade fixtures for valuation purposes. Tenant, at Tenant's sole cost and expense, shall have the right to protest or appeal the tax assessment for the Building. In the event Tenant protests or appeals the tax assessment as permitted in this section, Tenant hereby agrees to indemnify, defend and save Landlord harmless from and against any and all demands, claims, liabilities, losses, costs, expenses, actions, causes of action, damages or judgment, and all reasonable expenses incurred by Landlord in connection with any such appeal or protest of Tenant.

## 14. Condition of Demised Premises

- 14.1. Except as set forth in Section 14.2, Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the Demised Premises or the Building, or with respect to the suitability for the conduct of Tenant's business and Tenant accepts the Existing Premises in its condition on the Effective Date. The taking of possession of the Demised Premises by Tenant shall, except as otherwise agreed in writing by Landlord and Tenant, conclusively establish that the Demised Premises and Building were at such time in good, sanitary and satisfactory condition and repair.
- 14.2. Landlord represents and warrants to Tenant that, to Landlord's knowledge as of the Effective Date, all "Building Systems" in the Building are in good working order and repair. As used in this Lease, "Building Systems" means heating, ventilating, air conditioning, water, sewer, electrical, gas and telephone facilities and equipment servicing the Building, including the Demised Premises

## 15. Common Areas, Roof and Parking Facilities

15.1. Tenant shall have the non-exclusive right, in common with others, to use the Common Areas, subject to the rules and regulations adopted by Landlord and attached hereto

as Exhibit "E" together with such other reasonable and nondiscriminatory rules and regulations as are hereafter promulgated by Landlord in its discretion (the "Rules and Regulations").

- 15.2. Tenant shall have the non-exclusive right, in common with others, to use the portion of the Common Area (the "Atrium Area") set forth on the site plan as an atrium area of the Demised Premises. Use by Tenant of the Atrium Area is subject to all of the Rules and Regulations and additional particular restrictions Landlord may reasonably determine to be necessary in connection with the use of the Atrium Area.
- 15.3. As an appurtenance to the Demised Premises, Tenant shall have a non-exclusive license to use Tenant's Pro Rata Share of the non-handicapped parking spaces of the parking facilities serving the Building in common on a non-reserved basis with other tenants of the Building. Landlord shall designate five (5) non-exclusive parking spaces near the front entrance to the Building specifically for the use of "visitors;" provided, however, that Landlord shall have no responsibility for enforcing the rights of Tenant or its visitors to use such spaces.
- 15.4. As an appurtenance to the Demised Premises, Tenant shall have a non-exclusive revocable license to use certain portions of the roof of the Building and surrounding sites serving the Building in common with certain other tenants of the Building. Tenant's license with respect to the roof of the Building and surrounding sites serving the Building shall be limited to the right to install and maintain mechanical and other equipment in such locations. Tenant's license to use the roof shall be subject to the Rules and Regulations. Tenant's right to install or maintain any equipment on the roof is subject to Tenant's obligations regarding alterations set forth in Section 17.
- 15.5. Tenant agrees not to unreasonably overburden the parking facilities and agrees to cooperate with Landlord and other tenants in the use of parking facilities. Landlord reserves the right to determine that parking facilities are becoming overcrowded and to limit Tenant's use thereof. Upon such determination, Landlord may reasonably allocate parking spaces among Tenant and other tenants. In the alternative, if Landlord determines that Tenant's customers, clients, or invitees appear to be using more than the number of parking spaces that would otherwise be attributable to a reasonable number of parking spaces for Tenant's use, Landlord may require Tenant and its employees to obtain parking outside the Building for such unreasonable excess uses. However, nothing in this Section 15.5 is intended to create an affirmative duty on Landlord's part to monitor parking.
- 15.6. Landlord reserves the right to modify Common Areas including the right to add or remove exterior and interior landscaping; provided that Tenant's use of the Demised Premises in accordance with Section 10 is not materially adversely affected.

16. Utilities and Services

- 16.1. Tenant shall pay for all water, (including the cost to service, repair and replace reverse osmosis, deionized and other treated water, if any) gas, heat, light, power, telephone and other utilities supplied to the Demised Premises, together with any fees, surcharges and taxes thereon. If any such utility is not separately metered to Tenant, Tenant shall pay a reasonable proportion to be determined by Landlord of all charges jointly metered with other premises as part of Tenant's Pro Rata Share of Operating Expenses, or in the alternative, Landlord may, at its option, monitor the usage of such utilities by Tenant and charge Tenant with the cost of purchasing, installing and monitoring such metering equipment, which shall be paid by Tenant as Additional Rent.
- 16.2. Landlord shall not be liable for, nor shall any eviction of Tenant result from, the failure to furnish any such utility or service whether or not such failure is caused by accident, breakage, repairs, strikes, lockouts or other labor disturbances or labor disputes of any character, governmental regulation, moratorium or other governmental action, inability despite the exercise of reasonable diligence or by any other cause, including the gross negligence of Landlord. In the event of such failure, Tenant shall not be entitled to any abatement or reduction of Rent, nor be relieved from the operation of any covenant or agreement of this Lease. Notwithstanding the foregoing, in the event that the failure or interruption in services which has a material adverse effect upon Tenant's ability to use and enjoy the Demised Premises for the Permitted Use continues for a period in excess of ninety (90) days and is not caused by or contributed to by Tenant, beginning on the ninety-first (91st) as a material adverse effect upon Tenant's ability to use and enjoy the Demised Premises for the Permitted Use continues for a period in excess of fifteen (15) months and is not caused by or contributed to by Tenant, Tenant shall have the right to terminate this Lease prior to the restoration of such services upon not less than thirty (30) days prior written notice to Landlord.
- 16.3. Tenant shall pay directly to the applicable utility or service provider, prior to delinquency, for any separately metered utilities and services which may be furnished to Tenant or the Demised Premises during the Term.
- 16.4. Tenant shall not, without the prior written consent of Landlord, which consent shall not be unreasonably withheld or delayed (but which may be conditioned in accordance with Section 16.5), use any device in the Demised Premises, including, but without limitation, data processing machines, which will in any way increase the amount of ventilation, air exchange, gas, steam, electricity or water beyond the existing capacity of the Building as proportionately allocated to the Demised Premises based upon Tenant's Pro Rata Share as usually furnished or supplied for the use set forth in Section 2.1.6 or be in excess of Tenant's Pro Rata Share of the Building's capacity to provide such utilities or services.

16.5. If Tenant shall require services in excess of that usually furnished or supplied for similar space in the Building, by reason of equipment operated and/or extended hours of business operation, then Tenant shall first procure the consent of Landlord for use thereof, which consent Landlord may condition upon the availability of such excess utilities or services and Tenant's payment as Additional Rent of an amount equal to the cost to provide such excess services and utility capacity.

Tenant hereby acknowledges and agrees that any changes or upgrades in the electrical service furnished or supplied to the Demised Premises and/or the Building, including but not limited to upgrades or changes to the transformer, service panel or switch gears, caused by the Tenant Improvements, shall be at Tenant's sole cost and expense and shall not be considered part of Tenant's Work, as described in the Work Letter. Any such changes or upgrades in the electrical service servicing the Demised Premises shall be subject to the prior consent of Landlord which consent shall not be unreasonably withheld or delayed.

- 16.6. Landlord shall provide water in Common Areas for drinking and lavatory purposes only, but if Tenant requires, uses or consumes water for any purpose in addition to ordinary drinking and lavatory purposes, Landlord may install a water meter and thereby measure Tenant's water consumption for all purposes. Tenant shall pay Landlord for the cost of the meter and the cost of the installation thereof and throughout the duration of Tenant's occupancy, Tenant shall pay Landlord's cost to keep said meter and installation equipment in good working order and repair. Tenant agrees to pay for water consumed, as shown on said meter, as and when bills are rendered (a reasonable allocation for water usage for the Building shall be included in Tenant's Pro Rata Share), and on default in making such payment, Landlord may pay such charges and collect the same from Tenant. Any such costs or expenses incurred, or payments made by Landlord for any of the reasons or purposes herein above stated shall be deemed to be Additional Rent payment by Tenant and collectible by Landlord as such.
- 16.7. The services provided by Landlord to the Building (the costs of which shall be payable by Tenant as part of Operating Expenses pursuant to Section 7.1) shall include the following: utilities to the Common Areas; trash collection; cleaning, including windows; maintenance of plumbing, electric, heating, ventilation and air conditioning systems (other than those systems contained within or exclusively servicing the Demised Premises); landscaping and maintenance of landscaping and grounds; maintenance of drives and parking area, including snow removal; and security services and security devices for the Common Areas.
- 16.8. Landlord reserves the right to stop service of the elevator, plumbing, ventilation, air conditioning and electric systems, when necessary, by reason of accident or emergency or for repairs, alterations or improvements, in the reasonable judgment of Landlord desirable or necessary to be made, until said repairs, alterations or improvements shall have been completed. Landlord shall have no responsibility or liability for failure to supply elevator

facilities, plumbing, ventilation, air conditioning or electric service, when prevented from doing so by strike or accident, or by laws, rules, order, ordinances, directions, regulations or requirements of any federal, state, country or municipal authority or failure to deliver gas, oil or other suitable fuel supply or inability by exercise of reasonable diligence to obtain gas, oil or other suitable fuel. It is expressly understood and agreed that any covenants on Landlord's part to furnish any service pursuant to any of the terms, covenants, conditions, provisions or agreements of this Lease, or to perform any act or thing for the benefit of Tenant, shall not be deemed breached if Landlord is unable to furnish or perform the same by virtue of a strike or labor trouble or any act of God. Landlord shall use its commercially reasonable efforts to minimize the disruption to Tenant's business as a result of Landlord causing any service or utility to be interrupted (for any reason) to the Demised Premises or the Building. Notwithstanding the foregoing, in the event that the failure or interruption in services which has a material adverse effect upon Tenant's ability to use and enjoy the Demised Premises for the Permitted Use, which shall continue for a period in excess of fifteen (15) months and is not caused by or contributed to by Tenant, Tenant shall have the right to terminate this Lease prior to the restoration of such services upon not less than thirty (30) days prior written notice to Landlord.

#### 17. Alterations

17.1. Other than Tenant's Work, Tenant shall make no alterations, additions or improvements in or to the Demised Premises the cost of which exceeds \$10,000.00 in the aggregate in any twelve (12) month period without Landlord's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed (<u>provided, however</u>, that in the event any proposed alteration, addition or improvement (including those which costs do not exceed \$10,000.00) adversely affects (i) any structural portions of the Building including exterior walls, roof, foundation and core of the Building, (ii) the exterior of the Building or (iii) any Building systems, including elevator, plumbing, air conditioning, heating electrical, security, life safety and power, then Landlord may withhold its consent with respect thereto in its sole and absolute discretion), and then only by architects, contractors, suppliers or mechanics approved by Landlord in Landlord's reasonable discretion. Tenant shall provide Landlord, at least fourteen (14) days in advance of any proposed construction (including those which costs do not exceed \$10,000.00), with plans, specifications, bid proposals, work contracts and such other information concerning the nature and cost of the alterations as may be reasonably requested by Landlord.

17.2. Tenant agrees that there shall be no construction of partitions or other obstructions which might interfere with free access to mechanical installation or service facilities of the Building or interfere with the moving of Landlord's equipment to or from the enclosures containing said installations or facilities without Landlord's prior written consent, which approval shall not be unreasonably withheld.

- 17.3. Tenant agrees that any work by Tenant shall be accomplished in such a manner as to permit any fire sprinkler system and fire water supply lines to remain fully operable at all times, unless otherwise agreed to in advance in writing by the Landlord.
- 17.4. All such work shall be done at such times and in such manner as Landlord may from time to time designate. Tenant covenants and agrees that all work done by Tenant shall be performed in full compliance with all laws, rules, orders, ordinances, directions, regulations, and requirements of all governmental agencies, offices, departments, bureaus and boards having jurisdiction, and in full compliance with the rules, orders, directions, regulations, and requirements of any applicable fire rating bureau. Tenant shall provide Landlord with "as-built" plans showing any change in the Demised Premises.
- 17.5. Before commencing any work, Tenant shall give Landlord at least fourteen (14) days prior written notice of the proposed commencement of such work and shall, if required by Landlord, secure at Tenant's own cost and expenses a completion and lien indemnity bond reasonably satisfactory to Landlord for said work.
- 17.6. All alterations, attached equipment, decorations, fixtures, trade fixtures, additions and improvements, subject to Section 17.8, attached to or built into the Demised Premises, made by either of Landlord or Tenant, including (without limiting the generality of the foregoing) the Existing Tenant Fixtures, all floor and wallcovering, built-in cabinet work and paneling, plumbing fixtures, exterior venting fume hoods and walk-in freezers and refrigerators, clean rooms, climatized rooms, ductwork, conduits, electrical panels and circuits (collectively, the "Tenant Alterations"), shall become the property of Landlord upon the expiration or earlier termination of the term of this Lease, and shall remain upon and be surrendered with the Demised Premises as a part thereof; provided, however, that Landlord may, at any time, elect to cause Tenant to remove any such Tenant Alteration from the Demised Premises upon the expiration or earlier termination of this Lease, and, if Landlord so elects, Tenant shall, at its sole cost and expenses, remove such Tenant Alterations, attached equipment, decorations, fixtures, trade fixtures, additions and improvements upon the expiration or earlier termination of this Lease and restore any damage caused by or occasioned as a result of such removal.

Notwithstanding the foregoing, upon written request by Tenant made prior to the installation of any Tenant Alteration, Landlord agrees to make the determination whether Tenant shall be required to cause such Tenant Alteration to be removed in the event that Landlord determines to require removal, upon the expiration or earlier termination of this Lease; provided, however, that such determination is revocable by Landlord at any time in Landlord's sole discretion.

17.7. Tenant shall repair any damage to the Demised Premises caused by Tenant's removal of any property from the Demised Premises. During any such restoration period,

Tenant shall pay Rent to Landlord as provided herein as if said space were otherwise occupied by Tenant.

17.8. Except as to the Existing Tenant Fixtures (defined below), all business and trade fixtures, built-in furniture and cabinets, together with all additions and accessories thereto, installed in and upon the Demised Premises shall be and remain the property of Landlord and shall not be removed by Tenant at any time during the Term, except that items which wear out or become obsolete may be removed and replaced by Tenant with items of at least equal quality. If Tenant shall fail to remove from the Demised Premises its personal property and all items required to be removed by Tenant in accordance with Landlord's election pursuant to Section 17.6 prior to expiration or earlier termination of this Lease, then Landlord may, at its option, remove the same in any manner that Landlord shall choose, and store said effects without liability to Tenant for loss thereof or damage thereto, and Tenant agrees to pay Landlord upon demand any expenses reasonably incurred in connection with such removal and storage or Landlord may, at its option, without notice, sell said property or any of the same, at private sale and without legal process, for such price as Landlord may obtain and apply the proceeds of such sale against any amounts due under this Lease from Tenant to Landlord and against any reasonable expenses incident to the removal, storage and sale of said personal property.

17.9. Notwithstanding any other provision of this Article 17 to the contrary, in no event may Tenant remove any improvement from the Demised Premises as to which Landlord contributed payment, including without limitation, the Tenant Improvements made pursuant to the Work Letter without Landlord's prior written consent, which may be withheld in Landlord's sole discretion.

17.10. Tenant shall pay to Landlord as Additional Rent an amount equal to three percent (3%) of the cost to Tenant of all charges incurred by Tenant of its contractors or agents in connection with any alterations, additions or improvements to the Demised Premises to cover Landlord's overhead and expenses for plan review, coordination, scheduling and supervision thereof. For purposes of payment of such sum, Tenant shall submit to Landlord copies of all bills, invoices, and statements covering the costs of such charges, which will be accompanied by payment to Landlord of the percentage fee set forth above. Tenant shall reimburse Landlord for any extra expense incurred by Landlord by reason of faulty work done by Tenant or its contractors, or by reason of delays caused by such work, or by reason of inadequate cleanup.

## 18. Repairs and Maintenance

18.1. Landlord shall repair and maintain the structural and exterior portions of the Building (including the roof and any structural or exterior portions of Common Areas in the Demised Premises) and the structural and exterior and interior portions of the Common Areas, including, without limitations, roofing and covering materials, foundations, exterior walls, the

plumbing, fire sprinkler system (if any), heating, ventilating, air conditioning, elevator, and electrical systems (excluding any Building Systems exclusively serving the Demised Premise) installed or furnished by Landlord (and the full cost thereof shall be included as a part of Operating Expenses), unless such maintenance or repairs are required in whole or in part because of any act, neglect, fault of or omissions of any duty by Tenant, its agents, servants, employees or invitees, in which case Tenant shall pay to Landlord the cost of such maintenance and repairs.

- 18.2. Subject to Section 22 and except for services of Landlord, if any, required by Sections 18.1, Tenant shall at Tenant's sole cost and expense keep the Demised Premises and every part thereof in good condition and repair, damage thereto from ordinary wear and tear excepted, including, without limitation, all Building Systems exclusively serving the Demised Premises. Subject to Section 22, Tenant shall, upon the expiration or earlier termination of this Lease, surrender the Demised Premises to Landlord in as good as condition as when received, ordinary wear and tear excepted. Other than as specifically set forth in Section 18.1 and in the Work Letter, Landlord shall have no obligation to alter, remodel, improve, repair, decorate or paint the Demised Premises or any part thereof.
- 18.3. Landlord shall not be liable for any failure to make any repairs or to perform any maintenance which is an obligation of Landlord unless such failure shall persist for an unreasonable time after written notice of the need of such repairs or maintenance is given to Landlord by Tenant. Tenant waives the rights under any applicable law, statute or ordinance now or hereafter in effect to make repairs at Landlord's expense.
  - 18.4. Repairs under this Article 18 which are obligations of Landlord are subject to allocation among Tenant and other tenants as Operating Expenses.
- 18.5. This Article 18 relates to repairs and maintenance arising in ordinary course of operation of the Building and any related facilities. In the event of fire, earthquake, flood, vandalism, war, or similar cause of damage or destruction, this Article 18 shall not be applicable and the provisions of Article 22 shall apply and control.

#### 19. Liens

19.1. Subject to the immediately succeeding sentence, Tenant shall keep the Demised Premises, the Building and the Land free from any liens arising out of work performed, materials furnished or obligations incurred by Tenant. Tenant further covenants and agrees that except with respect to Landlord's Work, Landlord's services or Landlord's repair obligations, any mechanic's lien filed against the Demised Premises, the Building or against the Land for work claimed to have been done for, or materials claimed to have been furnished to Tenant, will be discharged by Tenant, by bond or otherwise, within twenty (20) days after the filing thereof, at the sole cost and expense of Tenant.

- 19.2. Should Tenant fail to discharge any lien of the nature described in Section 19.1, Landlord may at Landlord's election pay such claim or post a bond or otherwise provide security to eliminate the lien as a claim against title and the cost thereof shall be immediately due from Tenant as Additional Rent.
- 19.3. In no event may Tenant allow any mortgage, deed of trust, financing statement, encumbrance, lease, hypothecation or any lien to encumber any of the Tenant Improvements, without Landlord's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed; provided that Tenant provides Landlord evidence satisfactory to Landlord, in Landlord's sole discretion, that any such lien is not applicable to Landlord's interest in the Building, the Land nor to the Tenant Improvements.
- 19.4. In the event Tenant shall lease or finance the acquisition of office equipment, furnishings, or other personal property of a removable nature utilized by Tenant in the operation of Tenant's business, Tenant warrants that any Uniform Commercial Code Financing Statement executed by Tenant will upon its face or by exhibit thereto indicate that such Financing Statement is applicable only to removable personal property of Tenant located within the Demised Premises. In no event shall the address of the Building be furnished on the statement without qualifying language as to applicability of the lien only to removable personal property, located in an identified suite held by Tenant. Should any holder of a Financing Statement executed by Tenant record or place of record a Financing Statement which appears to constitute a lien against any interest of Landlord or against equipment which may be located other than within the Demised Premises, Tenant shall within ten (10) days after filing such Financing Statement (i) cause a copy of the Security Agreement or other documents to which Financing Statement pertains to be furnished to Landlord to facilitate Landlord's being in a position to show such lien is not applicable to Landlord's interest nor to any of the Tenant Improvements, and (ii) cause Tenant's lender to amend any documents of record so as to clarify that such lien is not applicable to any interest of Landlord in the Building, the Land nor any interest of Tenant in any of the Tenant Improvements.
  - 19.5. Landlord shall subordinate its landlord's lien to any encumbrance which is expressly permitted by Section 19.4.

## 20. Indemnification and Exculpation

20.1. Tenant hereby indemnifies and agrees to defend and save Landlord harmless from and against any and all demands, claims, liabilities, losses, costs, expenses, actions, causes of action, damages or judgments, and all reasonable expenses incurred in investigating or resisting the same (including, without limitation, reasonable attorneys' fees, charges and disbursements), for injury or death to person or injury to property occurring within or about the Demised Premises, arising directly or indirectly out of Tenant's, it's employees, agents or guests use or occupancy of the Demised Premises or a breach or default by Tenant in the

performance of any of its obligations hereunder, unless caused solely by the willful act or gross negligence of the Landlord.

- 20.2. Landlord shall not be liable to Tenant and Tenant assumes all risk of damage to personal property or scientific research, including loss of records kept within the Demised Premises if the cause of such damage is of a nature which, if Tenant had elected to maintain fire and theft insurance with extended coverage and business records endorsement available on a commercially reasonable basis, would be a loss subject to settlement by the insurance carrier, including, but not limited to, damage or losses caused by fire, electrical malfunctions, gas explosion, and water damage of any type, including, but not limited to, broken water lines, malfunction of fire sprinkler system, roof leakage or stoppages of lines, unless and except if such loss is due to Landlord's willful misconduct or the willful disregard of Landlord after written notice by Tenant of need for a repair which Landlord is responsible to make for an unreasonable period of time. Tenant further waives any claim for injury to Tenant's business or loss of income relating to any such damage or destruction of personal property including any loss of records.
  - 20.3. Landlord shall not be liable for any damages arising from any act, omission or neglect of any other tenant in the Building or of any other third party.
- 20.4. Security devices and services, if any, while intended to deter crime may not in given instances prevent theft or other criminal acts. Tenant acknowledges and agrees that Landlord shall not be liable for injuries or losses caused by criminal acts of third parties and the risk that any security device or service may malfunction or otherwise be circumvented by a criminal is assumed by Tenant. Tenant shall at Tenant's cost obtain insurance coverage to the extent Tenant desires protection against such criminal acts.

#### 21. Insurance - Waiver of Subrogation

21.1. Landlord, as part of Operating Expenses, shall carry insurance upon the Building (including the Tenant Improvements), in an amount equal to full replacement cost (exclusive of the costs of excavation, foundations, and footings, and without reference to depreciation taken by Landlord upon its books or tax returns) or such lesser coverage as Landlord may elect provided such coverage is not less than ninety percent (90%) of such full replacement cost or, if higher, the amount of such insurance Landlord's mortgage lender requires Landlord to maintain, providing protection against any peril generally included within the classification "Fire and Extended Coverage" together with insurance against sprinkler damage (if applicable), vandalism and malicious mischief. Landlord, subject to availability thereof and, as part of Operating Expenses, shall further insure as Landlord deems appropriate coverage against flood, environmental hazard and earthquake, loss or failure of building equipment, rental loss during the period of repair or rebuild, workmen's compensation insurance and fidelity bonds for employees employed to perform services. Notwithstanding the foregoing, Landlord may, but shall not be deemed required to, provide insurance as to any

improvements installed by Tenant or which are in addition to the standard improvements customarily furnished by Landlord without regard to whether or not such are made a part of the Building.

- 21.2. Landlord, as part of Operating Expenses, shall further carry public liability insurance with a single loss limit of not less than Two Million Dollars (\$2,000,000.00) for death or bodily injury, or property damage with respect to the Building and all Tenant Improvements.
- 21.3. Tenant at its own cost shall procure and continue in effect from the Term Commencement Date and continuing throughout the Term (and occupancy by Tenant, if any, after the expiration or earlier termination of this Lease) comprehensive public liability insurance with limits of not less than Two Million Dollars (\$2,000,000.00) per occurrence for death or bodily injury and not less than Two Million Dollars (\$2,000,000.00) for property damage with respect to the Demised Premises.
- 21.4. The aforesaid insurance required of Tenant shall name Landlord, its officers, employees and agents, as an additional insured. Said insurance shall be with companies having a rating of not less than policyholder rating of A and financial category rating of at least Class XII in "Best's Insurance Guide." Tenant shall obtain for Landlord from the insurance companies or cause the insurance companies to furnish certificates of coverage to Landlord. No such policy shall be cancelable or subject to reduction of coverage or other modification or cancellation except after thirty (30) days prior written notice to Landlord from the insurer. All such policies shall be written as primary policies, not contributing with and not in excess of the coverage which Landlord may carry. Tenant's policy may be a "blanket policy" which specifically provides that the amount of insurance shall not be prejudiced by other losses covered by the policy. Tenant shall, at least twenty (20) days prior to the expiration of such policies, furnish Landlord with renewals or binders. Tenant agrees that if Tenant does not take out and maintain such insurance, Landlord may (but shall not be required to) procure said insurance on Tenant's behalf and at its cost to be paid as Additional Rent.
- 21.5. Tenant assumes the risk of damage to any fixtures, goods, inventory, merchandise, equipment, and leasehold improvements, and Landlord shall not be liable for injury to Tenant's business or any loss of income therefrom relative to such damage all as more particularly heretofore set forth within this Lease. Tenant at Tenant's cost shall carry such insurance as Tenant desires for Tenant's protection with respect to personal property of Tenant or business interruption.
- 21.6. In each instance where insurance is to name Landlord as additional insured, Tenant shall upon written request of Landlord also designate and furnish certificates so evidencing Landlord as additional insured to (i) any lender of Landlord holding a security interest in the Building or the Land, and/or (ii) the landlord under any lease wherein Landlord is tenant of the real property whereupon the Building is located if the interest of Landlord is or

shall become that of a tenant under a ground lease rather than that of a fee owner, and/or (iii) any management company retained by Landlord to manage the Building.

- 21.7. Landlord and Tenant each hereby waive any and all rights of recovery against the other or against the officers, directors, employees, agents, and representatives of the other, on account of loss or damage occasioned to such waiving party or its property or the property of others under its control to the extent that such loss or damage is insured against under any fire and extended coverage insurance policy which either may have in force at the time of such loss or damage. Such waivers shall continue as long as their respective insurers so permit. Any termination of such a waiver shall be by written notice of circumstances as hereinafter set forth. Landlord and Tenant, upon obtaining the policies of insurance required or permitted under this Lease, shall give notice to the insurance carrier or carriers that the foregoing mutual waiver of subrogation is contained in this Lease. If such policies shall not be obtainable with such waiver or shall be so obtainable only at a premium over that chargeable without such waiver, the party seeking such policy shall notify the other thereof, and the latter shall have ten (10) days thereafter to either (i) procure such insurance with companies reasonably satisfactory to the other party or (ii) agree to pay such additional premium (in the Tenant's case, in the proportion which the area of the Demised Premises bears to the insured area). If neither (i) nor (ii) are done, this Section 21.7 shall have no effect during such time as such policies shall not be obtainable or the party in whose favor a waiver of subrogation is desired refuses to pay the additional premium. If such policies shall at any time be unobtainable, but shall be subsequently obtainable, neither party shall be subsequently liable for a failure to obtain such insurance until a reasonable time after notification thereof by the other party. If the release of either Landlord or Tenant, as set forth in the first sentence of this Section 21.7 shall contravene any law with respect to exculpatory agreements, the
- 21.8. Landlord may require insurance policy limits to be raised to conform with (a) the requirements of Landlord's lender and/or (b) the coverage limits then being required of new tenants within the Building.

## 22. Damage or Destruction

22.1. Except as provided in Sections 22.6 and 22.8 hereof, in the event of a partial destruction of the Building by fire or other perils covered by extended coverage insurance, not exceeding twenty-five percent (25%) of the full insurable value thereof, and if the damage thereto is such that the Building may be repaired, reconstructed or restored within a period of six (6) months from the date of the happening of such casualty and Landlord will receive insurance proceeds sufficient to cover the cost of such repairs (except for any deductible amount provided by Landlord's policy, which deductible amount if paid by Landlord shall be an Operating Expense), Landlord shall commence and proceed diligently with the work of repair, reconstruction and restoration and this Lease shall continue in full force and effect.

- 22.2. In the event of any damage to or destruction of the Building, other than as provided in Section 22.1, Landlord may elect to repair, reconstruct and restore the Building, in which case this Lease shall continue in full force and effect. If Landlord elects not to repair then this Lease shall terminate as of the date of destruction.
  - 22.3. Landlord shall give written notice to Tenant of its election not to repair, reconstruct or restore the Building within the sixty (60) day period following the date of damage or destruction.
- 22.4. Upon any termination of this Lease under any of the provisions of this Article, the parties shall be released thereby without further obligation to the other from the date possession of the Demised Premises is surrendered to the Landlord except for items which have theretofore occurred.
- 22.5. In the event of repair, reconstruction and restoration as herein provided, the rental provided to be paid under this Lease shall be abated proportionately based on the extent to which Tenant's use of the Demised Premises is impaired during the period of such repair, reconstruction or restoration, unless Landlord provides Tenant with other space during the period of repair, which in Tenant's reasonable opinion is suitable for the temporary conduct of Tenant's business.
- 22.6. Notwithstanding anything to the contrary contained in this Article, should Landlord be delayed or prevented from completing the repair or restoration of the damage to the Demised Premises after the occurrence of such damage or destruction by reason of acts of God or war, governmental restrictions, inability to procure the necessary labor or materials, strikes, or other uses beyond the control of Landlord, the time for Landlord to commence or complete repairs shall be extended, provided, at the election of Landlord, Landlord shall be relieved of its obligation to make such repairs or restoration and Tenant shall be released from its obligation under this Lease as of the end of eight (8) months from date of destruction, if repairs required to provide Tenant use of the Demised Premises are not then substantially complete.
- 22.7. If Landlord is obligated to or elects to repair or restore as herein provided, Landlord shall be obligated to make repairs or restoration only of those portions of the Building and the Demised Premises which were originally provided at Landlord's expense, including the Tenant Improvements; the repair and restoration of items (other than the Tenant Improvements) not provided at Landlord's expense shall be the obligation of Tenant. In the event Tenant elected to upgrade certain improvements from the standard normally provided by Landlord, Landlord shall, upon the need for replacement due to an insured loss, provide only the standard Landlord improvements unless Tenant shall elect to again upgrade and pay any additional cost of such upgrades, except to such extent as insurance proceeds which, if received, the excess proceeds are adequate to provide such upgrades, in addition to providing for basic reconstruction and standard improvements.

- 22.8. Notwithstanding anything to the contrary contained in this Article, Landlord shall not have any obligation whatsoever to repair, reconstruct or restore the Demised Premises when the damage resulting from any casualty covered under this Article occurs during the last twenty-four (24) months of the Term, or to the extent that insurance proceeds are not available therefor.
- 22.9. Notwithstanding anything to the contrary contained in this Article, in the event Landlord makes the determination that the repair or restoration of the damage to the Demised Premises resulting from a casualty covered by this Article, shall take in excess of fifteen (15) months from the date of such damage to complete, within ten (10) days after Landlord has notified Tenant of its determination and prior to the commencement of any such repairs of the damages, Tenant shall have the right to terminate this Lease upon not less than thirty (30) days prior written notice to Landlord.

## 23. Eminent Domain

- 23.1. In the event the whole of the Demised Premises, or such part thereof as shall substantially interfere with the Tenant's use and occupancy thereof, shall be taken for any public or quasi-public purpose by any lawful power or authority by exercise of the right of appropriation, condemnation or eminent domain, or sold to prevent such taking, Tenant or Landlord may terminate this Lease effective as of the date possession is required to be surrendered to said authority.
- 23.2. In the event of a partial taking of the Building or of drives, walkways, and parking areas serving the Building for any public or quasi-public purpose by any lawful power or authority by exercise of right of appropriation, condemnation, or eminent domain, or sold to prevent such taking, then without regard as to whether any portion of the Demised Premises occupied by Tenant was so taken, Landlord may elect to terminate this Lease as of such taking if such taking is, in the sole opinion of Landlord, of a material nature such as to make it uneconomical to continue use of the unappropriated portion for purposes of office rentals or laboratory space.
- 23.3. Tenant shall be entitled to any award which is specifically awarded as compensation for the taking of Tenant's personal property, which was installed at Tenant's expense and for costs of Tenant moving to a new location. Except as before set forth, any award for such taking shall belong to Landlord.
- 23.4. If, upon any taking of the nature described in this Article 23, this Lease continues in effect, the Landlord shall promptly proceed to restore the Demised Premises and the Building to substantially their same condition prior to such partial taking. To the extent such restoration is feasible, as determined by Landlord in its reasonable discretion, the Rent shall be abated proportionately based upon the extent to which Tenant's use of the Demised

Premises has decreased on the basis of the percentage of the rental value of the Demised Premises after such taking and the rental value of the Demised Premises prior to such taking.

## 24. Defaults and Remedies

- 24.1. Late payment by Tenant to Landlord of Rent and other sums due will cause Landlord to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult and impracticable to ascertain. Such costs include, but are not limited to, processing and accounting charges and late charges which may be imposed on Landlord by the terms of any mortgage or trust deed covering the Demised Premises. Therefore, if any installment of Rent due from Tenant is not received by Landlord within five (5) days after the date such payment is due, Tenant shall pay to Landlord an additional sum of six percent (6%) of the overdue Rent as a late charge. The parties agree that this late charge represents a fair and reasonable estimate of the costs that Landlord will incur by reason of late payment by Tenant. In addition to the late charge, Rent not paid when due shall bear interest from the 5th day after date due until paid at the lesser of (i) twelve percent (12%) per annum or (ii) the maximum rate permitted by law.
- 24.2. No payment by Tenant or receipt by Landlord of a lesser amount than the Rent payment herein stipulated shall be deemed to be other than on account of the Rent, nor shall any endorsement or statement on any check or any letter accompanying any check or payment as Rent be deemed an accord and satisfaction, and Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or pursue any other remedy provided. If at any time a dispute shall arise as to any amount or sum of money to be paid by Tenant to Landlord, Tenant shall have the right to make payment "under protest" and such payment shall not be regarded as a voluntary payment, and there shall survive the right on the part of Tenant to institute suit for recovery of the payment paid under protest.
- 24.3. If Tenant fails to pay any sum of money required to be paid by it hereunder, or shall fail to perform any other act on its part to be performed hereunder, Landlord may, without waiving or releasing Tenant from any obligations of Tenant, but shall not be obligated to, make such payment or perform such act. Landlord shall provide Tenant with written notice within a reasonable period of time in advance of the date on which Landlord intends to make such payment or perform such act. All sums so paid or incurred by Landlord, together with interest thereon, from the date such sums were paid or incurred, at the annual rate equal to twelve percent (12%) per annum or highest rate permitted by law, whichever is less, shall be payable to Landlord on demand as Additional Rent
  - $24.4. \ The occurrence of any one or more of the following events shall constitute a "\underline{Default}" hereunder by Tenant:$ 
    - 24.4.1 The abandonment or vacation of the Demised Premises by Tenant;

- 24.4.2 The failure by Tenant to make any payment of Rent or Additional Rent within 5 days after same shall be due;
- 24.4.3 The failure by Tenant to observe or perform any obligation or covenant contained herein (other than described in Section 24.4.1 and 24.4.2) to be performed by Tenant, where such failure shall continue for a period of fifteen (15) days after written notice thereof from Landlord to Tenant. Such notice shall be in lieu of, and not in addition to, any notice required under any applicable law; provided that if the nature of Tenant's default is such that it reasonably requires more than fifteen (15) days to cure, then Tenant shall not be deemed to be in default if Tenant shall commence such cure within said fifteen (15) day period and thereafter diligently prosecute the same to completion, <u>provided</u>, <u>however</u>, that such cure is completed no later than forty-five (45) days from the date of written notice;
  - 24.4.4 Tenant makes a general assignment for the benefit of creditors;
  - 24.4.5 A receiver, trustee or custodian is appointed to, or does, take title, possession or control of all, or substantially all, of Tenant's assets which is not dismissed within 90 days;
- 24.4.6 Tenant files a voluntary petition under the Bankruptcy Code (or any similar law) or an order for relief is entered against Tenant pursuant to a voluntary or involuntary proceeding commenced under any chapter of the Bankruptcy Code which is not dismissed within 90 days;
- 24.4.7 Any involuntary petition if filed against the Tenant under any chapter of the Bankruptcy Code and is not dismissed or bonded against to Landlord's reasonable satisfaction or as may be required by law within ninety (90) days; or
- 24.4.8 Tenant's interest in this Lease is attached, executed upon, or otherwise judicially seized and such action is not released or bonded against to Landlord's reasonable satisfaction or as may be required by law within ninety (90) days of the action.

Notices given under this Section 24.4 shall specify the alleged default and shall demand that Tenant perform the provisions of this Lease or pay the Rent that is in arrears, as the case may be, within the applicable period of time, or quit the Demised Premises. No such notice shall be deemed a forfeiture or a termination of this Lease unless Landlord elects otherwise in such notice.

24.5. In the event of a Default by Tenant, and at any time thereafter, with or without notice or demand and without limiting Landlord in the exercise of any right or remedy which Landlord may have, Landlord shall be entitled to terminate Tenant's right to possession of the Demised Premises by any lawful means, in which case this Lease shall terminate and Tenant shall immediately surrender possession of the Demised Premises to Landlord. In such event,

Landlord shall have the immediate right to re-enter and remove all persons and property, and such property may be removed and stored in a public warehouse or elsewhere at the cost of, and for the account of Tenant. In the event that Landlord shall elect to so terminate this Lease, then Landlord shall be entitled to recover from Tenant all damages incurred by Landlord by reason of Tenant's default, including:

- 24.5.1 The worth at the time of award of any unpaid Rent which had been earned at the time of such termination; plus
- 24.5.2 The worth at the time of award of the amount by which the unpaid Rent which would have been earned after termination until the time of award exceeds that portion of such rental loss which Tenant proves could have been reasonably avoided; plus
- 24.5.3 The worth at the time of award of the amount by which the unpaid Rent for the balance of the term after the time of award exceeds that portion of such rental loss which Tenant proves could have been reasonably avoided; plus
- 24.5.4 Any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform its obligation under the Lease or which in the ordinary course of things would be likely to result therefrom, including but not limited to, the cost of restoring the Demised Premises to the condition required under the terms of this Lease, leasing commissions, advertising and any other costs of re-letting; plus
  - 24.5.5 At the Landlord's election, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by applicable law.

As used in Sections 24.5.1 and 24.5.2 above, "worth at the time of award" shall be computed by allowing interest at the rate specified in Section 24.1. As used in Section 24.5.3 above, the "worth at the time of the award" shall be computed by taking the present value of such amount, by using the discount rate of the Federal Reserve Bank of San Francisco at the time of the award plus six (6) percentage points.

- 24.6. If Landlord does not elect to terminate this Lease as provided in this Section, then Landlord may, from time to time, recover all Rent as it becomes due under this Lease. At any time thereafter, Landlord may elect to terminate this Lease and to recover damage to which Landlord is entitled.
- 24.7. In the event Landlord elects to terminate this Lease and relet the Demised Premises, it may execute any new lease in its own name. Tenant hereunder shall have no right or authority whatsoever to collect any Rent from such tenant except as provided below. The proceeds of any such reletting shall be applied as follows:

First, to the payment of any indebtedness other than Rent due hereunder from Tenant to Landlord, including, but not limited to, storage charges or brokerage commissions owing from Tenant to Landlord as the result of such reletting;

Second, to the payment of the costs and expenses of reletting the Demised Premises, including alterations and repairs which Landlord deems reasonably necessary and advisable and reasonable attorneys' fees, charges and disbursements incurred by Landlord in connection with the retaking of the Demised Premises and such reletting;

Third, to the payment of Rent and other charges due and unpaid hereunder; and

Fourth, to the payment of future Rent and other damages payable by Tenant under this Lease.

- 24.8. All rights, options, and remedies of Landlord contained in this Lease shall be construed and held to be nonexclusive and cumulative. Landlord shall have the right to pursue any one or all of such remedies or any other remedy or relief which may be provided by law, whether or not stated in this Lease. No waiver of any default of Tenant hereunder shall be implied from any acceptance by Landlord of any Rent or other payments due hereunder or any omission by Landlord to take any action on account of such default if such default persists or is repeated, and no express waiver shall affect defaults other than as specified in said waiver.
- 24.9. Termination of this Lease or Tenant's right to possession by Landlord shall not relieve Tenant from any liability to Landlord which has theretofore accrued or shall arise based upon events which occurred prior to the last to occur of (i) the date of Lease termination or (ii) the date possession of Demised Premises is surrendered.
- 24.10. Except as may otherwise be provided in this Lease, Landlord shall not be in default unless Landlord fails to perform obligations required of Landlord within a reasonable time, but in no event shall such failure to continue be for more than thirty (30) days after written notice by Tenant specifying wherein Landlord has failed to perform such obligation; provided, however, that if the nature of Landlord's obligation is such that more than thirty (30) days are required for performance, then Landlord shall not be in default if Landlord commences performance within such thirty (30) day period and thereafter diligently prosecutes the same to completion.
- 24.11. In the event of any default on the part of Landlord, Tenant will give notice by registered or certified mail to any beneficiary of a deed of trust or mortgagee or a mortgage covering the Demised Premises and to any landlord of any lease of any building in which Demised Premises is located whose name and address shall have been furnished to Tenant in writing, and Tenant shall offer such beneficiary, mortgagee and/or landlord a reasonable opportunity to cure the default, including time to obtain possession of the Building by power of sale or a judicial action if such should prove necessary to effect a cure, provided the

Landlord shall have furnished to Tenant in writing the names and addresses of all such persons who are to receive such notices.

## 25. Assignment or Subletting

- 25.1. Except as hereinafter provided, Tenant shall not, either voluntarily or by operation of law, directly or indirectly, sell, hypothecate, assign, pledge, encumber or otherwise transfer this Lease, or sublet the Demised Premises or any part thereof, or permit or suffer the Demised Premises or any part thereof to be used or occupied as work space, storage space, mailing privileges, concession or otherwise by anyone other than Tenant or Tenant's employees, without the prior written consent of Landlord in each instance, which consent shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, Tenant may sublease up to twenty percent (20%) of the useable square footage of the Demised Premises to third parties collaborating or consulting with Tenant; provided that Tenant notify Landlord in writing of such subleases prior to the commencement of such subleases.
- 25.2. If Tenant is a corporation, the shares of which are not actively traded upon a stock exchange or in the over-the-counter market, a transfer or series of transfers whereby twenty-five percent (25%) or more of the issued and outstanding shares of such corporation are, or the voting control is, transferred (but excepting transfers upon deaths of individual shareholders) from a person or persons or entity or entities which were owners thereof at time of execution of this Lease shall be deemed an assignment of this Lease requiring the consent of Landlord as provided in Section 25.1 above.
- 25.3. If Tenant desires to assign this Lease to any entity into which Tenant is merged, with which Tenant is consolidated, or which acquires all or substantially all of the assets of Tenant, provided that the assignee first executes., acknowledges and delivers to Landlord an agreement whereby the assignee agrees to be bound by all of the covenants and agreements in this Lease and that the assignee has a net worth (determined in accordance with generally accepted accounting principles consistently applied) immediately after such assignment which is at least equal to the net worth (as so determined) of Tenant immediately prior to the assignment, then Landlord, upon receipt of proof of foregoing shall, consent to such assignment.
- 25.4. In the event Tenant desires to assign, sublease, hypothecate or otherwise transfer this Lease or sublet the Demised Premises, then at least forty-five (45) days, but not more than ninety (90) days, prior to the date when Tenant desires the assignment or sublease to be effective (the "<u>Assignment Date</u>"), Tenant shall give Landlord a notice (the "<u>Assignment Notice</u>") containing information (including references) concerning the character of the proposed assignee or sublessee, the Assignment Date, any ownership or commercial relationship between Tenant and the proposed assignee or sublessee, and the consideration and all other material terms and conditions of the proposed assignment or sublease along with such other information as Landlord may reasonably require, all in such detail as Landlord shall

reasonably require. Tenant shall also reimburse Landlord for Landlord's reasonable attorneys fees and other actual out-of-pocket costs paid by Landlord in reviewing Tenant's request for such assignment or sublease.

- 25.5. Landlord in making its determination as to whether consent should be given to a proposed assignment or sublease, may give consideration to the financial strength of such successor (notwithstanding the assignor remaining liable for Tenant's performance), any change in use which such successor proposes to make in use of Demised Premises. In no event shall Landlord be deemed to be unreasonable for declining to consent to transfer to a successor of poor reputation, lacking financial qualifications, or seeking change in use.
  - 25.6. As conditions precedent to Landlord considering a request by Tenant to Tenant's transfer of rights or subletting of the Demises Premises, Landlord may require any or all of the following:
  - 25.6.1 Tenant shall remain fully liable under this Lease during the unexpired Term;
- 25.6.2 Tenant shall provide Landlord with evidence reasonably satisfactory to Landlord respecting the relevant business experience and financial responsibility and status of the third party concerned;
- 25.6.3 Tenant shall reimburse Landlord's actual out-of-pocket costs and expenses, including, without limitation, reasonable attorneys' fees, charges and disbursements incurred in connection with the review, processing and documentation of such request;
- 25.6.4 If Tenant's transfer of rights or subletting of the Demised Premises provides for the receipt by, on behalf or on account of Tenant of any consideration of any kind whatsoever (including, but not by way of limitation, a premium rental for a sublease or lump sum payment for an assignment) in excess of (a) the Rent and Additional Rent under this Lease and (b) any costs of subleasing such space, including, but not limited to, brokers' commissions and tenant improvement costs paid by Tenant (amortized over the remaining Term of the Lease), Tenant shall pay fifty percent (50%) of said excess to Landlord. If said consideration consists of cash paid to Tenant, said payment to Landlord shall be made upon receipt by Tenant of said cash payment;
- 25.6.5 Written agreement from any third party concerned that in the event Landlord gives such third party notice that Tenant is in default under this Lease, such third party shall thereafter make all payments otherwise due Tenant directly to Landlord, which payments will be received by Landlord without any liability on Landlord except to credit such payment against those due under the Lease, and any such third party shall agree to attorn to Landlord or its successors and assigns should this Lease be terminated for any reason;

provided, however, that in no event shall Landlord or its successors or assigns be obligated to accept such attornment;

- 25.6.6 Any such transfer and consent shall be effected on forms reasonably approved by Landlord as to form and substance;
- 25.6.7 Tenant shall not then be in default hereunder in any respect;
- 25.6.8 Such third party's proposed use of the Demised Premises shall be the same as Tenant's permitted use in Section 2.1.9;
- 25.6.9 Landlord shall not be bound by any provision of any agreement pertaining to Tenant's transfer of rights or subletting of the Demised Premises;
- 25.6.10 Any agreement pertaining to Tenant's transfer of this Lease or subletting of any portion of the Demised Premises shall be in a form reasonably acceptable to Landlord in Landlord's reasonable discretion (which shall be deemed to include the determination by Landlord's REIT advisor that any such agreement may interfere with compliance by Landlord of its obligations as a real estate investment trust), and any such agreement shall not be modified or amended without Landlord's prior written consent, which may not be unreasonably withheld or delayed;
- 25.6.11 Tenant shall deliver to Landlord one original executed copy of any and all written instruments evidencing or relating to Tenant's transfer of rights or subletting of the Demised Premises; and
- 25.6.12 A list of Hazardous Materials, certified by the proposed sublessee to be true and correct, which the proposed sublessee intends to use or store in the Demised Premises. Additionally, Tenant shall deliver to Landlord, on or before the date any proposed sublessee takes occupancy of the Demised Premises, all of the items relating to Hazardous Materials of such proposed sublessee.
- 25.7. Any sale, assignment, hypothecation or transfer of this Lease or subletting of the Demised Premises that is not in compliance with the provisions of this Article 25 shall be void and shall, at the option of Landlord, terminate this Lease.
- 25.8. The consent by Landlord to an assignment or subletting shall not relieve Tenant or any assignees of this Lease or sublessee of the Demised Premises from obtaining the consent of Landlord to any further assignment or subletting nor shall it release Tenant or any assignee or sublessee of Tenant from full and primary liability under the Lease.
  - 25.9. Notwithstanding any subletting or assignment, Tenant shall remain fully and primarily liable for the payment of all Rent and other sums due, or to become due hereunder,

and for the full performance of all other terms, conditions, and covenants to be kept and performed by Tenant. The acceptance of Rent or any other sum due hereunder, or the acceptance of performance of any other term, covenant, or condition thereof, from any other person or entity shall not be deemed to be a waiver of any of the provisions of this Lease or a consent to any subletting, assignment or other transfer of the Demised Premises.

#### 25.10. [Intentionally Omitted]

25.11. If Tenant shall sublet the Demised Premises or any part, Tenant hereby immediately and irrevocably assigns to Landlord, as security for Tenant's obligations under this Lease, all rent from any subletting of all or a part of the Demised Premises and Landlord as assignee and as attorney-in-fact for Tenant, or a receiver for Tenant appointed on Landlord's application, may collect such rent and apply it toward Tenant's obligations under this Lease; except that, until the occurrence of an act of default by Tenant, Tenant shall have the right to collect such rent.

#### 26. Attorneys' Fees and Costs

- 26.1. Tenant shall be responsible for (i) all of Tenant's legal and related costs and fees in connection with this Lease, and (ii) all of Landlord's reasonable legal and related costs and fees if Landlord is required to consult an attorney regarding the enforcement of this Lease.
- 26.2. If either party commences an action against the other party arising out of or in connection with this Lease, the prevailing party shall be entitled to have and recover from the non-prevailing party reasonable attorneys' fees, charges and disbursements and costs of suit.

## 27. Bankruptcy

- 27.1. In the event a debtor, trustee, or debtor in possession under the Bankruptcy Code, or other person with similar rights, duties and powers under any other law, proposes to cure any default under this Lease or to assume or assign this Lease, and is obliged to provide adequate assurance to Landlord that (i) a default will be cured, (ii) Landlord will be compensated for its damages arising from any breach of this Lease, or (iii) future performance under this Lease will occur, then adequate assurance shall include any or all of the following, as designated by Landlord:
- 27.1.1 Those acts specified in the Bankruptcy Code or other law as included within the meaning of adequate assurance, even if this Lease does not concern a shopping center or other facility described in such laws:
  - 27.1.2 A prompt cash payment to compensate Landlord for any monetary defaults or actual damages arising directly from a breach of this Lease;

- 27.1.3 A cash deposit in an amount at least equal to the Security Deposit as referenced in 2.1.8 originally required at time of execution of this Lease.
- 27.1.4 The assumption or assignment of all of Tenant's interest and obligations under this Lease.

## 28. Estoppel Certificate

Tenant or Landlord shall within fifteen (15) days of written notice from Landlord or Tenant, as the case may be, execute, acknowledge and deliver a statement in writing substantially in the form attached to this Lease as Exhibit "G" with the blanks filled in, and on any other form reasonably requested by a proposed lender or purchaser, (i) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification and certifying that this Lease as so modified is in full force and effect) and the dates to which the rental and other charges are paid in advanced, if any, (ii) acknowledging that there are not, to such party's knowledge, any uncured defaults on the part of Landlord or Tenant, as the case may be, hereunder, or specifying such defaults if any are claimed and (iii) setting forth such further information with respect to this Lease or the Demised Premises as may be reasonably requested thereon. Any such statement may be relied upon by any prospective purchaser or encumbrancer of all or any portion of the real property of which the Demised Premises are a part. Either party's failure to deliver such statement within such time shall, at the option of the other party, constitute a Default under this Lease, and, in any event, shall be conclusive upon Tenant or Landlord, as the case may be, that the Lease is in full force and effect and without modification except as may be represented by such party in any certificate delivered to the other party for execution.

## 29. Intentionally Omitted

## 30. Definition of Landlord; Limitation of Landlord's Liability

30.1. The term "Landlord" as used in this Lease, so far as covenants or obligations on the part of Landlord are concerned, shall be limited to mean and include only Landlord or the successor-in-interest of Landlord under this Lease at the time in question. In the event of any transfer, assignment or the conveyance of Landlord's fee title or leasehold interest, the landlord herein named (and in case of any subsequent transfers or conveyances, the then grantor) shall be automatically freed and relieved from, and after the date of such transfer, assignment or conveyance, of all liability for the performance of any covenants or obligations contained in this Lease thereafter to be performed by Landlord and, without further agreement, the transferee of such title or leasehold shall be deemed to have assumed and agreed to observe and perform any and all obligations of Landlord hereunder during its ownership or ground lease of the Demised Premises. Landlord may transfer its interest in the Demised Premises or this Lease without the consent of Tenant and such transfer or subsequent

transfer shall not be deemed a violation on the part of Landlord or the then grantor of any of the terms or conditions of this Lease.

- 30.2. If Landlord is in default of this Lease, and as a consequence, Tenant recovers a money judgment against Landlord, the judgment shall be satisfied only out of the proceeds of sale received on execution of the judgment and levy against the right, title and interest of Landlord in the Building, and out of rent or other income from such real property receivable by Landlord or out of the consideration received by Landlord from the sale, financing, refinancing, or other disposition of all or any part of Landlord's right, title, and interest in the Building.
- 30.3. Landlord shall not be personally liable for any deficiency. If Landlord is a partnership, limited liability company or joint venture, the members of such limited liability company or the partners of such partnership shall not be personally liable and no member or partner of Landlord shall be sued or named as a party in any suit or action or service of process be made against any partner of Landlord except as may be necessary to secure jurisdiction of the partnership, limited liability company or joint venture. If Landlord is a corporation, the shareholders, directors, officers, employees, and/or agents of such corporation shall not be personally liable and no shareholder, director, officer, employee or agent of Landlord shall be sued or named as a party in any suit or action or service of process made against any shareholder, director, officer, employee or agent of Landlord shall be required to answer or otherwise plead to any service of process and no judgment will be taken or writ of execution levied against any partner, member, shareholder, director, employee or agent of Landlord.
- 30.4. Each of the covenants and agreements of this Article 30 shall be applicable to any covenant or agreement either expressly contained in this Lease or imposed by statute or by common law and shall survive the termination of this Lease.

#### 31. Project Control by Landlord

- 31.1. Subject to Sections 2.1.9 and 10, Landlord reserves full control over the Building to the extent not inconsistent with Tenant's enjoyment of the Demised Premises under the terms of this Lease. This reservation includes but is not limited to right of Landlord to expand the Building into a larger project, subdivide the real property upon which the Building is located, convert the Building to condominium units, the right to grant easements and licenses to others and the right to maintain or establish ownership of the Building separate from fee title to the Land.
  - 31.2. Landlord further reserves the right to combine the Building with any other project in the area of the Building and owned by Landlord or its affiliates.

- 31.3. Tenant shall, should Landlord so request, promptly join with Landlord in execution of such documents as may be reasonably appropriate to assist Landlord to implement any such action, provided that Tenant need not execute any document which is of nature wherein liability is created or increased in Tenant or, if by reason of the terms of such document, Tenant will be deprived of the quiet enjoyment and use of the Demised Premises as granted by this Lease.
- 31.4. Landlord may, at any and all reasonable times during non-business hours (or during business hours if Tenant so requests), and upon reasonable advance notice of not less than 24 hours (provided that no time restrictions shall apply or advance notice need be given if an emergency necessitates an immediate entry), enter the Demised Premises to (a) inspect the same and to determine whether Tenant is in compliance with its obligations hereunder, (b) supply any service Landlord is required to provide hereunder, (c) show the Demised Premises to prospective lenders, insurers, investors, purchasers or, during the last 9 months of the Term, tenants, (d) post notices of nonresponsibility, (e) access the telephone equipment, electrical substation and fire risers, and (f) alter, improve or repair any portion of the Building other than the Demised Premises, but for which access to the Demised Premises is necessary. In connection with any such alteration, improvement or repair, Landlord may erect in the Demised Premises or elsewhere in the Building scaffolding and other structures reasonably required for the work to be performed. In no event shall Tenant's Rent all times retain a key with which to unlock all of the doors in the Demised Premises. If an emergency necessitates immediate access to the Demised Premises, Landlord may use whatever force is necessary to enter the Demised Premises and any such entry to the Demised Premises shall not constitute a forcible or unlawful entry to the Demised Premises, an unlawful detainer of the Demised Premises, or an eviction of Tenant from the Demised Premises, or any portion thereof.

## 32. Quiet Enjoyment

So long as Tenant is not in default beyond any applicable notice and cure periods, Landlord covenants that Landlord or anyone acting through or under Landlord will not disturb Tenant's occupancy of the Demised Premises except as permitted by the provisions of this Lease.

#### 33. Quitclaim Deed

Tenant shall execute and deliver to Landlord on the expiration or termination of this Lease, immediately on Landlord's request, in recordable form, a quitclaim deed to the Demised Premises or such other documentation reasonably requested by Landlord evidencing termination of this Lease.

## 34. Rules and Regulations

Tenant shall faithfully observe and comply with the Rules and Regulations attached hereto as Exhibit "E" and all reasonable and nondiscriminatory modifications thereof and additions thereto from time to time put into effect by Landlord. To the extent Landlord enforces any of the Rules and Regulations, Landlord shall use its reasonable efforts to enforce the Rules and Regulations in a non-discriminatory fashion against all tenants of the Building, but shall not be responsible to Tenant for the violation or non-performance by any other tenant or any agent, employee or invitee thereof of any of said Rules and Regulations.

## 35. Subordination and Attornment

- 35.1. Subject to Section 35.4, this Lease shall be subject and subordinate to the lien of any mortgage, deed of trust, or lease in which Landlord is tenant now or hereafter in force against the Building and to all advances made or hereafter to be made upon the security thereof without the necessity of the execution and delivery of any further instruments on the part of Tenant to effectuate such subordination.
- 35.2. Subject to Section 35.4, Tenant shall execute and deliver upon demand such further instrument or instruments evidencing such subordination of this Lease to the lien of any such mortgage or mortgages or deeds of trust or lease in which Landlord is tenant as may be reasonably required by Landlord. However, if any such mortgagee, beneficiary or Landlord under lease wherein Landlord is tenant so elects, this Lease shall be deemed prior in lien to any such lease, mortgage, or deed of trust upon or including the Demised Premises regardless of date and Tenant will execute a statement in writing to such effect at Landlord's request. If Tenant fails to execute any document required from Tenant under this Section within ten (10) days after written request therefor, Tenant hereby constitutes and appoints Landlord or its special attorney-in-fact to execute and deliver any such document or documents in the name of Tenant. Such power is coupled with an interest and is irrevocable
- 35.3. In the event any proceedings are brought for foreclosure, or in the event of the exercise of the power of sale under any mortgage or deed of trust made by the Landlord covering the Demised Premises, the Tenant shall at the election of the purchaser at such foreclosure or sale attorn to the purchaser upon any such foreclosure or sale and recognize such purchaser as the Landlord under this
- 35.4. Tenant's subordination of this Lease shall be subject to receiving a commercially reasonable non-disturbance agreement (a "Non-Disturbance Agreement") from such mortgagee, beneficiary or lessor which Non-Disturbance Agreement provides that Tenant's possession of the Demised Premises, and this Lease, including any options to extend the term hereof, will remain in full force and effect, so long as Tenant is not in Default hereof, after any applicable grace and cure periods.

## 36. Surrender

- 36.1. No surrender of possession of any part of the Demised Premises shall release Tenant from any of its obligations hereunder unless accepted by Landlord.
- 36.2. The voluntary or other surrender of this Lease by Tenant shall not work a merger, unless Landlord consents and shall, at the option of Landlord, operate as an assignment to it of any or all subleases or subtenancies
- 36.3. The voluntary or other surrender of any ground or underlying lease that now exists or may hereafter be executed affecting the Building, or a mutual cancellation, thereof, or of Landlord's interest therein, shall not work a merger and shall, at the option of the successor of Landlord's interest in the Building, operate as an assignment of this Lease.
- 36.4. Upon the expiration or earlier termination of this Lease, Tenant shall surrender the Demised Premises to Landlord broom clean and free of debris; with all of the "Existing Tenant Fixtures" (defined below) in place, in good working order and repair, but with all of Tenant's other personal property and effects removed therefrom; with all alterations, improvements and fixtures required by Landlord pursuant to this Lease to be removed from the Demised Premises (including any portion of the Existing Tenant Fixtures Landlord may designate) actually removed and all damage as a result of or caused by such removal repaired (all at the sole cost and expense of Tenant); and with all licenses, permits and similar items which restrict or affect the used of the Demised Premises released and fully terminated.
  - 36.5. As used in the Lease, "Existing Tenant Fixtures" means all of the personal property and fixtures listed on Exhibit "F" to this Lease.

# 37. Waiver and Modification

No provision of this Lease may be modified, amended or added to except by an agreement in writing. The waiver by Landlord of any breach of any term, covenant or condition herein contained shall not be deemed to be a waiver of any subsequent breach of the same or any other term, covenant or condition herein contained.

#### 38. Waiver of Trial and Counterclaims

THE PARTIES HERETO SHALL AND THEY HEREBY DO WAIVE TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM BROUGHT BY EITHER OF THE PARTIES HERETO AGAINST THE OTHER ON ANY MATTERS WHATSOEVER ARISING OUT OF OR IN ANY WAY CONNECTED WITH THIS LEASE, THE RELATIONSHIP OF LANDLORD AND TENANT, TENANT'S USE OR OCCUPANCY OF THE DEMISED PREMISES, AND OR ANY CLAIM OF INJURY OR DAMAGE.

## 39. Intentionally Omitted

## 40. Hazardous Materials

40.1. Prohibition/Compliance. Subject to Section 40.2, Tenant shall not cause or permit any Hazardous Materials (as hereinafter defined) to be brought upon, kept or used in or about the Demised Premises, the Building or the Land in violation of applicable law by Tenant, its agents, employees, contractors or invitees. If Tenant breaches the obligation stated in the preceding sentence, or if the presence of Hazardous Materials during the term of this Lease or any extension or renewal hereof or holding over hereunder results in the contamination of the Demised Premises, the Building, the Land or any adjacent property, Tenant hereby indemnifies and shall defend and hold Landlord, its officers, directors, employees, agents and contractors harmless from any and all claims, judgments, damages, penalties, fines, costs, liabilities, or losses (including, without limitation, diminution in value of the Demised Premises or any portion of the Building or Land, damages for the loss or restriction on use of rentable or usable space or of any amenity of the Demised Premises or the Building, damages arising from any adverse impact on marketing of space in the Demised Premises or the Building, and sums paid in settlement of claims, attorneys' fees, consultant fees and expert fees) which arise during or after the Lease term as a result of such contamination. This indemnification of Landlord by Tenant includes, without limitation, costs incurred in connection with any investigation of site conditions or any cleanup, remedial, removal, or restoration work required by any federal, state or local governmental agency or political subdivision because of Hazardous Materials present in the air, soil or ground water above on or under the Demised Premises. Without limiting the foregoing, if the presence of any Hazardous Materials on the Demised Premises, the Building, the Land or any adjacent property to the condition existing prior to the time of such contamination, provided that Landlord's approval of such action shall first be obtained,

40.2. <u>Business.</u> Landlord acknowledges that it is not the intent of this Article 40 to prohibit Tenant from operating its business as described in Section 2.1.9 above. Tenant may operate its business according to the custom of the industry so long as the use or presence of Hazardous Materials is strictly and properly monitored according to all applicable governmental requirements. As a material inducement to Landlord to allow Tenant to use Hazardous Materials in connection with its business, Tenant agrees to deliver to Landlord prior to the Term Commencement Date a list identifying each type of Hazardous Materials to

be present on the Demised Premises and setting forth any and all governmental approvals or permits required in connection with the presence of such Hazardous Materials on the Demised Premises ("Hazardous Materials List"). Tenant shall deliver to Landlord an updated Hazardous Materials List at least once a year and shall also deliver an updated list before any new Hazardous Materials is brought onto the Demised Premises. Tenant shall deliver to Landlord true and correct copies of the following documents (the "Documents") relating to the handling, storage, disposal and emission of Hazardous Materials prior to the Term Commencement Date, or if unavailable at that time, concurrent with the receipt from or submission to a governmental agency: permits; approvals; reports and correspondence; storage and management plans, notice of violations of any laws; plans relating to the installation of any storage tanks to be installed in or under Building or the Land (provided, said installation of tanks shall only be permitted after Landlord has given Tenant its written consent to do so, which consent may be withheld in Landlord's sole and absolute discretion); and all closure plans or any other documents required by any and all federal, state and local governmental agencies and authorities for any storage tanks installed in, on or under the Building or the Land for the closure of any such tanks. Tenant is not required, however, to provide Landlord with any portion(s) of the Documents containing information of a proprietary nature which, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities. It is not the intent of this Section to provide Landlord with information which could be detrimental to Tenant's business should such information become possessed by Tenant's competitors. At the written request of Landlord, Tenant agrees that it shall enter into a written agreement with other tenants at the Building concerning the equitable allocation of fire control areas (as defined in the Un

40.3. <u>Termination of Lease/Withholding Approval of Assignment or Sublease</u>. Notwithstanding the provisions of Section 40.1 above, if Tenant or any existing sublessee of Tenant, with respect to the Demised Premises or the Building, or any proposed assignee or sublessee, with respect to the Demised Premises, is subject to an uncured enforcement order issued by any governmental authority in connection with the use, disposal or storage of Hazardous Materials, Landlord shall have the right, with respect to any such matter involving Tenant or an existing sublessee of Tenant, to terminate this Lease in Landlord's sole and absolute discretion, and, with respect to any such matter involving a proposed assignee or sublessee, it shall not be unreasonable for Landlord to withhold its consent to any proposed assignment or subletting. Notwithstanding the foregoing, after the first occurrence of any event with respect to Tenant or any existing sublessee of Tenant described above (a "Termination Event"), Landlord

hall deliver written notice to Tenant, and such sublessee, if applicable, of the occurrence of such event and Tenant shall have thirty (30) days after receipt of such notice to cure, or cause to be cured, the condition causing such Termination Event. After the expiration of such thirty (30) day period, or upon the occurrence of any subsequent Termination Event, Landlord shall have the right to terminate this Lease in Landlord's sole and absolute discretion.

- 40.4. <u>Testing.</u> At any time, and from time to time, prior to the expiration or earlier termination of the Term, Landlord shall have the right to conduct appropriate tests of the Demised Premises, the Building or the Land to demonstrate that contamination has occurred as a result of Tenant's use of the Demised Premises. In the event such test determines that any contamination exists in, on or around the Demised Premises, the Building or the Land as a result of Tenant's actions, Tenant shall pay for the cost of the Demised Premises.
- 40.5. <u>Testing of Expansion Space</u>. Prior to delivery of possession of the Expansion Space to Tenant, Landlord shall retain a qualified contractor to perform an inspection of the Expansion Space to determine whether any Hazardous Materials exist within the Expansion Space. The cost of such contractor to perform the inspection shall be shared equally by Landlord and Tenant. Landlord shall deliver possession of the Expansion Space to Tenant free of any Hazardous Materials identified by such contractor.
- 40.6. <u>Underground Tanks</u>. If underground or other storage tanks storing Hazardous Materials are located on the Demised Premises or are hereafter placed on the Demised Premises by any party, Tenant shall monitor the storage tanks, maintain appropriate records, implement reporting procedures, properly close any underground storage tanks, and take or cause to be taken all other steps necessary or required under the applicable federal, state, and local rules, regulations, laws, statues, ordinances relating to Hazardous Materials in Maryland, as they now exist or may hereafter be adopted or amended.
- 40.7. <u>Tenant's Obligations</u>. Tenant's obligations under this Article 40 with respect to contamination caused by Tenant during the Term shall survive the expiration or earlier termination of the Lease. During any period of time employed by Tenant or Landlord after the termination of this Lease to complete the removal from the Demised Premises of any such Hazardous Materials and the release and termination of any licenses or permits restricting the use of the Demised Premises, Tenant shall continue to pay the full Rent in accordance with this Lease, which Rent shall be prorated daily.
- 40.8. <u>Definition of "Hazardous Materials.</u>" As used herein, the term "<u>Hazardous Materials</u>" means any hazardous or toxic substance, material or waste which is or becomes regulated by any local governmental authority, the State of Maryland or the United States government and includes, without limitation, any material or substance which is (i) defined as a "hazardous waste," "extremely hazardous waste" or "restricted hazardous waste" under any applicable law, (ii) defined as a "hazardous material," "hazardous substance" or "hazardous waste" under Maryland

Environmental Code Ann., Title 7, Subtitle 2 (1993), as amended with regulations promulgated thereunder and defined as "oil" under Maryland Environment Code Ann., Section 4-401(g) (1993), (v) petroleum, (vi) asbestos, (vii) designated as a "hazardous substance" pursuant to Section 311 of the Federal Water Pollution Control Act (33 U.S.C. Section 1317), (viii) defined as a "hazardous waste" pursuant to Section 1004 of the Federal Resource Conversation and Recovery Act, 42 U.S.C. Section 6901, et. seq. (42 U.S.C. Section 6903), or (ix) defined as a "hazardous substance" pursuant to Section 101 of the Comprehensive Environmental Response Compensation and Liability Act, 42 U.S.C. Section 9601 et. seq. (42 U.S.C. Section 9601). For purposes of this Lease, the term "Hazardous Materials" shall not be deemed to include substances and materials commonly used by tenants of commercial office space in compliance with all applicable laws. Nonetheless, Tenant shall only store reasonable quantities of such substances and materials and shall store, use and dispose of the same in compliance with all applicable laws and insurance and labeling requirements.

## 41. Right to Extend Term

Tenant shall have the right to extend the Term of the Lease upon the following terms and conditions:

- 41.1. Tenant shall have one (1) right (an "Extension Right") to extend the term of this Lease for five (5) years (an "Extension Term") on the same terms and conditions as the Lease. During the Extension Term, Basic Annual Rent shall be payable at the Renewal Rate (as defined below), but in no event less than the Basic Annual Rent payable on the date immediately preceding the commencement such Extension Term, as adjusted pursuant to Section 6 hereof. Basic Annual Rent shall be adjusted on the commencement of each Extension Term and on each one (1) year anniversary of the commencement such Extension Term in accordance with Section 6 above. As used herein, "Renewal Rate" shall mean the then existing Basic Annual Rent plus the then existing Improvement Rent, if applicable, adjusted upward in an amount equal to three percent (3.0%) of the then existing Basic Annual Rent plus the then existing Improvement Rent, if applicable.
  - 41.2. Extension Rights are personal to Antex Biologics Inc. and are not assignable separate and apart from this Lease.
- 41.3. Extension Rights are conditional upon Tenant giving Landlord written notice of its election to exercise its Extension Right at least nine (9) months prior to the expiration of the initial term of the Lease.
  - 41.4. Notwithstanding anything set forth above to the contrary, Extension Rights shall not be in effect and Tenant may not exercise any of the Extension Rights:

- 41.4.1 during any period of time that Tenant is in default under any provision of this Lease which is monetary in nature; or
- 41.4.2 if Tenant has been in default under any provision of this Lease three (3) or more times, whether or not the defaults are cured, during the twelve (12) month period immediately prior to the date that Tenant intends to exercise an Extension Rights.
- 41.5. The Extension Rights shall terminate and be of no further force or effect even after Tenant's due and timely exercise of an Extension Right, if, after such exercise, but prior to the commencement date of an Extension Term, (1) Tenant fails to timely cure any default by Tenant under this Lease; or (2) Tenant has defaulted three (3) or more times during the period from the date of the exercise of an Extension Right to the date of the commencement of the Extension Term, whether or not such defaults are cured.

## 42. Tenant's Right for Early Termination

Tenant shall have a one-time right to terminate this Lease upon the following terms and conditions:

- 42.1. Tenant must notify Landlord, in writing, no later than the date which is thirty-six (36) months after the Effective Date, of Tenant's election (the "Termination Election") to terminate this Lease.
  - 42.2. If Tenant makes the Termination Election, all of the following shall apply:
    - (A) This Lease shall terminate on the date which is forty-eight (48) months after the Term Commencement Date;
- (B) Subject to exclusion under Section 42.3, Tenant shall pay to Landlord an amount equal to the sum of (a) the "Unamortized Allowance" (defined below) plus (b) the "Unamortized Brokers' Fee" (defined below);
- (C) Landlord shall pay to Tenant the sum of One Hundred Seventy Thousand and Fifty Dollars (\$170,050) as compensation for the Existing Tenant Fixtures. If Landlord elects to have Tenant remove any of the Existing Tenant Fixtures pursuant to Section 36.4, the Fixture Payment shall be reduced by the amount indicated on Exhibit "F" as the "Value" of such item being removed.
- 42.3. If Tenant makes the Termination Election and relocates to a building of not less than 35,000 rentable square feet owned by Landlord or an affiliate of Landlord, Tenant shall not be obligated to pay the Unamortized Allowance nor the Unamortized Brokers' Fee.

42.4. As used in this Lease, "<u>Unamortized Allowance</u>" means, as of a date of measurement, (a) the Additional Allowance that is actually paid by Landlord multiplied by (b) a fraction, the numerator of which is (i) the difference of 120 and the number of months from the Term Commencement Date to the Improvement Rent Commencement Date minus (ii) the number of full calendar months that have elapsed since the Improvement Rent Commencement Date, and the denominator of which is 120. As used in this Lease, "<u>Unamortized Brokers' Fee</u>" means the sum of One Hundred Thirty-nine Thousand Four Hundred Fifty-four and 59/100 Dollars (\$139,454.59) multiplied by a fraction, the numerator of which is (i) 120 minus (ii) the number of full calendar months that have elapsed since the Term Commencement Date, and the denominator of which is 120.

#### 43. Miscellaneous

- 43.1. <u>Terms and Headings.</u> Where applicable in this Lease, the singular includes the plural and the masculine or neuter includes the masculine, feminine and neuter. The section headings of this Lease are not a part of this Lease and shall have no effect upon the construction or interpretation of any part hereof.
- 43.2. Examination of Lease. Submission of this instrument for examination or signature by Tenant does not constitute a reservation of or option for lease, and it is not effective as a lease or otherwise until execution by and delivery to both Landlord and Tenant.
  - 43.3. Time. Time is of the essence with respect to the performance of every provision of this Lease in which time of performance is a factor.
  - 43.4. Covenants and Conditions. Each provision of this Lease performable by Tenant shall be deemed both a covenant and a condition.
  - 43.5. Consents. Whenever consent or approval of either party is required, that party shall not unreasonably withhold such consent or approval, except as may be expressly set forth to the contrary.
- 43.6. Entire Agreement. The terms of this Lease are intended by the parties as a final expression of their agreement with respect to the terms as are included herein, and may not be contradicted by evidence of any prior or contemporaneous agreement. The Basic Lease Provisions, General Provisions, Work Letter, and Exhibits all constitute a single document and are incorporated herein.
- 43.7. Severability. Any provision of this Lease which shall prove to be invalid, void, or illegal in no way affects, impairs or invalidates any other provision hereof, and such other provisions shall remain in full force and effect.

- 43.8. Recording, Landlord may, but shall not be obligated to, record a short form memorandum hereof without the consent of Tenant. Neither party shall record this Lease.
- 43.9. Impartial Construction. The language in all parts of this Lease shall be in all cases construed as a whole according to its fair meaning and not strictly for or against either Landlord or Tenant.
- 43.10. <u>Inurement.</u> Each of the covenants, conditions and agreements herein contained shall inure to the benefit of and shall apply to and be binding upon the parties hereto and their respective heirs, legatees, devisees, executors, administrators, successors, assigns, sublessees, or any person who may come into possession of said Demised Premises or any part thereof in any manner whatsoever. Nothing in this Section 43.10 contained shall in any way alter the provisions against assignment or subletting in this Lease provided.
- 43.11. <u>Notices.</u> Any notice, consent, demand, bill, statement, or other communication required or permitted to be given hereunder must be in writing and may be given by personal delivery or reputable overnight courier, and if given by other means shall be deemed given when received, addressed to Tenant at the Demised Premises, or to Tenant or Landlord at the addresses shown in Sections 2.1.10 and 2.1.11 of the Basic Lease Provisions. Either party may, by notice to the other given pursuant to this Section, specify additional or different addresses for notice purposes.
- 43.12. <u>Jurisdiction.</u> This Lease has been negotiated and entered into in the State of Maryland and shall be governed by, construed and enforced in accordance with the laws of the State of Maryland, applied to contracts made in Maryland to be wholly performed in Maryland.
- 43.13. <u>Authority.</u> That individual or those individuals signing this Lease guarantee, warrant and represent that said individual or individuals have the power, authority and legal capacity to sign this Lease on behalf of and to bind all entities, corporations, partnerships, joint venturers or other organizations and/or entities on whose behalf said individual or individuals have signed.
- 43.14. Letters of Credit. In lieu of depositing cash for (i) the Tenant Excess Cost Deposit for purposes of Section 4.4, or (ii) the Security Deposit for purposes of Section 9.1, Tenant shall have the right, but not the obligation, to deliver to Landlord an unconditional, irrevocable standby letter of credit in the amount of the Tenant Excess Cost Deposit for purposes of this Section 4.4 and in the amount of the Security Deposit for purposes of Section 9.1 (either letter of credit shall be referred to as "Letter of Credit"), which Letter of Credit shall (u) be in a form reasonably acceptable to Landlord, (v) be issued by LC Bank and confirmed by Confirming Bank or such other financial institution selected by Tenant and reasonably acceptable to Landlord, (w) be for the benefit of Landlord, but shall be assignable by Landlord to any subsequent purchaser or encumbrancer of the Building, (x) be automatically renewable from

125486.11-Los AngelesS2A

year to year until the Tenant Improvements are substantially complete, in case of the Letter of Credit issued pursuant to Section 4.4, and from year to year throughout the term of the Lease in the case of the Letter of Credit issued in pursuant to Section 9.1, (y) be payable by draft sight in Pasadena, California, upon presentation of a certification signed by an officer of Landlord which states that a default under the Lease has occurred and has not been cured within any applicable cure period, and (z) be payable in the event such Letter of Credit is not renewed on or before the date which is thirty (30) days prior to its expiration.

43.15. No <u>Third-Party Rights.</u> Except as may specifically set forth in this Lease, nothing in this Lease shall confer any right upon any other person or other entity other than the parties hereto and their successors and permitted assigns.

[INTENTIONALLY LEFT BLANK]

125486.11-Los AngelesS2A

IN WITNESS WHEREOF, the parties hereto have executed this Lease as of the date first above written.

Landlord:

ARE-QRS, CORP., a Maryland corporation

By: /s/ Lynn Anne Shapiro Name: Lynn Anne Shapiro Its: General Counsel

Tenant:

ANTEX BIOLOGICS INC., a Delaware corporation

By: /s/ Gregory C. Zalcarian

Name: Gregory C. Zalcarian Its: Vice President + Chief Financial Officer

125486.11-Los AngelesS2A

#### FIRST AMENDMENT TO LEASE

This First Amendment to Lease (the "First Amendment") is made as of this 30<sup>th</sup> day of September, 2004, by and between ARE-QRS, CORP., a Maryland corporation, having an address at 135 North Los Robles Avenue, Suite 250, Pasadena, California 91101 ("Landlord"), and ANTEX BIOLOGICS INC., a Delaware corporation, having an address at 300 Professional Drive, Suite 100, Gaithersburg, Maryland 20879 ("Tenant").

#### RECITALS

- A. Landlord and Tenant have entered into that certain Lease dated as of December 1, 1998 (the "Lease"), wherein Landlord leased to Tenant certain premises (the "Premises") located at 300 Professional Drive, Gaithersburg, Maryland 20879 (the "Project") and more particularly described in the Lease.
- B. Tenant desires to expand the Premises demised under the Lease by adding approximately 12,252 rentable square feet of the Project (the "Expansion Space") as more particularly described on Exhibit A attached hereto and incorporated herein and Landlord is willing to lease the Expansion Space to Tenant on the terms and conditions herein set forth.

#### **AGREEMENT**

Now, therefore, the parties hereto agree that the Lease is amended as follows:

- 1. <u>Premises</u>. Subject to the completion of the Renovations (as hereinafter defined), effective as of October 1, 2004 (the "Effective Date") the Premises demised under the Lease are hereby expanded to include the Expansion Space; provided, however, that if the Renovations are not complete on or before October 1, 2004, the Effective Date shall be the date the Renovations are complete. The Renovations shall be deemed completed by the parties upon Landlord obtaining notice of substantial completion from the Tenant's Authorized Representative, Gaudreau, Inc. From and after the Effective Date, the Basic Annual Rent payable under the Lease on the Expansion Space shall be \$13,273 per month (or \$13.00 per rentable square foot) (the "Expansion Space Base Rent") and Tenant's Pro Rata Share shall be increased to be 76.57%. Notwithstanding the foregoing, the Expansion Space Base Rent shall be abated for a period of three (3) months following the Effective Date. Additionally, it is understood and agreed that the Expansion Space Base Rent shall remain at \$13.00 per rentable square foot through December 31, 2005. The Term of the Lease shall expire, unless terminated earlier pursuant to the Lease, on November 30, 2008.
- 2. <u>Improvement of Expansion Space</u>. Effective upon the execution and delivery of this First Amendment, Landlord shall provide Tenant a tenant improvement allowance ("TI Allowance") of \$4.00 per rentable square foot or \$49,008 in the aggregate, which amount is included in Expansion Space Base Rent. The TI Allowance shall be applied against those costs and expenses to be incurred by Landlord in making those certain Tenant requested non-structural, normal and customary office renovations to the Expansion Space in accordance with this <u>Paragraph 2</u> (collectively, the "Renovations"). Landlord and Tenant agree that the general contractor and any subcontractor for the Renovations shall be selected by Landlord. Prior to the commencement of the Renovations, Landlord shall prepare for Tenant's review and approval, which approval shall not be unreasonably withheld, conditioned or delayed, (i) a schematic drawing and outline specifications detailing the Renovations (the "Renovation Specifications"), and a detailed breakdown of the costs of the Renovations (the "Budget"). Tenant shall respond

to Landlord regarding its approval of the Renovations Specifications and Budget, within 10 business days of Tenant's receipt thereof. Tenant recognizes and acknowledges that the TI Allowance shall not be used to reimburse Tenant for any cost of purchasing furniture, personal property or any non-Building System materials or equipment not incorporated into the Improvements unless otherwise agreed upon in advance by both parties. To the extent the costs of the Renovations exceed the TI Allowance, any such excess cost shall be the sole responsibility of Tenant and shall be paid to Landlord upon Tenant's receipt of written demand for payment from Landlord.

- 3. Operating Expense Adjustment. Section 7.6 of the Lease is hereby amended by adding the following sentence to the end thereof:
  - For purposes of clarification, the adjustment, if any, made to Tenant's Operating Expenses shall apply only to charges that are variable in direct proportion to occupancy within the Building, and not fixed charges.
- 4. Additional Rent for Alterations. Section 17.10 of the Lease shall not apply to the Renovations reference in Paragraph 2 of this First Amendment.
- 5. Workstation Purchase. Tenant hereby expressly recognizes and acknowledges that (i) the Expansion Space currently contains certain existing work stations (the "Work Stations") which are the property of the neighboring tenant, Wisor Telecom Corporation, a Delaware corporation ("Wisor"); (ii) Landlord has no right in or to the Work Stations; and (iii) no right to the Work Stations is conveyed under this Lease Amendment. Tenant further acknowledges and agrees that it will engage in independent negotiations with Wisor regarding Tenant's purchase of the Work Stations and that if Tenant is unsuccessful in purchasing the Workstations from Wisor, Tenant shall have the sole responsibility of removing the Work Stations from the Expansion Space. If the Renovations Specifications and its associated Budget does not exceed the dollar value of the TI Allowance, Tenant shall have the right to have the remaining balance of the TI Allowance credited against Tenant's Rent obligations, in an amount equal to the costs incurred by Tenant for the purchase or removal of the Work Stations. Upon Landlord's receipt, review and approval of receipts associated with such purchase or removal by Tenant, Tenant shall receive a credit from Landlord in such amount against Tenant's Rent obligations for the month immediately following such approval, and such credit shall be reflected in the applicable Rent invoice from Landlord.
- 6. **Default for Non-Payment**. Section 24.4.2 of the Lease is hereby amended by deleting the existing language in its entirety and replacing the same with the following:
  - Tenant shall fail to pay any installment of Rent, Additional Rent or any other payment hereunder when due; provided, however, that Landlord will give Tenant notice and an opportunity to cure any failure to pay Rent within 3 days of any such notice not more than twice in any 12 month period and Tenant agrees that such notice shall be in lieu of and not in addition to, or shall be deemed to be, any notice required by law;
- 7. Share Transfers. Section 25.2 of the Lease is hereby deleted in its entirety.

8. Subletting to Affiliate(s). A new Section 25.12 shall be added to the Lease, as follows:

Notwithstanding anything in the Lease to the contrary, and provided there remains fewer than six (6) years remaining on the Lease Term, Tenant shall have the right upon prior notice to Landlord, to freely sublet all or any portion of the Demised Premises to an Affiliate. An "Affiliate" as used herein shall mean any entity that directly or indirectly (through one or more intermediaries) controlled by, or is under common control with, the Tenant.

9. Right to Extend Term. Section 41.1 is hereby amended by deleting the existing language in its entirety and replacing the same with the following:

#### 41.1. Extension Right.

41.1.1. Tenant shall have the right (an "Extension Right") to extend the term of this Lease for five (5) years (the "Extension Term") on the same terms and conditions as this Lease (other than Rent). Upon the commencement of the Extension Term, Basic Annual Rent shall be \$26.50 per rentable square foot, and thereafter shall be adjusted on each annual anniversary of the commencement of the Extension Term by four percent (4%) and no Improvement Rent shall be payable by Tenant during the Extension Term.

#### 10. Miscellaneous.

- (a) This First Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This First Amendment may be amended only by an agreement in writing, signed by the parties hereto.
- (b) This First Amendment is binding upon and shall inure to the benefit of the parties hereto, their respective agents, employees, representatives, officers, directors, divisions, subsidiaries, affiliates, assigns, heirs, successors in interest and shareholders.
- (c) This First Amendment may be executed in any number of counterparts, each of which shall be deemed an original, but all of which when taken together shall constitute one and the same instrument. The signature page of any counterpart may be detached therefrom without impairing the legal effect of the signature(s) thereon provided such signature page is attached to any other counterpart identical thereto except having additional signature pages executed by other parties to this First Amendment attached thereto.
- (d) Landlord and Tenant each represent and warrant that it has not dealt with any broker, agent or other person (collectively "Broker") in connection with this transaction, and that no Broker brought about this transaction. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this leasing transaction.

(e) Except as amended and/or modified by this First Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this First Amendment. In the event of any conflict between the provisions of this First Amendment and the provisions of the Lease, the provisions of this Amendment shall prevail. Whether or not specifically amended by this Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this First Amendment.

IN WITNESS WHEREOF, the parties hereto have executed this First Amendment as of the day and year first above written.

# TENANT:

# ANTEX BIOLOGICS INC.,

a Delaware corporation

By: /s/ Robert G. Kramer

Name: Robert G. Kramer, Sr.

Title: President

# LANDLORD:

# ARE-QRS CORP.,

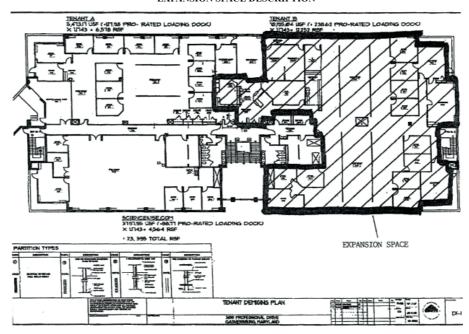
a Maryland corporation

By: /s/ Jennifer Pappas

Name: Jennifer Pappas

Title: V.P. & Assistant Secretary

# EXHIBIT A EXPANSION SPACE DESCRIPTION



# DATED 13th December 1996

# SLOUGH PROPERTIES LIMITED

- to -

# AZUR ENVIRONMENTAL LIMITED

# LEASE

Premises known as Winnersh 540 Winnersh Triangle Wokingham Berkshire

> Nabarro Nathanson 50 Stratton Street London WIX 6NX

> Tel: 0171 493 9933

JE/JUS/S2883/224/lms WP2077A 31/10/96

# **PARTICULARS**

DATE OF THIS DEED 13th December 1996

LANDLORD SLOUGH PROPERTIES LIMITED

Registered office 234 Bath Road Slough SL1 4EE

Company Registration No. 448911

TENANT AZUR ENVIRONMENTAL LIMITED

Registered office The Coach House 24A Tile House

Street Hitchin Hertfordshire SG5

Company Registration No. 2538199

SURETY None

the area from time to time comprising the Landlord's estate at Winnersh Triangle ESTATE

Workingham of which the Premises form part the present such area being shown for identification only edged red on the Estate Plan

LAND the land off Eskdale Road on the

Estate shown edged red on the Lease Plan

BUILDING the building (presently known as Winnersh

540) on the Land which (with the Fixtures and any car parking and landscaping facilities) is described in the First

Schedule

COMMENCEMENT DATE 25th November 1996

20 years together with the period of any continuation or extension of the tenancy granted by this Lease TERM

9th December 1996 RENT COMMENCEMENT DATE

RENT until 25th May 1997 the sum of

£47.916 per annum and thereafter £95.832 per annum subject to review as provided in

this Lease

REVIEW DATES 25th November 2001 and each

fifth anniversary of that date

PERMITTED USE

use for any purpose within Classes B1 and B8 of the Schedule to the Town and Country Planning (Use Classes) Order 1987 (as amended or replaced from time to time)

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THIS LEASE is made on the date and between the parties stated in the Particulars

# WITNESSES as follows:

# 1. <u>DEFINITIONS</u>

In this Lease the following expressions have the meanings indicated:

"Accessways" the roads and ways shown for the purpose of identification only hatched brown on the Lease Plan

the "Act" means the Landlord and Tenant (Covenants) Act 1995

"Additional Access" the areas shown for the purpose of identification only hatched brown and cross hatched black on the Lease Plan

"Adjoining Premises" the premises known as Winnersh 545 demised by a lease of even date made between the Landlord and the Tenant

"Authorised the meaning defined in and for the purposes of

Guarantee Agreement" Section 16 of the Act and the form of such Agreement shall be as reasonably required by the Landlord

"Common Areas" the Estate other than the Premises and other areas let or intended by the Landlord to be let but including the whole of the Estate Roads

"Conducting Media" all sewers drains pipes wires watercourses subways cables apparatus conduits and any other media or works for the conduct or transmission of any service matter

or material (including any

media and works in respect of the sprinkler system at the Estate)

"Estate Plan"

the plan marked Estate Plan attached to this Lease

"Estate Roads"

- the roads pavements and paths shown for the purpose of identification only hatched brown on the Estate Plan (or any road pavement or path at any time replacing any of them) and
- 2. such other roads pavements and paths at Winnersh Triangle (whether or not on or forming part of the Estate) as may from time to time serve or be available for use generally by tenants and occupiers in connection with premises on the Estate but excluding any that may be or become any public highway or footpath

"First Schedule"

the schedule referred to in the First Schedule including any amended or substituted schedule describing any other building (and its fixtures equipment and other items) erected on the Land by the Landlord pursuant to this Lease

"Fixtures"

the Landlord's fixtures from time to time on or forming part of the Land including the fixtures equipment and items which with the Building are described in the First Schedule

2

"Full Reinstatement Value" the costs (including demolition professional fees and any value added tax payable) which would be likely to be incurred in carrying out repair or reinstatement

in accordance with the requirements of this Lease at the time when such repair or reinstatement is likely to take place having regard to current building

techniques and materials

"Insured Risks" fire lightning earthquake explosion aircraft riot storm tempest flood burst pipes malicious damage and impact damage and such other insurable risks and on

such terms and subject to such exclusions as the Landlord may from time to time consider reasonably necessary but excluding any risks which the Landlord shall decide from time to time not to include in any policy (whether on the grounds of unavailability of insurance cover for that risk or otherwise) but so that

the Landlord shall give at least fourteen days' prior notice in writing to the Tenant of any risk ceasing to be covered by any policy

"Landscaped Areas" those parts of the Land as are hatched green on the Lease Plan

"Lease Plan" the plan marked "Lease Plan" attached to this Lease

"Loss of Rent" the loss of the rent first reserved by clause 3 for such period (being not less than three years) as

	4
"Service Charge"	the aggregate of the costs and liabilities referred to in Part 1 of the Sixth Schedule
"Prescribed Rate"	three per centum above the Base Rate of National Westminster Bank PLC from time to time (or such other clearing bank as the Landlord shall nominate) or (if such rate shall cease to be published) such other reasonable or comparable rate as the Landlord shall from time to time designate
"Premises"	the Land together with the Building (or any other building erected by the Landlord in its place) and all additions and the Fixtures and a reference to the "Premises" includes a reference to any part
"Planning Acts"	includes the Town and Country Planning Act 1990 the Planning (Listed Buildings and Conservation Areas) Act 1990 the Planning (Hazardous Substances) Act 1990 and (the Planning (Consequential Provisions) Act 1990
"Parking Area"	such area or areas within the Land as are designated for parking and shown on the Lease Plan as demised car parking
	may reasonably be required by the Landlord from time to time having regard to the likely period required for reinstatement in the event of both partial and total destruction and in an amount which would take into account potential increases of rent in accordance with clause 7

"Service Charge Period" the period in respect of which the Service Charge is calculated as determined from time to time by the Landlord and notified to the Tenant and

initially is each consecutive period of twelve months ending on 31 December

"Sign Display" the panel or panels installed by the Landlord on the Building for the display of name and logo signs the part of the Service Charge for which

the Tenant is liable which shall be such fair and

"Tenant's Proportion of the Service Charge" proper proportion as the Landlord's Surveyor shall from time to time determine acting as an expert

"Winnersh 500" means that part of the Estate (of which the Premises form part) shown edged blue on the Lease Plan

# 2. <u>INTERPRETATION</u>

2.1 The expressions "the Landlord" and "the Tenant" shall wherever the context so admits include their respective successors in title

Where the Tenant or the Surety (if any) for the time being are two or more persons the terms "the Tenant" and "the Surety" (if any) include the plural number and obligations expressed or implied to be made by such party are deemed to be made by such persons jointly and each of them severally

2.3 Words importing one gender include all other genders and words importing the singular include the plural and vice versa

2.4 References in this Lease to any statute or legislation (whether specific or general) include any other statute or legislation replacing amending or

supplementing the same and any orders regulations bye-laws notices permissions approvals or consents thereunder

References in the Sixth Schedule to gross external areas mean such areas from time to time.

#### 3 DEMISE

2.5

The Landlord demises to the Tenant the Premises together with the Rights referred to in Part 1 of the Second Schedule but subject to the Exceptions and Reservations referred to in Part 2 of the Second Schedule and to any documents and matters referred to in the Fifth Schedule to hold to the Tenant for the Term starting on the Commencement Date yielding and paying therefor during the Term:

# 3.1 <u>Ren</u>

yearly the Rent and all increases arising from any review pursuant to the provisions in this Lease for the review of rent to be paid without any deduction or set off by equal quarterly payments in advance on the Twenty-fifth day of March the Twenty-fourth day of June the Twenty-ninth day of September and the Twenty-fifth day of December in every year the first payment for the period from and including the Rent Commencement Date up to and including the day immediately preceding the quarter day next after the date of this Lease to be made on the date of this Lease

# 3.2 <u>Service Charge for the Estate</u>

as additional rent the Tenant's Proportion of the Service Charge in respect of the Estate in accordance with Part 1 of the Sixth Schedule

# 3.3 Winnersh 500 facilities

as additional rent the sums payable by the Tenant in respect of Winnersh 500 pursuant to and in accordance with Part 2 of the Sixth Schedule

# 3.4 <u>Additional Access</u>

as additional rent the sums payable by the Tenant in respect of the Additional Access pursuant to and in accordance with Part 3 of the Sixth Schedule

# 3.5 <u>Insurance</u>

as additional rent from time to time a sum or sums of money equal to the expense incurred by the Landlord in effecting or maintaining insurance in accordance with clause 5.2 (including any increased premium payable in respect of the Premises or any neighbouring property by reason of any act or omission by (or permitted by) the Tenant or an undertenant) as the Landlord shall from time to time effect such insurance for the Landlord's benefit in the Full Reinstatement Value against the Insured Risks and the Loss of Rent such sum or sums to be paid on demand

# 4. <u>TENANT'S COVENANTS</u>

The Tenant covenants with the Landlord as follows:

# 4.1 <u>Payment of rents</u>

To pay the respective rents and sums of money reserved and made payable at the times and in the manner in which the same are set out or referred to in clause 3 without any deduction or set off and to make all such payments to the Landlord on the due date through the Tenant's bankers by the direct debit system

#### 4.2 Interest on late payments

If the Tenant shall fail to pay any rents or any other sum payable under this Lease when the same is due (whether formally demanded or not) to pay to the Landlord as additional rent (but without prejudice to any other rights of the Landlord including those under clause 6) interest on all such rents or other sums from the due date for payment until the date actually paid

at the Prescribed Rate current at such due date and any such interest shall be recoverable by the Landlord as rent in arrear

# 4.3 <u>Payment of rates</u>

- 4.3.1 To pay and indemnify the Landlord against all existing and future rates or other outgoings whatsoever imposed or charged upon the Premises or upon the owner or occupier in respect of the Premises
- 4.3.2 To pay and be responsible for all electricity gas and other services to the Premises

# 4.4 Exterior painting

In every third year and in the last year of the Term to prepare and paint the outside of the Building where usually or previously so painted in a good and workmanlike manner and otherwise properly to clean treat or decorate other parts of the outside of the Building as the same ought to be cleaned treated and decorated (such painting and decorating to be carried out in colours and patterns first approved in writing by the Landlord such approval not to be unreasonably withheld or delayed) and whenever necessary to renew or replace all seats and mastics

# 4.5 <u>Interior painting</u>

In every fifth year and in the last year of the Term to prepare and paint all the interior of the Building where usually or previously so painted in a good and workmanlike manner (all such painting in the last year of the Term to be carried out in colours and patterns first approved in writing by the Landlord) such approval not to be unreasonably withheld or delayed

# 4.6 Repair

4.6.1 Well and substantially to repair and maintain the Premises and the walls fences roads and Conducting Media in on or under the Premises (damage by any of the Insured Risks excepted unless the

insurance moneys are withheld in whole or in part or the policy avoided by reason of any act or omission on the part of the Tenant or any undertenant or any employee contractor or invitee of either of them) and at all times to keep the same in good and substantial repair and condition and so repaired cleaned painted and maintained and further to keep all parts of the Premises clean and tidy and free from rubbish and waste materials

- 4.6.2 To keep the Parking Area for and suitable for the parking of vehicles only
- 4.6.3 Subject to clause 4.6.4 to keep the Landscaped Areas as landscaped areas maintained and planted as laid out and planted by the Landlord and in accordance with any general scheme for the Estate from time to time specified by the Landlord and to replace with equivalent specimens any plants that may die or need replacement and regularly to cut the grass and generally to tend nurture and maintain the Landscaped Areas
- 4.6.4 If the Landlord so requires at any time or from time to time not to do the things referred to in clause 4.6.3 (or such of them as may be notified to the Tenant) and shall give to the Tenant reasonable notice of such requirement but instead to pay to the Landlord on demand the reasonable and proper costs incurred by the Landlord in doing so or (where the Landlord incurs costs in relation to such Areas and all or any of the other areas shown hatched green on the Lease Plan) a proper proportion (as defined in paragraph 1.2 Part 2 of the Fifth Schedule) of the costs so incurred by the Landlord

4.6.5 Not in any event to harm or damage any of the Landscaped Areas or the landscaping or plants on them nor to alter such Areas or the scheme of landscaping and plants

# 4.7 <u>Yielding Up</u>

At the expiration or sooner determination of the Term to yield up the Premises in good and substantial repair and consistent with the full and due compliance by the Tenant with its obligations under this Lease and to remove such tenant's trade fixtures and fittings and any signs erected by or at the instance of the Tenant making good any damage caused by such removal

# 4.8 Reinstatement

- 4.8.1 Three months before the expiry or sooner determination of the Term (unless or to the extent otherwise required in writing by the Landlord) to carry out such works as shall be necessary or desirable in order to ensure that the Premises or such part or parts of them as may be required by the Landlord conform with the description in the First Schedule
- 4.8.2 Immediately before the assignment or underletting of this Lease or of the lease of the Adjoining Premises (whether with or without the Landlord's consent) separately from the other to carry out all such works as shall be necessary to ensure that the Premises and the Adjoining Premises are rendered separate and to reinstate any party walls and to remove all doors windows or other openings and to seal off any Conducting Media
- 4.8.3 All such works shall be carried out to the satisfaction of the Landlord and the Tenant shall apply for any necessary planning permission or

approval which may be required under the Planning Acts or other legislation

# 4.9 Landlord's access

On the giving of reasonable prior notice in writing to permit the Landlord or its agents at all times during the Term during reasonable hours in the day (or at any time in the case of emergency) with or without workmen and others to enter the Premises for the purpose of ascertaining that the covenants and conditions of this Lease have been performed and observed by the Tenant and examining (including opening up floors walls and ceilings where necessary to examine) the state of repair and condition of the Premises or for the purpose of taking inventories of the Landlord's fixtures or of carrying out works on the adjoining property of the Landlord and of exercising any of the Exceptions and Reservations referred to in Part 2 of the Second Schedule the Landlord causing as little damage and inconvenience as practicable and as soon as practicable making good all damage caused in the exercise of such right

# 4.10 <u>Default remedies of the Landlord</u>

If within three months after service of a notice from the Landlord requiring the Tenant to remedy any breach of covenant relating to the state of repair or condition of the Premises or otherwise to the carrying out of any works or actions (or earlier in case of emergency) the Tenant shall not have commenced and proceeded diligently and expeditiously such works or actions then to permit the Landlord to enter upon the Premises and execute all or any such works or actions and the Landlord's proper costs and expenses (including the Landlord's surveyors and other professional fees in connection therewith) together with interest thereon at the Prescribed Rate current at the date one month after service of such notice for the

period from that date to the date of payment shall be a debt due from the Tenant to the Landlord and be forthwith recoverable as rent in arrear

# 4.11 Signs and aerials

Not to erect any pole mast or aerial or erect or display any sign noticeboard or advertisement on any part of the Premises but the Tenant shall install and maintain in the Sign Display an appropriate sign (to the prior written approval of the Landlord not to be unreasonably withheld) showing the name of the Tenant and (if applicable) its logo but showing no other information

# 4.12 <u>Use</u>

- 4.12.1 Not to use the Premises or any part thereof otherwise than for the Permitted Use and not at any time to store anything on any part of the Premises outside the Building
- To use only for the parking of vehicles the Parking Area (but not to park any trailers on such Area) and to require employees to use only such Area for the parking of their vehicles and to enforce such requirement by all reasonable means available to the Tenant as an employer

# 4.13 Refuse and rubbish

- 4.13.1 To ensure that all refuse rubbish and waste material is put in secure and closed containers designed for that purpose and to take all appropriate measures to prevent escape of refuse rubbish or waste materials from such containers
- 4.13.2 To make and maintain satisfactory arrangements for the regular removal of all refuse rubbish and waste materials from the Premises so often as is necessary

- 4.13.3 If the Tenant fails to take immediately such steps as may be necessary to comply with clause 4.13.1 or 4.13.2 after notice from the Landlord requiring it to do so to permit the Landlord or others authorised by it (if the Landlord decides to do so) to enter the Premises to carry out removal of refuse rubbish or waste materials (whether or not on a regular basis) and to pay to the Landlord on demand all proper costs and expenses incurred by the Landlord in connection with any removal arrangements which it makes
- 4.14 Nuisance
- 4.14.1 Not to use the Premises or any part of them for any illegal purpose nor to carry out on or from the Premises any noisy noxious dangerous or offensive act activity or business nor anything which may be or become a nuisance or damage to the Landlord or any of its tenants or the occupiers of any premises in the neighbourhood and in particular not to do or permit to be done anything which might cause electronic or radio interference with any adjoining or neighbouring premises
- 4.14.2 Not to do anything which would or might lead to any contamination of the Premises or pollution of the environment or lead to the pollution obstruction damaging or overloading of the Conducting Media and to carry out (or at the Landlord's election to pay to the Landlord the proper costs and fees of carrying out) all works necessary to remedy the contamination or pollution or to remove the source of the contamination or pollution
- 4.14.3 Where the Tenant has failed to observe any of the obligations in this clause 4.14 to pay to the Landlord the proper costs incurred by it in obtaining such reports as the Landlord may reasonably require to

establish what damage or harm may have been caused to the Premises or other property of the Landlord and the remedial cleaning or other works necessary

4.14.4 Not to discharge or allow to enter into any underground or other waters any poisonous noxious or harmful effluent liquid or substance

# 4.15 <u>Estate Regulations</u>

4.16

To observe such reasonable regulations as may from time to time be made by the Landlord for the purposes of good estate management

# Estate Roads and Accessways etc

- 4.16.1 To take all necessary precautions to prevent damage or excessive wear and tear to or any avoidable obstruction of any of the Estate Roads the Accessways or the Additional Access and to pay to the Landlord on demand all proper costs and expenses of making good any damage (other than normal wear and tear) caused to any of them by the Tenant or any undertenant or any of their respective employees contractors or visitors
- 4.16.2 In particular not to impede or interfere with the reasonable use of the Additional Access by the occupiers of any other unit on Winnersh 500 entitled to use it
- 4.16.3 Not to park or permit the parking by the employees or contractors of or visitors to the Tenant of vehicles on any of the Estate Roads or Accessways or the Additional Access or elsewhere on the Estate other than in accordance with clause 4.12.2

#### 4.17 <u>Acts prejudicial to insurance</u>

4.17.1 Not to do anything as a result of which any policy of insurance against damage to the Premises or to any neighbouring premises may be prejudiced or payment of the policy moneys may be withheld in

whole or in part or whereby the rate of premium in respect of any such insurance may be increased and to give notice to the Landlord forthwith upon the happening of any event which might affect any insurance policy relating to the Premises

4.17.2 In relation to the insurance effected by the Landlord in respect of the Premises to pay to the Landlord any excess required by the insurers or by the Landlord on demand by the Landlord following any damage or destruction by any Insured Risks where such excess would be applicable to any claim in respect of such damage or destruction

# 4.18 <u>Safeguarding the Premises</u>

- 4.18.1 With respect to fire precautions and safeguarding the Premises against damage by any of the Insured Risks or otherwise to comply with all requirements and recommendations of the insurers of the Premises or the relevant insurance brokers or of the fire brigade or local authority
- 4.18.2 Not to store or bring on to or allow to remain on the Premises any article substance or liquid of a specially combustible inflammable or explosive nature or which may be a source of contamination PROVIDED that for so long as the Tenant is Azur Environmental Limited the storage on the Premises of reasonable quantities of the items listed in the Seventh Schedule for purposes solely connected with the business of Azur Environmental Limited shall be deemed not to be a breach of this clause
- 4.18.3 To give written notice to the Landlord upon the occurrence of any contamination of the Premises and also upon the occurrence of any pollution of the environment in breach of any legislative provision caused by any use of or action or activity on the Premises

# 4.19 Planning Applications

Not without the prior written consent of the Landlord (such consent not to be unreasonably withheld or delayed) to make any application for any consent under the Planning Acts

# 4.20 Alterations

Not to erect or place any new building or structure whatsoever on the Premises (including any temporary or moveable building or structure) and not to make any alteration whether structural or otherwise or any addition to the Premises or to the Building or to any buildings which may be erected on the Premises PROVIDED THAT the Tenant may with the written consent of the Landlord (such consent not to be unreasonably withheld or delayed) erect install or alter internal demountable partitions not affecting the structure of the Building

# 4.21 <u>Statutory obligations</u>

- 4.21.1 At the Tenant's expense to comply in all respects with the provisions of all statutes and legislation (whether now or subsequently in force) affecting or applicable to the Premises or their use and forthwith to give notice to the Landlord of any notice direction or order made by any local or competent authority
- 4.21.2 Where required by statute or legislation the Tenant shall maintain a health and safely file for any works carried out to the Premises and shall comply with the Construction (Design and Management) Regulations 1994 in respect thereof and provide to the Landlord upon reasonable request a copy of such file

#### 4.22 Alienation

4.22.1

Not to charge or mortgage either the whole or any part of the Premises nor to assign underlet share or part with the possession or

	occupation of any part of the Premises nor to permit any such dealing under a permitted underlease
4.22.2	Not to hold or occupy the Premises or any part as nominee trustee or agent or otherwise for the benefit of any other person
4.22.3	Not to assign or underlet the whole of the Premises without the prior consent in writing of the Landlord (such consent not to be unreasonably withheld where the provisions hereinafter contained are satisfied)
4.22.4	It is agreed that the Landlord will not be deemed to be unreasonable in withholding consent to a proposed assignment of the whole of the Premises if it is withheld on the ground (and it is the case) that one or more of the circumstances mentioned below exist (whether or not such withholding is solely on such ground or on that ground together with other grounds):
4.22.4.1	that in the reasonable opinion of the Landlord the effect of the proposed assignment upon the value of the Landlord's reversionary interest in the Premises would be to diminish or otherwise adversely affect such value
4.22.4.2	that in the reasonable opinion of the Landlord the effect of the assignment would mean that there is a reduced likelihood of the tenant's covenants and obligations in this Lease being fulfilled
4.22.4.3	that the proposed assignee is an associated company of the Tenant
4.22.5	On any assignment:-
4.22.5.1	The Tenant will enter into an Authorised Guarantee Agreement which will be in such form as the Landlord may reasonably

request and be prepared by or on behalf of the Landlord and at the cost of the Tenant and under which the assignor will agree (inter alia) with the Landlord:

- 4.22.5.1.1.1 that it is liable as sole or principal debtor in respect of all obligations to be owed by the assignee under the Tenant Covenants (as defined in Section 28 of the Act) in this Lease
- 4.22.5.1.1.2 to be liable as guarantor in respect of the assignee's performance the Tenant Covenants (as above defined) in this Lease (provided that such liability shall be no more onerous than the liability to which the assignor would be subject in the event of his being liable as sole or principal debtor in respect of the obligations owed by the assignee under the said Tenant Covenants)
- 4.22.5.1.1.3 In the event of this Lease being disclaimed to enter into a new lease of the Premises the term of which shall expire simultaneously with the date upon which (but for any such disclaimer) this Lease would have expired by effluxion of time (and not by any other means) and the Tenant Covenants shall be identical to (mutatis mutandis but in any event no

more onerous than) the Tenant Covenants in this Lease

- 4.22.5.2 If the Landlord reasonably so requires the Tenant shall obtain acceptable guarantors for any person to whom this Lease is to be assigned who will covenant with the Landlord on the terms (mutatis mutandis) set out in the Third Schedule
- 4.22.5.3 If the Landlord reasonably so requires the proposed assignee will prior to the assignment enter into such reasonable rent deposit arrangement and/or provide such additional security for performance by the proposed assignee of its obligations under this Lease as the Landlord may reasonably require
- 4.22.5.4 The proposed assignee shall enter into a covenant with the Landlord to pay the rents reserved by and perform and observe the covenants on the part of the Tenant contained in this Lease
- 4.22.5.4.1 clauses 4.22.4 and 4.22.5 shall operate without prejudice to the right of the Landlord to impose any further conditions upon a grant of consent where such imposition is reasonable
- Not to underlet the whole of the Premises without the prior consent in writing of the Landlord otherwise than at a rent which is not less than the open market rental value of the Premises (being in any event not less than the rent then payable under this Lease) without a line or premium and with provision for upwards only rent reviews coinciding with the reviews under this Lease and in other respects with materially the same covenants and conditions as are contained in this Lease

at all times to perform and observe the Tenant's covenants (except as to the payment of rent) and the conditions contained in this Lease

4.22.6 The Landlord may as a condition for giving its consent for any permitted underletting require the proposed underlessee to enter into a direct covenant with the Landlord to perform and observe the Tenant's covenants and the conditions contained in this Lease (save as to payment of rent)

4.22.7 Upon the Landlord consenting to an underletting of the Premises procure that the underlessee covenants with the Landlord:

Not to vary the terms of any underlease permitted under this clause 4.22 without the Landlord's written consent and throughout the term of any underlease to require the undertenant

- 4.22.7.1 Not to assign (or agree to do so) any part of the Premises (as distinct from the whole) and not to charge or underlet or share or (save by way of an assignment of the whole) part with possession of or permit any person to occupy the whole or any part of the Premises
- 4.22.7.2 Not to assign (or agree to do so) the whole of the Premises without the prior consent in writing of the Landlord (such consent not to be unreasonably withheld)
- 4.22.8 To notify the Landlord in writing with relevant details within fourteen days of any rent payable under an underlease being reviewed

4.22.5

4.22.9 In the event that any circumstances or conditions specified in clauses 4.22.4 and 4.22.5 above are framed by reference to any matter falling to be determined by the Landlord (or by any other person) if the Tenant disputes such determination then either the Landlord or the Tenant shall be entitled to require the matter or matters in question

to be referred to an independent expert who in the absence of agreement between the parties shall be appointed on the application of either party by the President of the Royal Institution of Chartered Surveyors and the determination of such independent expert shall be conclusive as to the matter or matters in question and shall be final and binding on the parties and his costs shall be met by the parties in such proportions as the independent expert shall determine

# 4.23 <u>Registration of dealings</u>

Within one month after the execution of any assignment or underlease permitted under this Lease or any assignment of such underlease or after any devolution by will or otherwise of the Term or after any other dealing with this Lease to supply a certified copy of the deed or instrument effecting the same to the Landlord and to pay such reasonable fee as the Landlord may require for registration

# 4.24 Reletting and sale boards

To permit the Landlord or its agents to enter upon the Premises and to affix upon any suitable part (which does not obscure the Tenant's own signs) a notice board for reletting or selling the same and not to remove or obscure the same and to permit all persons authorised in writing by the Landlord or its agents on the giving of reasonable prior written notice to view the Premises during business hours in the daytime

# 4.25 Costs of licences and notices as to breach of covenant

To pay on demand and indemnify the Landlord against all costs charges and expenses) (including professional fees) reasonably and properly incurred by the Landlord arising out of or incidental to any application made by the Tenant for any consent or approval of the Landlord and against all costs charges and expenses (including any professional fees) properly incurred

by the Landlord arising out of or incidental to any breach of the Tenant's covenants or the preparation and service of a schedule or interim schedule of dilapidations or any notice which the Landlord may serve on the Tenant whether served before or after the determination of this Lease (including a notice under Section 146 of the Law of Property Act 1925) requiring the Tenant to remedy any breach of any of its covenants or arising out of or in connection with any proceedings referred to in Sections 146 or 147 of that Act notwithstanding that forfeiture may be avoided otherwise than by relief granted by the Court

# 4.26 <u>Indemnity</u>

To be responsible for and to indemnify the Landlord against:

- 4.26.1 all damage loss or injury occasioned to the Premises or any adjoining premises or to the Accessways the Additional Access the Landscaped Areas or any Conducting Media or to any person or chattel (whether or not upon the Premises) caused by any act default or negligence of the Tenant or any undertenant or the servants agents licensees or invitees of either of them or by reason of any defect in the Premises and
- 4.26.2 all losses damages costs expenses claims and proceedings incurred by or made against the Landlord arising out of any breach by the Tenant of any of its obligations arising by virtue of this Lease

# 4.27 <u>VAT</u>

To pay to the Landlord upon demand any value added tax chargeable upon:

4.27.1 any supply made by the Landlord to the Tenant pursuant to this Lease so that all consideration for any such supply is exclusive of value added tax

4.27.2 any supply (whether made to the Landlord or to a third person) where pursuant to this Lease the Tenant is required to pay to the Landlord any sum in respect of any costs fees expenses or other expenditure or liability (of whatever nature) in connection with that supply except to the extent that any such value added tax may be recoverable by the Landlord from H.M. Customs and Excise

PROVIDED ALWAYS that the Landlord will produce a valid VAT invoice to the Tenant within 14 days of receipt of any payment of VAT from the Tenant

# 4.28 Defects

To inform the Landlord as soon as practicable in writing of any defect in the Premises which might give rise to a duty imposed by common law or statute on the Landlord and to indemnify the Landlord against all actions costs claims and liabilities suffered or incurred by or made against the Landlord in respect of the Premises under the Defective Premises Act 1972

#### 4.29 Costs of party items

In so far as the Tenant is not obliged to contribute to the costs of the same under any other provision of this Lease to pay a fair and proper proportion of the expense (including any professional fees) of repairing rebuilding painting maintaining cleaning and lighting all party structures and all roofs conducting media boundary structures forecourts yards roads ways entrances passages staircases balconies and other amenities or things the use or benefit of which is common to the Premises and any adjoining or neighbouring premises such proportion to be determined by the Landlord's Surveyor whose determination shall (save in the case of manifest error) be final and binding on the Tenant

# 4.30 <u>Documents affecting title</u>

To perform and observe the provisions of the documents and the other matters referred to in the Fifth Schedule so far as they affect or relate to the Premises

# 5. <u>LANDLORD'S COVENANTS</u>

The Landlord covenants with the Tenant:

# 5.1 Quiet enjoyment

That the Tenant performing and observing the covenants conditions and agreements contained in this Lease shall and may peaceably and quietly hold and enjoy the Premises during the Term without any lawful interruption or disturbance by the Landlord or any person rightfully claiming through or under it

# 5.2 <u>Insurance</u>

At all times during the Term to keep the Premises insured for the Landlord's benefit in the Full Reinstatement Value against the Insured Risks and if the Premises are damaged or destroyed by any of the Insured Risks the Landlord will with all convenient and practicable speed repair or reinstate the Premises using such materials as are then appropriate subject to all necessary consents and licences being obtained

#### Provided that

- 5.2.1 the Landlord's obligations under this covenant shall cease if the insurance shall be rendered void or voidable or the policy moneys withheld in whole or in part by reason of any act or default of the Tenant or any undertenant or any of their respective employees contractors licensees or invitees
- 5.2.2 if the Premises are destroyed or so seriously damaged by any Insured Risk as to require (in the opinion of the Landlord's surveyor whose

decision shall be final and binding upon the Parties) substantial reconstruction then the Landlord may at any time within six months' notice in writing to determine this Lease and immediately upon the expiry of that notice this demise shall determine but without prejudice to the rights and remedies of any party against any other in respect of any antecedent claim or breach of covenant and all insurance money shall be the absolute property of the Landlord

# 5.3 <u>Estate Roads and Parking etc</u>

Subject to payment by the Tenant of the Tenant's Proportion of the Service Charge in accordance with Part 1 of the Sixth Schedule and any sums payable in accordance with Part 2 of the Sixth Schedule the Landlord shall:

- 5.3.1 maintain and repair such of the Estate Roads as are within the Estate and use all reasonable endeavours to do so (or to procure that it be done) in respect of the remainder of the Estate Roads until (in each case) adoption by the highway authority and
- 5.3.2 maintain and repair the Accessways and the Additional Access.

#### 6. CONDITIONS

6.1.1

Provided always and it is hereby agreed and declared as follows:

# 6.1 <u>Re-possession on Tenant's default</u>

If at any time during the Term:

- the rents reserved by this Lease or any of them or any part of them shall be in arrear for fourteen days after the same shall have become due (whether legally demanded or not) or
- 6.1.2 the Tenant shall at any time fail or neglect to perform or observe any of the covenants conditions or agreements on its part to be performed and observed contained in this Lease or in any licence approval or consent given by the Landlord to the Tenant in relation

to the Premises or in any other deed supplemental to this Lease or by which this Lease may be varied or

- 6.1.3 the Tenant either shall (being a corporation) have an application made for an administration order (whether or not at its instance) or enter into liquidation whether compulsory or voluntary (not being a voluntary liquidation for the purpose of reconstruction only) or (being an individual) become bankrupt or
- 6.1.4 the Tenant shall make any arrangement or composition with creditors or suffer any distress or execution to be levied on property of the Tenant or have an encumbrancer take possession or a receiver appointed in respect of the same

then and in any such case it shall be lawful for the Landlord (or any person or persons duly authorised by it in that behalf) to re-enter into or upon the Premises and thereupon the Term shall absolutely cease and determine but without prejudice to the rights and remedies of the Landlord in respect of any antecedent breach of any of the covenants conditions or agreements contained in this Lease

# 6.2 Benefit of insurance and abatement of rent

6.2.1 The benefit of all insurance effected by the Landlord under this Lease or otherwise in respect of the Premises or the Estate shall belong solely to the Landlord but if the Premises or any part of them shall at any time be destroyed or damaged by any of the Insured Risks so as to be unfit for occupation or use then and in every such case (unless the Landlord's policy of insurance in relation to the Premises shall have been rendered void or voidable or the policy moneys withheld in whole or in part by reason of the act default or omission of the Tenant or any undertenant or any of their respective employees

contractors licensees or invitees) the rent first reserved by this Lease or a fair and just proportion thereof according to the nature and extent of the damage sustained shall be suspended and cease to be payable until the Building shall have been repaired or reinstated and made fit for occupation or use in accordance with clause 5.2

- 6.2.2 No account shall be taken of damage in relation to any alteration or improvement to the Premises carried out otherwise than by the Landlord unless such alteration or improvement has in fact been taken into account in effecting both the insurance of the Premises and the insurance in respect of the Loss of Rent
- Any dispute between the Landlord and the Tenant concerning the proportion or duration of the suspension or cesser shall be determined by an arbitrator appointed in default of agreement between the Landlord and the Tenant on the application of either of them by the President of the Royal Institution of Chartered Surveyors and any such reference shall be a submission to arbitration within the Arbitration Acts 1950 and 1979
- 6.3 Notices

The provisions of Section 196 Law of Property Act 1925 (as amended) shall apply to the giving and service of all notices and documents under or in connection with this Lease

6.4 Repair of Estate Roads etc

The Landlord shall have no liability to the Tenant:

6.4.1 in relation to any failure to maintain and repair the Estate Roads the Accessways or the Additional Access unless the Tenant has given written notice to the Landlord of the relevant aspect of non maintenance or disrepair or

on the grounds of disrepair of the Estate Roads caused by traffic using the Estate Roads for the purposes of the development of other parts of the Estate or the carrying out of works on the Estate but so that the disrepair shall be made good within a reasonable period after the Estate Roads have ceased to be so used

# 6.5 <u>Closure of facilities</u>

Subject to the Landlord using all reasonable endeavours to procure alternative access to the Premises the Landlord may temporarily close or withdraw from use any of the Estate Roads the Accessways or the Additional Access to permit the carrying out of any repairs maintenance or works by it or any person authorised by it and in such circumstances the Tenant shall have no claim against the Landlord in connection with any such closure or withdrawal the person carrying out such works endeavouring to keep such closure or withdrawal to the minimum reasonably required

# 7. <u>RENT REVIEW</u>

# 7.1 In this clause:

"Assumptions"

means the assumptions that:

- 1. the Premises are in good and substantial repair and condition
- 2. the Landlord and the Tenant have complied with all their respective covenants and obligations imposed by this Lease on each of them
- 3. all parts of the Premises are fit and ready for use for the Permitted Use

- 4. that the rent at which the Premises could reasonably be expected to be let is that which would be payable after the expiry of any rent free period or after the receipt of such other rent concession or inducement (in each case for whatever reason) as may be negotiated in the open market between a landlord and a tenant upon a letting of the Premises
- 5. no work has been carried out on the Premises during the Term which has diminished the rental value of the Premises and
- 6. any damage to or destruction of the Premises or any means of access to them has been fully reinstated

"Current Rent"

means the yearly rent reserved by this Lease (disregarding any suspension of rent under any other provision of this Lease) as varied from time to time pursuant to this clause

"Matters to be Disregarded"

means each of the following matters so far as they may affect rental value:

- 1. the fact that the Tenant has previously been in occupation of the Premises
- 2. any goodwill attaching to the Premises by reason of the carrying on of the business of the Tenant at the Premises and

3. any improvement to the Premises carried out during the Term by the Tenant or undertenant other than improvements effected at the expense of the Landlord or pursuant to any obligation to the Landlord whether under the provisions of this Lease or any other deed or document

"New Rent"

as at any Review Date means the higher of:

- 1. the Current Rent immediately before that Review Date and
- 2. the Rental Value as at that Review Date

"President"

means the President for the time being of the Royal Institution of Chartered Surveyors any other body reasonably specified by the Landlord

"Rental Value"

as at any Review Date means the open market rental value of the Premises at that Review Date:

- 1. as agreed by the Landlord and the Tenant or
- 2. as determined by a Valuer pursuant to the provisions of this clause

"Valuer"

7.2

means a chartered surveyor who has experience of practice in property of the nature and type of the Premises and who is acquainted with the market in the area in which the Premises are located

The New Rent shall be payable from and including each Review Date.

- 7.3 If the New Rent has not been agreed by the date which is three months before the relevant Review Date either the Landlord or the Tenant may require the Rental Value to be determined by a Valuer
- 7.4 Where the Rental Value is to be determined by a Valuer and the Landlord and the Tenant do not agree as to his appointment within twenty one days of either of them putting forward a nomination to the other such Valuer shall be appointed at the request of either party by the President
- 7.5 The Valuer shall act as an expert and not as an arbitrator and his decision (including any decision as to the costs of such determination) shall be final and binding on the parties
- 7.6 The Valuer shall upon appointment either by the parties or the President be required upon his determination to provide a reasoned award to the Landlord and the Tenant
- 7.7 Notwithstanding that the Valuer shall act as an expert the Landlord and the Tenant shall each be entitled to make representations and counter-representations to such Valuer a copy of which shall be supplied by the Valuer to the other of them and in making an award as to costs the Valuer shall have regard to the representations and counter-representations made to him
- 7.8 The Valuer shall determine the Rental Value as the best yearly open market rack rental value at which the Premises might reasonably be expected to be let with vacant possession in the open market by a willing lessor to a willing lessee for a term of years equal in length to the balance unexpired of the Term as at the relevant Review Date and on the terms and conditions of a lease which are otherwise the same as this Lease except as to the actual amount of the Current Rent and the date on which the term commences

and making the Assumptions but taking no account of the Matters to be Disregarded

- 7.9 If by the relevant Review Date the New Rent has not been ascertained (whether or not negotiations have commenced) the Tenant shall continue to pay the Current Rent on each day appointed by this Lease for payment of Rent until the New Rent has been ascertained and upon such ascertainment of the New Rent the Tenant will pay to the Landlord as arrears of rent an amount equal to the difference between the New Rent and the Current Rent actually paid for the period since the relevant Review Date together with interest on the difference at 3% below the Prescribed Rate
- 7.10 In no event shall the yearly rent payable by the Tenant to the Landlord after the relevant Review Date be less than the yearly rent payable by the Tenant to the Landlord immediately before such relevant Review Date
- 7.11 A memorandum in the form set out in the Fourth Schedule of any increased rent determined pursuant to this clause 7 shall as soon as may be after such determination be prepared in duplicate and signed by or on behalf of the Landlord and Tenant

#### 8. <u>TENANT'S OPTION TO DETERMINE</u>

8.1

- In this clause "Termination Date" means November 2001 or November 2006
- 8.2 Subject to the pre-conditions in clause 8.3 being satisfied on the relevant Termination Date, and subject to clause 4.8 the Tenant may determine the Term on a Termination Date by giving the Landlord not less than six months' written notice, which notice must be expressed to be given under section 24(2) of the Landlord and Tenant Act 1954. The Term will then determine on the relevant Termination Date, but without prejudice to any

- 8.3 The pre-conditions are that:
- 8.3.1 vacant possession of the whole of the Premises is given to the Landlord; and
- 8.3.2 all rent and other sums due under this Lease up to the relevant Termination Date have been paid in full and all the Tenant's obligations in this Lease up to the relevant Termination Date have been substantially complied with
- 8.4 The Landlord may waive any of the pre-conditions set out in clause 8.3 at any time before the relevant Termination Date by written notice to the Tenant
- 8.5 The Tenant will cancel any registration it has made in connection with this clause within 15 working days of the relevant Termination Date
- 8.6 Time will be of the essence for the purposes of this clause

IN WITNESS of which this Lease has been executed and is delivered as a deed on the date appearing as the date of this Lease

# FIRST SCHEDULE

# **Description of the Building and Fixtures**

The schedule annexed to this Lease headed "The First Schedule"

# SECOND SCHEDULE

# Part 1

# The Rights

1. The right in common with the Landlord and all other persons now or at any time after the date of this Lease similarly entitled to pass at all times and for all purposes connected with the proper use of the Premises in accordance with this Lease:

- 1.1 with or without vehicles over and along the Estate Roads and the Accessways and (except for that part hatched purple on the Lease Plan) the Additional Access until in each case adoption by the highway authority and
- 1.2 on foot only over and along that part of the Additional Access shown hatched purple on the Lease Plan
- 2. The right in common with the Landlord and all other persons now or at any subsequent time entitled to a similar right to the free passage and running of water soil gas electricity and other services from and to the Premises through the Conducting Media in the Estate other than those adopted by the relevant statutory undertaker
- 3. The right of support and protection for the Premises from the remainder of Winnersh 500
- 4. So far as necessary and in any event subject to any licence required by clause 4.20 the right to enter upon so much of the area shown hatched green on the Lease Plan as lies to the rear of the Land to install and thereafter at all times to maintain repair renew and rebuild an air conditioning plant

# Part 2

# **The Exceptions and Reservations**

- 1. To the Landlord and all others authorised by it the free and uninterrupted passage and running of water soil gas electricity and telephone or any other service or supply from the other buildings and land of the Landlord and its tenants adjoining or near the Premises and from the land and premises of others so authorised as aforesaid through the Conducting Media which are now or may hereafter be in through under or over the Premises
- . To the Landlord and all others authorised by it the right at all times to enter the Premises with all necessary equipment for the purposes of:

- 2.1 carrying any repairs maintenance or works to or in relation to the Accessways and (where clause 4.6.5 applies) the Landscaped Areas including the right to use and take water from any external water supply at the Premises for the purposes of maintenance of planting and landscaping at Winnersh 500
- 2.2 laying constructing installing replacing repairing maintaining or altering any Conducting Media now or hereafter in through under or over the Premises or any adjoining property or making connections to any such Conducting Media
- 2.3 carrying out inspections of or tests to any such Conducting Media
- doing such other things in relation to any Conducting Media which directly or indirectly serve or are connected to other premises as the Landlord considers proper to ensure that such Conducting Media are in good working order and condition and
- 2.5 exercising any of the rights of the Landlord contained in this Lease.
  - The Landlord causing as little damage and inconvenience as practicable in the exercise of such rights and as soon as practicable making good all damage caused
- 3. To the Landlord full right and liberty at any time hereafter or from time to time to execute works and erections upon or to alter or rebuild any of the buildings erected on any part of the Estate and to use its Estate and each part of it in such manner as the Landlord may think fit notwithstanding that the access of light and air to the Premises may thereby be interfered with
- 4. To the Landlord and other the tenants and occupiers of other parts of Winnersh 500 the right of support and protection from the Premises
- 5. To the Landlord the right to install and retain on the Land columns for the provision of lighting security or other services for Winnersh 500 and the right to enter the Premises with all necessary equipment for such purposes or for

maintaining altering or replacing such column the Landlord causing as little damage and inconvenience as practicable in the exercise of such rights and as soon as practicable making good all damage caused

# THIRD SCHEDULE

# **Obligations of the Surety**

- I. If at any time the Tenant shall not pay any of the rents or other sums payable under this Lease or perform and observe any of the covenants conditions or other terms of the Lease the Surety shall pay such rents or other sums or observe or perform such covenants conditions or other terms
- By way of separate and additional liability and notwithstanding that the guarantee in paragraph 1 may be unenforceable or invalid for any reason the Surety indemnifies the Landlord against all proper losses damages costs and expenses suffered or incurred by the Landlord arising out of or in connection with any failure by the Tenant to pay any of the rents and sums or to perform and observe any of the covenants conditions or other terms referred to in paragraph 1
- 3. I

3.1

- the Tenant shall be wound up or (being an individual) become bankrupt and its liquidator or trustee in bankruptcy shall disclaim this Lease or
- 3.2 the Tenant shall cease to exist or shall die or
- 3.3 this Lease shall be forfeited

(the date on which such event occurs being called the "Relevant Date") the Landlord may within three months after the Relevant Date by notice in writing require the Surety to accept a lease of the Premises for a term commencing on the Relevant Date and continuing for the residue then remaining of the Term at the same rents and with the same covenants and conditions as are reserved by and are contained in this Lease and in such case the Surety shall take such lease

accordingly and execute a counterpart of it and pay all costs and duties in relation to it

The Surety undertakes with the Landlord that:

4.3

- 4.1 its obligations to the Landlord are primary obligations and it is jointly and severally liable with the Tenant (both before or after any disclaimer by a liquidator or trustee in bankruptcy) for the fulfillment of all the Tenant's covenants and obligations
- 4.2 the Surety shall not claim in any liquidation bankruptcy administration receivership composition or arrangement of the Tenant in competition with the Landlord and that the Surety shall remit to the Landlord the proceeds of all judgments and all distributions which the Surety may receive from any liquidator trustee in bankruptcy administrator administrative receiver receiver or supervisor of the Tenant and shall hold for the benefit of the Landlord all security and rights the Surety may have over assets of the Tenant while any liabilities of the Tenant or the Surety to the Landlord remain outstanding and
  - if the Landlord shall not require the Surety to take a new lease of the Premises the Surety shall nevertheless upon demand pay to the Landlord a sum equal to the rent first reserved under this Lease and all other sums that would have been payable under this Lease in respect of the period from and including the Relevant Date until the expiry of six months after such Date or until the Landlord shall have granted a lease of the Premises to a third party (whichever shall first occur) in addition and without prejudice to the Surety's other obligations to the Landlord
- 5. The Surety waives any right to require the Landlord to proceed against the Tenant or to pursue any other remedy of any kind which may be available to the Landlord before proceeding against the Surety

6.	The liabilities of the Surety under this Schedule shall not be affected by:
6.1	the granting of time or any other indulgence or concession to the Tenant or any compromise or compounding of the Landlord's rights
6.2	the Tenant being in liquidation or (as the case may be) declared bankrupt
6.3	any variation in the terms and conditions of this Lease
6.4	any delay in exercising or failure to exercise or other exercise (including re-entry under clause 6.1) of any of the Landlord's rights against the Tenant
6.5	any refusal by the Landlord to accept rent tendered by or on behalf of the Tenant following a breach by the Tenant of its obligations under this Lease
6.6	any legal limitation or any immunity disability or incapacity of the Tenant (whether or not known to the Landlord) or the fact that any dealings with the Landlord by the Tenant (including the acceptance by the Tenant of this Lease) may be outside or in excess of the powers of the Tenant or
6.7	any other thing (including the expiration or sooner determination of the Term or any such disclaimer or the death of the Surety (or any of the persons comprising the Surety) or (in relation to one or more of such persons) the discharge of the other person or persons) whereby (but for this provision) the Surety or any of them would be exonerated either wholly or in part from any of the Surety obligations hereunder
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# FOURTH SCHEDULE

# Rent Review Memorandum

# Winnersh 540 Winnersh Triangle

# Wokingham Berkshire

			Lease dated [ ] 1996 between	
			Slough Properties Limited (1) and	
			Azur Environmental Limited (2)	
ursuant to t	he above Lease [	] as Landlord and [	] as Tenant record that the yearly rent has been increased to the sum of $\mathfrak{t}[$	] with effect from [relevant Review Date]
Dated:	[ ]			
Signed:	Landlord/Tenant	_		

# FIFTH SCHEDULE

# **Documents and matters affecting title**

1. The covenants matters and stipulations set out or referred to in or contained or referred to in the documents referred to in the Property and Charges Registers of the Landlord's title number BK 167503 so far as the same affect or relate to the Premises other than the various agreements under Section 52 of the Town and Country Planning Act 1971 as varied by the Termination Agreement dated 30th June 1993

2. A lease dated 5th November 1996 between Slough Properties Limited (1) and Southern Electric plc (2) relating to an electricity substation to the south-east of the Premises

# SIXTH SCHEDULE

# Part 1

# Service Charge for the Estate

# Part A

#### **Heads of Expenditure**

Costs and liabilities which the Landlord (which in this Schedule shall where the context admits include any other company which is a member of the same group of companies as the Landlord) reasonably and properly incurs or becomes liable to pay or discharge in connection with the Estate or occupiers thereon including the costs of:

- . repairing maintaining cleaning renewing and resurfacing the Estate Roads (including the renewal of the line markings on the Roads)
- 2. repairing maintaining replacing and operating the lighting of the Estate Roads (including the cost of electricity)
  - repairing maintaining decorating and replacing any estate office for the Estate including:
    - the cost of services (including electricity gas and telephone) supplied in any such office
- 3.2 rates payable in respect of any such office

3.

- 3.3 the cost of equipment and materials in or for such office to the extent that they are intended to be provided for the purposes of such office
- repairing maintaining and renewing any Conducting Media in or for any part of the Estate to the extent that they are not the responsibility of any tenant of the Landlord on the Estate or of a statutory undertaker and do not exclusively serve premises occupied by such a tenant

- 5. repairing maintaining cleaning and keeping tidy the Common Areas including the tending care and replacement of plants and trees and the maintenance and upkeep of landscaped areas including nature strips in roads or on roundabouts at or at the approaches to Winnersh Triangle
- 6. repair maintenance and replacement of tanks pumps pipes and other equipment (excluding any that form part of the Premises) forming part of the sprinkler system at the Estate including the costs of inspection and maintenance contracts
- 7. repair maintenance decoration operation lighting and cleaning of any structures fences walls signs footpaths amenities and things on the Common Areas and benefiting the Estate or part of it including any entrance feature from time to time for the Estate and any equipment associated with it
- 8. employing staff for the benefit of the Estate or the provision of any services on or for the Estate (including for the purposes of operating an estate office) including the costs of statutory and other insurance health pension welfare and other payments contributions and premiums and the costs incidental to the performance of the duties of any such staff but where engaged also to perform duties not connected with the Estate only a proportion of each of such costs
- 9. rates taxes assessments duties charges burdens impositions and outgoings imposed or charged upon the Common Areas or any part of them (including any estate office) or upon the owner or occupier thereof
- 10. insurance in such sum and against such risks as the Landlord shall consider appropriate in respect of damage to any part of the Common Areas (including the Estate Roads) and the structures buildings walls fences and other things thereon
- 11. public liability insurance in respect of any liability of the Landlord in relation to the Estate and the Estate Roads
- 12. calculating the Service Charge and the Tenant's liability under this Lease including preparation of accounts and certification

13.	providing such security service for the benefit of the Estate as the Landlord may from time to time consider appropriate
14.	the management of the Estate including the fees and disbursements of:
14.1	any managing agents for or in connection with such management (including the collection of rent and other sums payable by tenants of the Estate to the Landlord but excluding the costs of court proceedings in recovering arrears from tenants other than the Tenant) and the performance of any other duties or services in or about the Estate
14.2	the Landlord's Surveyor for or in connection with the performance of any function for the purposes of this Lease
14.3	any other individual firm or company engaged to perform services for the Estate or any part of it
14.4	the Landlord where it carries out any service or function to such management (including a fee charged by the Landlord for the collection of rent and other sums payable by tenants of the Estate to the Landlord but excluding the costs of court proceedings in recovering arrears from tenants other than the Tenant)
15.	any other facility service amenity or thing provided on or for the Estate and intended to benefit the Estate and in the interests of good estate management
16.	any value added tax payable on any of the costs referred to in this Part

# Part B

# Calculation of the Service Charge

The Landlord shall as soon as practicable after the end of each Service Charge Period:

prepare an account giving particulars of the Service Charge for that Period and showing the Tenant's Proportion of the Service Charge and

1.1

1.1.1

1.1.2	supply to the Tenant a copy of such account	
1.2	Upon such account being certified by the Landlord's Surveyor it shall be conclusive evidence for the purposes of this Lease of all matters of fact referred to in it save in respect of manifest error	
2.1	Advance payments on account of the Tenant's Proportion of the Service Charge in respect of a Service Charge Period shall be paid to the Landlord by the Tenant according to the reasonable and proper estimate made by the Landlord's Surveyor acting as expert of the amount of the Service Charge for that Period	
2.2	Written notice of such estimate shall be promptly given to the Tenant	
2.3	Such payments shall be made by equal instalments on each of the quarter days occurring during the relevant Period or (if the estimate is notified to the Tenant after such a quarter day) on such of them as occur after such notification.	
2.4	The first advance payment shall be:	
2.4.1	in respect of the period from the Commencement Date until the next quarter day after the date of this Lease	
2.4.2	paid by the Tenant on the date of this Lease and	
2.4.3	calculated according to an estimate of the Service Charge made in accordance with 2.1 and notified in writing to the Tenant	
3.	If the Tenant's Proportion of the Service Charge for a Service Charge Period:	
3.1	exceeds any amounts paid by the Tenant to the Landlord as advance payments on account thereof the amount of the excess (or the whole Proportion if no advance payments have been made) shall (notwithstanding the expiration or sooner determination of the Term) be paid by the Tenant to the Landlord within twenty-one days of the supply to the Tenant of the account pursuant to paragraph 1 or	

- 3.2 is less than such amounts so paid the amount of the difference shall be credited to the Tenant against the next payments of rents due
- 4. In respect of each of the Service Charge Periods in which occur the Commencement Date and the date of the expiration or sooner determination of the Term the Tenant shall only be obliged to pay the Tenant's Proportion of the Service Charge in respect of that part of the Service Charge for that Period as bears to the whole of that Service Charge the same proportion that the number of days of the Term occurring in the relevant Period bears to 365

## Part 2

# Costs of Winnersh 500 facilities

# Accessways and landscaping

1.1	The Tenant shall pay to the Landlord on written demand the proper proportion of the costs liabilities fees and expenses which the Landlord incurs or becomes liable to pay in
	connection with:

- 1.1.1 the Accessways and any signs or direction notices on or for them including all sums incurred pursuant to clause 5.3 or otherwise in the maintenance repair cleaning lighting renewal and resurfacing of them and
- 1.1.2 the maintenance of landscaping at Winnersh 500 so far as not demised to any tenant
- 1.2 In this paragraph 1 the "proper proportion" means (subject to clause 6.8) a fair proportion (which may take into account the extent and nature of use) to be certified by the Landlord's Surveyor whose decision shall be final and binding on the parties

# Other facilities

2.1 The Tenant shall pay to the Landlord on written demand the proper proportion of the costs liabilities fees and expenses which the Landlord

incurs or becomes liable to pay in connection with the provision and maintenance of any other facility service amenity or thing for the benefit or use of the tenants or occupiers of and in Winnersh 500

In this paragraph 2 the proper proportion means (subject to Clause 6.8) the proportion which the gross external area of the Building bears to the aggregate of that area and the gross external area of the other buildings at Winnersh 500 (or any buildings replacing such buildings)

# Part 3

# Costs of Additional Access

- 1. The Tenant shall pay to the Landlord on written demand the proper proportion of the costs liabilities fees and expenses which the Landlord incurs or becomes liable to pay in connection with:
  - repairing maintaining cleaning renewing and resurfacing the Additional Access or
  - repairing maintaining replacing and operating any lighting of the Additional Access

2.2

1.1

1.2

In this Part 3 the proper proportion means (subject to clause 6.8) the proportion which the gross external area of the Building bears to the aggregate of that area and the gross external area of Building 535

# SEVENTH SCHEDULE

# Materials referred to in clause 4.18.2

The schedule annexed to this Lease and headed "The Seventh Schedule"

( THE COMMON SEAL of SLOUGH

( PROPERTIES LIMITED was

( affixed to this deed in the

( presence of:

Director /s/ [Illegible]

Secretary /s/ [Illegible]

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# FIRST SCHEDULE

#### BUILDING NO. 540 ESKDALE ROAD WINNERSH TRIANGLE WINNERSH

A two storey, office/production building measuring approximately, 18.25m (59'10") by 31.52m (103'5") comprising at ground floor, office and production areas and first floor office, the whole providing gross external areas of:-

Production Area	364.96 m <sup>2</sup>	(3,928 sq.ft.)
First Floor Office	185.41m <sup>2</sup>	(1,996 sq. ft.)
Ground Floor Office	185.41 m <sup>2</sup>	(1,996 sq. ft)
Total	735.78 m <sup>2</sup>	(7,920 sq. ft)

# FOUNDATIONS

Mass concrete bases and trench fill foundations, to structural engineer's design and specification.

# FRAME

Steel frame of columns and beams all to structural engineer's design and specification.

# **ROOF**

Roof comprises profiled steel sheeting with light grey coloured plastisol finish and supported on galvanised mild steel purlins and galvanized zed spacers. Internal roof lining of galvanised PVF2 coated profiled lining sheets, cavity between containing 80mm layer of rockwool insulation.

Rainwater is conducted away via insulated, galvanised pressed steel gutters discharging into internal PVCu rainwater pipes connected to the below ground surface water drainage system.

# EXTERNAL WALLS

Cavity wall construction of 103mm facing bricks and internal skin of 100mm blockwork finished fair faced and emulsion painted within the production area with a partially filled cavity containing 65mm rockwool insulation held against inner skin. Internal faces of the external walls to offices finished with plasterboard drylining with an emulsion paint finish.

Page 1

South (front) elevation comprises facing brick piers surmounted by facing brick parapet with PVF2 colour coated, galvanised steel copings and contains 4 No. full height panels of curtain walling and 1 No. recessed full height entrance screen.

The curtain walling/window system has a self-draining thermally broken and pressure equalised aluminum frame with an external coating of black powder coating with silver grey anolok 541 anodised cappings. The internal coatings being matt white polyester powder coat.

Double glazing within the curtain walling and windows consists of 6mm grey anti-sun outer pane, 12mm cavity and 6mm clear inner pane. Insulated look-a-like panels provided where vision not required.

Curtain walling panels each have four top hung opening lights. The curtain walling and entrance canopy are set within recesses and are provided with PVF2 coated galvanised steel brise solier over the ground floor windows.

The full height entrance screen contains two opening lights, a matching three panel door complete with polished stainless steel furniture, mortice lock and concealed bolts at head and foot. The entrance screen also contains PVF2 coated letter plate inset within the glazing units. A stainless steel, tubular framed feature panel is provided over the main entrance between brick piers left ready to receive tenant's signage.

East elevation contains three full height panels of curtain walling. One painted steel Henderson Defender door set including butt hinges and push bar panic latch, one electrically operated insulated sectional up and over loading door approximately 5 m x 3.85 m.

North elevation comprises cavity brickwork as previously described with feature brick walling. East elevation comprises double block party wall.

#### EXTERNAL AREAS

**South:** - Car parking in concrete block paving for five cars.

Landscaping incorporating shrubs and semi mature trees.

Block paving footpaths.

East: - 2.4m high x 200mm diameter painted mild steel tubular bollards with cranked tops to loading door reveals.

Two retractable anti ram bollards to loading bay door.

Remote landscaping incorporating shrubs and semi mature trees.

- Car parking in concrete block paving for fourteen cars.

Page 2

# INTERNAL

# WALLS

Internal blockwork walls forming at ground floor level division between office/production areas and staircase, disabled, male and female toilet accommodation and tea room and at first floor level, staircase, male and female toilet accommodation and plant area.

Dividing wall between production and office areas is of two skins of 100mm blockwork, remaining walls generally of 100mm blockwork.

General office areas and staircase are plasterboard drylined with emulsion paint finish. Toilet accommodation and tea room plasterboard drylined with ceramic tile finish. First floor cleaners' cupboard and plant room finished fair faced blockwork. All drylined walls provided with varnished ash skirtings. External windows provided with Durapal laminate faced window boards.

Internal walls contain at ground floor level six and first floor level four flush faced ash veneered semi solid core doors incorporating glazed vision panels to circulation areas. Fire doors glazed with Georgian wired polished plated glass.

Ground and first floor staircase entrances incorporate staircase screen in solid ash with Georgian wired polished plate glass. Doors complete with polished stainless steel door furniture, mortice latches or locks, kicking plates, door signage and door closers as appropriate all set in solid ash frames and architraves with clear varnished finish.

# **Toilet Accommodation**

Ground Floor:	2 No.	WC suites.
Male	2 No.	Hand basins.
	2 No.	Urinals.
Ground Floor: Female	2 No.	WC suites.
	2 No.	Hand basins.
Tea Room:	1 No.	Stainless steel single bowl, single drainer sink set in post formed melamine worktop with base units under.
Ground Floor:	1 No.	WC suite.
	1 No.	Hand basin.
Disabled Toilet	3 No.	Fixed grab rails.
	1 No.	Retractable grab rail.
First Floor:	1 No.	WC suite.
Male Toilet	1 No.	Hand basin.
	1 No.	Urinal.
First Floor:	1 No.	WC suite.

Female Toilet 1 No. Hand basin.

All sanitary fittings are white vitreous china (commercial standard) and provided with all taps, plugs, chains and wastes and connected to hot and cold water supplies as necessary and connected to the below ground foul drainage system. Mirrors provided over hand basins.

# FLOORS

Ground floor to production area comprises of a powerfloated reinforced concrete floor to BRE medium load classification incorporating proprietary anti-dust sealant.

Ground floor office of reinforced concrete floor designed for a uniformly distributed load of 6 KN per m<sup>2</sup> (120lb per sq. ft) with a raised access floor to PSA medium grade providing 150mm clear void. Raised access floor finished with Esco Pallas Excel or similar carpet tiles.

First floor comprises of precast prestressed concrete planks designed for a superimposed load excluding self weight of 3.5KN per m<sup>2</sup> (70lb per sq. ft.). Office areas complete with PSA medium grade raised access floor with 150mm clear void. Raised access floor finished with Esco Pallas Excel or similar carpet tiles.

Toilet areas to ground and first floors finished with Polyflor Finesse vinyl floor covering.

Staircase and associated lobbies finished with carpet tiles to match general office areas and incorporate non-slip safety nosings.

Matwell and Jaymart grimestopper mat inset provided to the main entrance lobby area.

#### **CEILINGS**

Ceiling to production area comprises underside of structural soffit to first floor offices.

Ceiling throughout remainder of offices, staircase and toilet accommodation comprises of 600mm x 600mm ceiling tiles. Rachter Systems Rafa Co-ordinate 9 Plain or similar tiles set in a micro look exposed grid.

# STAIRCASE

Staircase of precast reinforced concrete complete with polished stainless steel handrail. The stairs are fitted with solid ash strings and skirtings with clear varnish finish to match remainder of accommodation.

# **ELECTRICAL INSTALLATION**

#### Lighting is provided as follows:-

Ground Floor Office: 19 No. Recessed fluorescent luminaires (1200mm x 600mm).

Ground Floor Toilet 5 No. Recessed compact fluorescent downlights. Accommodation Concealed fluorescent batten luminaires above mirrors and WC's. Kitchenette & Lobby: 2 No. Circular recessed fluorescent fittings with prism louvres. Production Area: 9 No. Sodium boxed downlighters. Disabled Toilets: 1 No. Shallow dome, wall mounted fluorescent fitting. Staircase & 4 No. Recessed, compact, fluorescent downlights. Associated Lobbies: 3 No. Wall mounted, feature, fluorescent fittings. 3 No. Recessed, circular, fluorescent luminaires. First Floor Toilet 3 No. Compact fluorescent downlights Accommodation: 2 No. Concealed fluorescent batten luminaires above WC's. First Floor Office: 22 No. 1200mm x 600mm recessed fluorescent luminaires with V cross blade low brightness louvres.

Emergency lighting to office and production areas comprises of self contained emergency lighting unit installed to meet fire officers requirements for an open plan office and production area.

Compact fluorescent downlights to canopy over entrance. Tungsten floodlight over rear loading bay door.

# Small power is provided as follows:-

Ground Floor Office: 3 No. 13A switched socket outlet.

Ground Floor Toilet 1 No. 13A switched socket outlet.

Lobby:

Kitchenette: 1 No. 13A twin switched socket outlet.

Production Area: 1 No. Surface mounted 13A twin switched socket outlet.

Staircase and 2 No. 13A switched socket outlets.

Associated Lobbies:

External:

First Floor Office: 3 No. 13A switched socket outlets.

Plant Room: 1 No. Surface mounted 13A switched socket outlet.

#### Control and protection is provided by: -

A 200KVA electricity supply is provided complete with all necessary distribution equipment:

1 No. 400 A load switch (main incomer)
1 No. Dorman Smith switchgear load bar

Dorman Smith switchgear load bank distribution board provided with two 100A switches, a 32A switch for external lighting, two 25A

switches for fire alarm supply and heating and ventilation control equipment.

1 No. Lighting and power distribution board for offices.

1 No. Distribution board for production area lighting and power.

1 No. External lighting DB stop and control panel.

1 No. Lighting contactors panel.

The installation is wired in PVC cable of reputable manufacture and encased in welded steel screwed conduit and galvanised trunking fully complying with the present day good practise and the regulation of the Institute of Electrical Engineers.

#### HEATING

Heating is provided to the offices, toilets, tea room, staircase and circulation areas by a low pressure hot water system serving pressed metal radiators each complete with thermostatic radiator controls.

A gas fired low pressure hot water boiler complete with twin wall insulated flue and all necessary pumps, valves, thermostats and controls being located on the first floor plant area.

# **GAS INSTALLATION**

An incoming metered and valved gas supply is provided serving boiler installation.

#### HOT WATER

Hot water is provided to all sanitary accommodation via a wall mounted Heatrae Sadia instantaneous electric water heater. A further Heatrae Sadia 'Handy' water heater is provided within the disabled toilet.

# **TELECOMMUNICATIONS**

Incoming telephone duct is provided within the ground floor office left ready to receive tenant's installation.

# VENTILATION

Toilet areas are ventilated to provide six air changes per hour.

Thermostatically controlled roof mounted extract fans installed to exhaust air from the first floor office ceiling void to reduce void temperature build up at times of high solar gain through the roof.

# WATER INSTALLATION

Incoming water main to supply Authority's meter. From the Authority's meter the supply is distributed within the building to serve drinking water points direct and sanitary appliances, from a storage tank.

# FIRE ALARM INSTALLATION

A multi zone electronic fire alarm system incorporating break glass points at all exit doors and electronic sounders installed to meet the Fire Officer's requirements for an open plan office and production area.

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# The Seventh Schedule

# CHEMICALS TO BE USED BY AZUR ENVIRONMENTAL AT ITS UK FACILITY

The solvents which will be used by Azur Environmental for the purposes of research and development will be those used by a typical life sciences laboratory and are most likely to be:

lower alcohols (methanol, ethanol, isopropanol) toluene, xylene and related compounds hydrochloric, sulphuric and nitric acids.

The maximum quantities of each held at any one time would not exceed two winchesters (2 x 2.5 litres) and all would be stored in compliance with existing fire and Health and Safety legislation, eg. solvents would be stored in an approved fireproof cabinet.

A variety of dry chemicals will be held but it is impossible to specify these except that they are unlikely to differ significantly from those found in a standard life science laboratory. These will be stored and used in accordance with current Health and Safety legislation.

No hazardous or unusual chemicals will be used in Manufacturing.

All chemicals will be disposed of in accordance with recommended practice.

A safety adviser with many years experience is being appointed to ensure compliance with current legislation.

# AZUR ENVIRONMENTAL LIMITED

- and -

# MICROSCIENCE LIMITED

# ASSIGNMENT OF LEASE

540 Eskdale Road Winnersh Triangle Wokingham Berkshire

> SHADBOLT & CO Reigate

THIS ASSIGNMENT is made the 27th day of September 2001

#### BETWEEN:

- (1) **AZUR ENVIRONMENTAL LIMITED** (Company Registration no 2538199) whose registered office is at 540/545 Eskdale Road Winnersh Triangle Wokingham Berkshire RG41 5TU ('the Assignor);
- (2) MICROSCIENCE LIMITED (Company Registration no 03270465) whose registered office is at 545 Eskdale Road Winnersh Triangle Wokingham RG41 5TU ('the Assignee')

#### WHEREAS

# (1) Lease or underlease

By a lease particulars of which are set out in the first schedule ('the Lease') the property more particularly described in the Lease the postal address of which is set out in the second schedule ('the Property') was demised to the Assignor for the term of years and at the yearly rent set out in the first schedule subject to the performance and observance of the covenants on the part of the Assignor and the conditions contained in the Lease and subject to and with the benefit of the document particulars of which are set out in the Third Schedule ("the documents").

#### (2) Agreement for sale

The Assignor has agreed with the Assignee in consideration of the covenant on the part of the Assignee contained below for the assignment to the Assignee of the Property for the residue of the term granted by the Lease subject to and with the benefit of the documents.

#### NOW THIS DEED WITNESSES as follows:

#### 1 Assignment

In pursuance of the above agreement and in consideration of the covenant on the part of the Assignee contained below the Assignor with full title guarantee assigns to the Assignee ALL THAT the Property TO HOLD the Property to the Assignee for the residue now unexpired of the term of years granted by the Lease SUBJECT henceforth to the payment of the rent reserved by and the performance and observance of the covenants and agreements on the part of the lessee and the conditions contained in the Lease and the documents.

#### 2. Covenant for indemnity

The Assignee covenants with the Assignor that it and its successors in title to the Property will during the continuance of the term granted by the Lease

pay the rent reserved by and perform and observe covenants conditions restrictions stipulations and other matters contained or referred to in the Lease and the documents and will keep the Assignor indemnified against all proceedings costs claims and expenses whatsoever on account of any omission to pay the rent reserved by or any breach of any of the covenants agreements and conditions contained in the Lease and in the documents.

## 3. Covenants for title

It is hereby agreed and declared between the Assignor and the Assignee that the covenants implied by section 4 of the Law of Property (Miscellaneous Provisions) Act 1994 shall be varied so that the Assignor shall be under no liability for any failure to carry out any works of repair renewal or decoration to the Property or for any other works required under the lease when ever those works are due to be carried out.

# 4. Rights of public record

It is further agreed and declared between the Assignor and the Assignee that for the purposes of section 6(2) Law of Property (Miscellaneous Provisions) Act 1994, all matters now recorded in registers open to public inspection are to be considered with in the actual knowledge of the Assignee.

# 5. Contracts (Rights of Third Parties) Act 1999

It is not intended that any term of this deed shall be enforceable pursuant to the Contracts (Rights of Third Parties) Act 1999.

#### 6. Certificate of value

It is hereby certified that the transaction hereby effected does not form part of a larger transaction or of a series of transactions in respect of which the amount or value of the aggregate amount or value of the consideration exceeds the sum of £60,000.

IN WITNESS of which this assignment has been executed as a deed and has been delivered on the date first written above

#### FIRST SCHEDULE

# Particulars of the Lease

13 December 1996: Slough Properties Limited (1) and the Assignor (2)

# SECOND SCHEDULE

# Postal address of the Property

540 Eskdale Road Winnersh Wokingham Berkshire

# THIRD SCHEDULE

## The documents

DateDocumentParties13 December 1996Licence for AlterationsSlough Estates Limited (1) and the Assignor (2)

4

EXECUTED as a deed by  AZUR ENVIRONMENTAL LIMITED  Acting by two directors or a director and the company secretary	)	
		Director /s/ [Illegible]
		Secretary /s/ [Illegible]
		For and on behalf of MAWLAW SECRETARIES LTD
EXECUTED as a deed by MICROSCIENCE LIMITED Acting by two directors or a director and the company secretary	)	
		Director /s/ [Illegible]
		Director/Secretary /s/ Jonathan RHH Pockson
		5

# DATED 13th December 1996

# SLOUGH PROPERTIES LIMITED

- to -

# AZUR ENVIRONMENTAL LIMITED

## LEASE

Premises known as Winnersh 545 Winnersh Triangle Wokingham Berkshire

> Nabarro Nathanson 50 Stratton Street London W1X 6NX

Tel: 0171 493 9933

JE/JUS/S2883/224/jvm WP3658A 20/11/96

## **PARTICULARS**

DATE OF THIS DEED 13th December 1996

LANDLORD SLOUGH PROPERTIES LIMITED

Registered office 234 Bath Road Slough SL1 4EE

Company Registration No. 448911

TENANT AZUR ENVIRONMENTAL LIMITED

The Coach House 24A Tile House Street Hitchin Hertfordshire SG5 2DY Registered office

Company Registration No. 2538199

SURETY None

the area from time to time comprising the Landlord's estate at Winnersh Triangle Wokingham of which the Premises form part the present such area being shown for identification only edged red on the Estate Plan ESTATE

LAND the land off Eskdale Road on the Estate shown edged red on the Lease Plan

the building (presently known as Winnersh 545) on the Land which (with the Fixtures and any car parking and landscaping facilities) is described in the First Schedule BUILDING

COMMENCEMENT DATE 25th November 1996

TERM 20 years together with the period of any continuation or extension of the tenancy granted by this Lease

RENT COMMENCEMENT DATE 25th November 1996

RENT until 25th May 1997 the sum of £47,916 per annum and thereafter £95,832 per annum subject to review as provided in

this Lease

REVIEW DATES  $25 \ensuremath{^{th}}$  November 2001 and each fifth anniversary of that date

use for any purpose within Classes B1 and B8 of the Schedule to the Town and Country Planning (Use Classes) Order 1987 (as amended or replaced from time to time) PERMITTED USE

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Part 2 Costs or Winnersh 500 facilities

Seventh Schedule Materials referred to in clause 4.18.2

THIS LEASE is made on the date and between the parties stated in the Particulars

#### WITNESSES as follows:

## **DEFINITIONS**

In this Lease the following expressions have the meanings indicated:

"Accessways" the roads and ways shown for the purpose of identification only hatched brown on the Lease Plan

the "Act" means the Landlord and Tenant (Covenants) Act 1995

"Adjoining Premises" the premises known as Winnersh 540 demised by a lease of even date made between the Landlord and the Tenant

the meaning defined in and for the purposes of Section 16 of the Act and the form of such Agreement shall be as reasonably required by the Landlord "Authorised Guarantee Agreement"

"Common Areas" the Estate other than the Premises and other areas let or intended by the Landlord to be let but including the whole of

the Estate Roads

"Conducting Media" all sewers drains pipes wires watercourses subways cables apparatus conduits and any other media or works for the

conduct or transmission of any service matter or material (including any media and works in respect of the sprinkler

system at the Estate)

"Estate Plan" the plan marked Estate Plan attached to this Lease "Estate Roads"

1. the roads pavements and paths shown for the purpose of identification only hatched brown on the Estate Plan (or any road pavement or path at any time replacing any of them) and

2. such other roads pavements and paths at Winnersh Triangle (whether or not on or forming part of the Estate) as may from time to time serve or be available for use generally by tenants and occupiers in connection with premises on the Estate but excluding any that may be or become any public highway or footpath

"First Schedule"

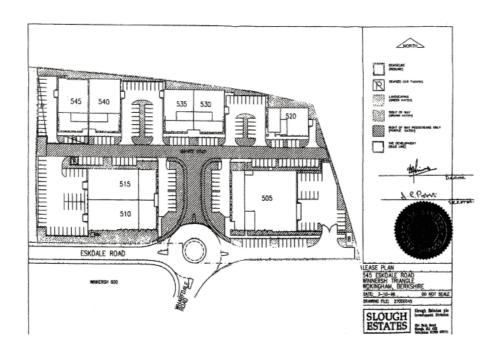
the schedule referred to in the First Schedule including any amended or substituted schedule describing any other building (and its fixtures equipment and other items) erected on the Land by the Landlord pursuant to this Lease

"Fixtures"

"Full Reinstatement Value"

the Landlord's fixtures from time to time on or forming part of the Land including the fixtures equipment and items which with the Building are described in the First Schedule

the costs (including demolition professional fees and any value added tax payable) which would be likely to be incurred in carrying out repair or reinstatement in accordance with the requirements of this Lease at the time when such



repair or reinstatement is likely to take place having regard to current building techniques and materials

"Insured Risks" fire lightning earthquake explosion aircraft riot storm tempest flood burst pipes malicious damage and impact damage

and such other insurable risks and on such terms and subject to such exclusions as the Landlord may from time to time consider reasonably necessary but excluding any risks which the Landlord shall decide from time to time not to include in any policy (whether on the grounds of unavailability of insurance cover for that risk or otherwise) but so that the Landlord shall give at least fourteen days' prior notice in writing to the Tenant of any risk ceasing to be

covered by any policy

"Landscaped Areas" those parts of the Land as are hatched green on the Lease Plan

"Lease Plan" the plan marked "Lease Plan" attached to this Lease

"Loss of Rent" the loss of the rent first reserved by clause 3 for such period (being not less than three years) as may reasonably be

required by the Landlord from time to time having regard to the likely period required for reinstatement in the event of

both partial and total destruction and in an amount

which would take into account potential increases of rent in accordance with clause 7

"Parking Area" such area or areas within the Land as are designated for parking and shown on the Lease Plan as demised car parking

"Planning Acts" includes the Town and Country Planning Act 1990 the Planning (Listed Buildings and Conservation Areas) Act 1990

the Planning (Hazardous Substances) Act 1990 and the Planning (Consequential Provisions) Act 1990

"Premises" the Land together with the Building (or any other building erected by the Landlord in its place) and all additions and the Fixtures and a reference to the "Premises" includes a reference to any part

"Prescribed Rate" three per centum above the Base Rate of National Westminster Bank PLC from time to time (or such other clearing

bank as the Landlord shall nominate) or (if such rate shall cease to be published) such other reasonable or comparable

rate as the Landlord shall from time to time designate

"Service Charge" the aggregate of the costs and liabilities referred to in Part 1 of the Sixth Schedule

"Service Charge Period" the period in respect of which the Service Charge is calculated as determined from time to time by the Landlord and

notified to the Tenant and

initially is each consecutive period of twelve months ending on 31 December

"Sign Display" the panel or panels installed by the Landlord on the Building for the display of name and logo signs

"Tenant's Proportion of the Service Charge" the part of the Service Charge for which the Tenant is liable which shall be such fair and proper proportion as the

Landlord's Surveyor shall from time to time determine acting as an expert

"Winnersh 500" means that part of the Estate (of which the Premises form part) shown edged blue on the Lease Plan

# . <u>INTERPRETATION</u>

2.3

2.4

2.1 The expressions "the Landlord" and "the Tenant" shall wherever the context so admits include their respective successors in title

Where the Tenant or the Surety (if any) for the time being are two or more persons the terms "the Tenant" and "the Surety" (if any) include the plural number and obligations expressed or implied to be made by such party are deemed to be made by such persons jointly and each of them severally

Words importing one gender include all other genders and words importing the singular include the plural and vice versa

References in this Lease to any statute or legislation (whether specific or general) include any other statute or legislation replacing amending or supplementing the same and any orders regulations bye-laws notices permissions approvals or consents thereunder

2.5 References in the Sixth Schedule to gross external areas mean such areas from time to time

#### 3. <u>DEMISE</u>

The Landlord demises to the Tenant the Premises together with the Rights referred to in Part 1 of the Second Schedule but subject to the Exceptions and Reservations referred to in Part 2 of the Second Schedule and to any documents and matters referred to in the Fifth Schedule to hold to the Tenant for the Term starting on the Commencement Date yielding and paying therefor during the Term:

#### 3.1 <u>Re</u>

3.3

3.4

yearly the Rent and all increases arising from any review pursuant to the provisions in this Lease for the review of rent to be paid without any deduction or set off by equal quarterly payments in advance on the Twenty-fifth day of March the Twenty-fourth day of June the Twenty-ninth day of September and the Twenty-fifth day of December in every year the first payment for the period from and including the Rent Commencement Date up to and including the day immediately preceding the quarter day next after the date of this Lease to be made on the date of this Lease

#### 3.2 <u>Service Charge for the Estate</u>

as additional rent the Tenant's Proportion of the Service Charge in respect of the Estate in accordance with Part 1 of the Sixth Schedule

# Winnersh 500 facilities

as additional rent the sums payable by the Tenant in respect of Winnersh 500 pursuant to and in accordance with Part 2 of the Sixth Schedule

#### Insurance

as additional rent from time to time a sum or sums of money equal to the expense incurred by the Landlord in effecting or maintaining insurance in accordance with clause 5.2 (including any increased premium payable in

respect of the Premises or any neighbouring property by reason of any act or omission by (or permitted by) the Tenant or an undertenant) as the Landlord shall from time to time effect such insurance for the Landlord's benefit in the Full Reinstatement Value against the Insured Risks and the Loss of Rent such sum or sums to be paid on demand

#### 4. <u>TENANTS COVENANTS</u>

The Tenant covenants with the Landlord as follows:

4.1 Payment of rents

To pay the respective rents and sums of money reserved and made payable at the times and in the manner in which the same are set out or referred to in clause 3 without any deduction or set off and to make all such payments to the Landlord on the due date through the Tenant's bankers by the direct debit system

4.2 <u>Interest on late payments</u>

If the Tenant shall fail to pay any rents or any other sum payable under this Lease when the same is due (whether formally demanded or not) to pay to the Landlord as additional rent (but without prejudice to any other rights of the Landlord including those under clause 6) interest on all such rents or other sums from the due date for payment until the date actually paid at the Prescribed Rate current at such due date and any such interest shall be recoverable by the Landlord as rent in arrear

4.3 <u>Payment of rates et</u>

4.3.1

4.3.2

To pay and indemnify the Landlord against all existing and future rates or other outgoings whatsoever imposed or charged upon the Premises or upon the owner or occupier in respect of the Premises

To pay and be responsible for all electricity gas and other services to the Premises

#### 4.4 <u>Exterior painting</u>

In every third year and in the last year of the Term to prepare and paint the outside of the Building where usually or previously so painted in a good and workmanlike manner and otherwise properly to clean treat or decorate other parts of the outside of the Building as the same ought to be cleaned treated and decorated (such painting and decorating to be carried out in colours and patterns first approved in writing by the Landlord such approval not to be unreasonably withheld or delayed) and whenever necessary to renew or replace all seals and mastics

## 4.5 <u>Interior painting</u>

In every fifth year and in the last year of the Term to prepare and paint all the interior of the Building where usually or previously so painted in a good and workmanlike manner (all such painting in the last year of the Term to be carried out in colours and patterns first approved in writing by the Landlord) such approval not to be unreasonably withheld or delayed

#### 4.6 Repair

4.6.1 Well and substantially to repair and maintain the Premises and the walls fences roads and Conducting Media in on or under the Premises (damage by any of the Insured Risks excepted unless the insurance moneys are withheld in whole or in part or the policy avoided by reason of any act or omission on the part of the Tenant or any undertenant or any employee contractor or invitee of either of them) and at all times to keep the same in good and substantial repair and condition and so repaired cleaned painted and maintained and further to keep all parts of the Premises clean and tidy and free from rubbish and waste materials

- 4.6.2 To keep the Parking Area for and suitable for the parking of vehicles only
- 4.6.3 Subject to clause 4.6.4 to keep the Landscaped Areas as landscaped areas maintained and planted as laid out and planted by the Landlord and in accordance with any general scheme for the Estate from time to time specified by the Landlord and to replace with equivalent specimens any plants that may die or need replacement and regularly to cut the grass and generally to tend nurture and maintain the Landscaped Areas
- 4.6.4 If the Landlord so requires at any time or from time to time not to do the things referred to in clause 4.6.3 (or such of them as may be notified to the Tenant) and shall give to the Tenant reasonable notice of such requirement but instead to pay to the Landlord on demand the reasonable and proper costs incurred by the Landlord in doing so or (where the Landlord incurs costs in relation to such Areas and all or any of the other areas shown hatched green on the Lease Plan) a proper proportion (as defined in paragraph 1.2 Part 2 of the Fifth Schedule) of the costs so incurred by the Landlord
- 4.6.5 Not in any event to harm or damage any of the Landscaped Areas or the landscaping or plants on them nor to alter such Areas or the scheme of landscaping and plants

#### 4.7 <u>Yielding up</u>

At the expiration or sooner determination of the Term to yield up the Premises in good and substantial repair and consistent with the full and due compliance by the Tenant with its obligations under this Lease and to remove such tenant's trade fixtures and fittings and any signs erected by or

at the instance of the Tenant making good any damage caused by such removal

#### Reinstatement

4.8

4.8.2

4.8.3

4.9

4.8.1 Three months before the expiry or sooner determination of the Term (unless or to the extent otherwise required in writing by the Landlord) to carry out such works as shall be necessary or desirable in order to ensure that the Premises or such part or parts of them as may be required by the Landlord conform with the description in the First Schedule

Immediately before the assignment or underletting of this Lease or of the lease of the Adjoining Premises (whether with or without the Landlord's consent) separately from the other to carry out all such works as shall be necessary to ensure that the Premises and the Adjoining Premises are rendered separate and to reinstate any party walls and to remove all doors windows or other openings and to seal off any Conducting Media

All such works shall be carried out to the satisfaction of the Landlord and the Tenant shall apply for any necessary planning permission or approval which may be required under the Planning Acts or other legislation

#### Landlord's access

On the giving of reasonable prior notice in writing to permit the Landlord or its agents at all times during the Term during reasonable hours in the day (or at any time in the case of emergency) with or without workmen and others to enter the Premises for the purpose of ascertaining that the covenants and conditions of this Lease have been performed and observed by the Tenant and examining (including opening up floors walls and ceilings

where necessary to examine) the state of repair and condition of the Premises or for the purpose of taking inventories of the Landlord's fixtures or of carrying out works on the adjoining property of the Landlord and of exercising any of the Exceptions and Reservations referred to in Part 2 of the Second Schedule the Landlord causing as little damage and inconvenience as practicable and as soon as practicable making good all damage caused in the exercise of such right

## 4.10 <u>Default remedies of the Landlord</u>

If within three months after service of a notice from the Landlord requiring the Tenant to remedy any breach of covenant relating to the state of repair or condition of the Premises or otherwise to the carrying out of any works or actions (or earlier in case of emergency) the Tenant shall not have commenced and proceeded diligently and expeditiously such works or actions then to permit the Landlord to enter upon the Premises and execute all or any such works or actions and the Landlord's proper costs and expenses (including the Landlord's surveyors' and other professional fees in connection therewith) together with interest thereon at the Prescribed Rate current at the date one month after service of such notice for the period from that date to the date of payment shall be a debt due from the Tenant to the Landlord and be forthwith recoverable as rent in arrear

# 4.11 <u>Signs and aerials</u>

Not to erect any pole mast or aerial or erect or display any sign noticeboard or advertisement on any part of the Premises but the Tenant shall install and maintain in the Sign Display an appropriate sign (to the prior written approval of the Landlord not to be unreasonably withheld) showing the name of the Tenant and (if applicable) its logo but showing no other information

4.12.1	Not to use the Premises or any part thereof otherwise than for the Permitted Use and not at any time to store anything on any part of the Premises outside the Building
4.12.2	To use only for the parking of vehicles the Parking Area (but not to park any trailers on such Area) and to require employees to use only such Area for the parking of their vehicles and to enforce such requirement by all reasonable means available to the Tenant as an employer
4.13	Refuse and rubbish
4.13.1	To ensure that all refuse rubbish and waste material is put in secure and closed containers designed for that purpose and to take all appropriate measures to prevent escape of refuse rubbish or waste materials from such containers
4.13.2	To make and maintain satisfactory arrangements for the regular removal of all refuse rubbish and waste materials from the Premises so often as is necessary
4.13.3	If the Tenant fails to take immediately such steps as may be necessary to comply with clause 4.13.1 or 4.13.2 after notice from the Landlord requiring it to do so to permit the Landlord or others authorised by it (if the Landlord decides to do so) to enter the Premises to carry out removal of refuse rubbish or waste materials (whether or not on a regula basis) and to pay to the Landlord on demand all proper costs and expenses incurred by the Landlord in connection with any removal arrangements which it makes

4.12

Use

# 4.14 Nuisance 4.14.1 Not to use the Premises or any part of them for any illegal purpose nor to carry out on or from the Premises any noisy noxious dangerous or offensive act activity or business nor anything which may be or become a muisance or damage to the Landlard or any of its tenants or the occupiers of any premises in the paid bourhood and in particular not to do.

anything which may be or become a nuisance or damage to the Landlord or any of its tenants or the occupiers of any premises in the neighbourhood and in particular not to do or permit to be done anything which might cause electronic or radio interference with any adjoining or neighbouring premises

Not to do anything which would or might lead to any contamination of the Premises or pollution of the environment or lead to the pollution obstruction damaging or overloading of the Conducting Media and to carry out (or at the Landlord's election to pay to the Landlord the proper costs and fees of carrying out) all works necessary to remedy the contamination or pollution or to remove the source of the contamination or pollution

Where the Tenant has failed to observe any of the obligations in this clause 4.14 to pay to the Landlord the proper costs incurred by it in obtaining such reports as the Landlord may reasonably require to establish what damage or harm may have been caused to the Premises or other property of the Landlord and the remedial cleaning or other works necessary

Not to discharge or allow to enter into any underground or other waters any poisonous noxious or harmful effluent liquid or substance

#### 4.15 <u>Estate regulations</u>

4.14.2

4.14.3

4.14.4

To observe such reasonable regulations as may from time to time be made by the Landlord for the purposes of good estate management

#### 4.16 Estate Roads and Accessways etc

- 4.16.1 To take all necessary precautions to prevent damage or excessive wear and tear to or any avoidable obstruction or any of the Estate Roads or the Accessways and to pay to the Landlord on demand all proper costs and expenses of making good any damage (other than normal wear and tear) caused to any of them by the Tenant or any undertenant or any of their respective employees contractors or visitors
- 4.16.2 Not to park or permit the parking by the employees or contractors of or visitors to the Tenant of vehicles on any of the Estate Roads or Accessways or elsewhere on the Estate other than in accordance with clause 4.12.2

#### 4.17 <u>Acts prejudicial to insurance</u>

- 4.17.1 Not to do anything as a result of which any policy of insurance against damage to the Premises or to any neighbouring premises may be prejudiced or payment of the policy moneys may be withheld in whole or in part or whereby the rate of premium in respect of any such insurance may be increased and to give notice to the Landlord forthwith upon the happening of any event which might affect any insurance policy relating to the Premises
- 4.17.2 In relation to the insurance effected by the Landlord in respect of the Premises to pay to the Landlord any excess required by the insurers or by the Landlord on demand by the Landlord following any damage or destruction by any Insured Risks where such excess would be applicable to any claim in respect of such damage or destruction

## 4.18 <u>Safeguarding the Premises</u>

4.18.1 With respect to fire precautions and safeguarding the Premises against damage by any of the Insured Risks or otherwise to comply with all requirements and recommendations of the insurers of the Premises or the relevant insurance brokers or of the fire brigade or local authority

4.18.2 Not to store or bring on to or allow to remain on the Premises any article substance or liquid of a specially combustible inflammable or explosive nature or which may be a source of contamination PROVIDED that for so long as the Tenant is Azur Environmental Limited the storage on the Premises of reasonable quantities of the items listed in the Seventh Schedule for purposes solely connected with the business of Azur Environmental Limited shall be deemed not to be a breach of this clause

To give written notice to the Landlord upon the occurrence of any contamination of the Premises and also upon the occurrence of any pollution of the environment in breach of any legislative provision caused by any use of or action or activity on the Premises

#### 4.19 <u>Planning Applications</u>

Not without the prior written consent of the Landlord (such consent not to be unreasonably withheld or delayed) to make any application for any consent under the Planning Acts

#### 4.20 Alterations

4.18.3

Not to erect or place any new building or structure whatsoever on the Premises (including any temporary or moveable building or structure) and not to make any alteration whether structural or otherwise or any addition to the Premises or to the Building or to any buildings which may be erected

on the Premises PROVIDED THAT the Tenant may with the written consent of the Landlord (such consent not to be unreasonably withheld or delayed) erect install or alter internal demountable partitions not affecting the structure of the Building

#### 4.21 <u>Statutory obligations</u>

- 4.21.1 At the Tenant's expense to comply in all respects with the provisions of all statutes and legislation (whether now or subsequently in force) affecting or applicable to the Premises or their use and forthwith to give notice to the Landlord of any notice direction or order made by any local or competent authority
- 4.21.2 Where required by statute or legislation the Tenant shall maintain a health and safety file for any works carried out to the Premises and shall comply with the Construction (Design and Management) Regulations 1994 in respect thereof and provide to the Landlord upon reasonable request a copy of such file

## 4.22 <u>Alienation</u>

4.22.1

- Not to charge or mortgage either the whole or any part of the Premises nor to assign underlet share or part with the possession or occupation of any part of the Premises nor to permit any such dealing under a permitted underlease
- 4.22.2 Not to hold or occupy the Premises or any part as nominee trustee or agent or otherwise for the benefit of any other person
- 4.22.3 Not to assign or underlet the whole of the Premises without the prior consent in writing of the Landlord (such consent not to be unreasonably withheld where the provisions hereinafter contained are satisfied)

4.22.4	It is agreed that the Landlord will not be deemed to be unreasonable in withholding consent to a proposed assignment of the whole of the Premises if it is withheld on the ground (and it is the case) that one or more of the circumstances mentioned below exist (whether or not such withholding is solely on such ground or on that ground together with other grounds):-
4.22.4.1	that in the reasonable opinion of the Landlord the effect of the proposed assignment upon the value of the Landlord's reversionary interest in the Premises would be to diminish or otherwise adversely affect such value
4.22.4.2	that in the reasonable opinion of the Landlord the effect or the assignment would mean that there is a reduced likelihood of the tenant's covenants and obligations in this Lease being fulfilled

4.22.4.3 that the proposed assignee is an associated company of the Tenant

4.22.5 On any assignment:-

4.22.5.1

The Tenant will enter into an Authorised Guarantee Agreement which will be in such form as the Landlord may reasonably request and be prepared by or on behalf of the Landlord and at the cost of the Tenant and under which the assignor will agree (inter alia) with the Landlord:-

4.22.5.1.1.1 that it is liable as sole or principal debtor in respect of all obligations to be owed by the assignee under the Tenant Covenants (as defined in Section 28 of the Act) in this Lease

4.22.5.1.1.2	to be liable as guarantor in respect of the assignee's performance of the Tenant Covenants (as above defined) in this Lease (provided that such liability shall be no more onerous than the liability to which the assignor would be subject in the event of his being liable as sole or principal debtor in respect of the obligations owed by the assignee under the said Tenant Covenants)
4.22.5.1.1.3	in the event of this Lease being disclaimed to enter into a new lease of the Premises the term of which shall expire simultaneously with the date upon which (but for any such disclaimer) this Lease would have expired by effluxion of time (and not by any other means) and the Tenant Covenants shall be identical to (mutatis mutandis but in any event no more onerous than) the Tenant Covenants in this Lease
4.22.5.2	If the Landlord reasonably so requires the Tenant shall obtain acceptable guarantors for any person to whom this Lease is to be assigned who will covenant with the Landlord on the terms (mutatis mutandis) set out in the Third Schedule
4.22.5.3	If the Landlord reasonably so requires the proposed assignee will prior to the assignment enter into such reasonable rent
	18

	deposit arrangement and/or provide such additional security for performance by the proposed assignee of its obligations under this Lease as the Landlord may reasonably require
4.22.5.4	The proposed assignee shall enter into a covenant with the Landlord to pay the rents reserved by and perform and observe the covenants on the part of the Tenant contained in this Lease
4.22.5.4.1	clauses 4.22.4 and 4.22.5 shall operate without prejudice to the right of the Landlord to impose any further conditions upon a grant of consent where such imposition is reasonable
4.22.6	Not to underlet the whole of the Premises without the prior consent in writing of the Landlord otherwise than at a rent which is not less than the open market rental value of the Premises (being in any event not less than the rent then payable under this Lease) without a fine or premium and with provision for upwards only rent reviews coinciding with the reviews under this Lease and in other respects with materially the same covenants and conditions as are contained in this Lease
4.22.5	Not to vary the terms of any underlease permitted under this clause 4.22 without the Landlord's written consent and throughout the term of any underlease to require the undertenant at all times to perform and observe the Tenant's covenants (except as to the payment of rent) and the conditions contained in this Lease
4.22.6	The Landlord may as a condition for giving its consent for any permitted underletting require the proposed underlessee to enter into a direct covenant with the Landlord to perform and observe the
	19

Tenant's covenants and the conditions contained in this Lease (save as to payment of rent)

4.22.7

4.22.7.1

4.22.7.2

4.22.8

4.22.9

Upon the Landlord consenting to an underletting of the Premises procure that the underlessee covenants with the Landlord:

Not to assign (or agree to do so) any part of the Premises (as distinct from the whole) and not to charge or underlet or share or (save by way of an assignment of the whole) part with possession of or permit any person to occupy the whole or any part of the Premises

Not to assign (or agree to do so) the whole of the Premises without the prior consent in writing of the Landlord (such consent not to be unreasonably withheld)

To notify the Landlord in writing with relevant details within fourteen days of any rent payable under an underlease being reviewed

In the event that any circumstances or conditions specified in clauses 4.22.4 and 4.22.5 above are framed by reference to any matter falling to be determined by the Landlord (or by any other person) if the Tenant disputes such determination then either the Landlord or the Tenant shall be entitled to require the matter or matters in question to be referred to an independent expert who in the absence of agreement between the parties shall be appointed on the application of either party by the President of the Royal Institution of Chartered Surveyors and the determination of such independent expert shall be conclusive as to the matter or matters in question and shall be final and binding on the parties and his costs shall be met by the parties in such proportions as the independent expert shall determine

#### 4.23 <u>Registration of dealings</u>

Within one month after the execution of any assignment or underlease permitted under this Lease or any assignment of such underlease or after any devolution by will or otherwise of the Term or after any other dealing with this Lease to supply a certified copy of the deed or instrument effecting the same to the Landlord and to pay such reasonable fee as the Landlord may require for registration

#### 4.24 Reletting and sale boards

To permit the Landlord or its agents to enter upon the Premises and to affix upon any suitable part (which does not obscure the Tenant's own signs) a notice board for reletting or selling the same and not to remove or obscure the same and to permit all persons authorised in writing by the Landlord or its agents on the giving of reasonable prior written notice to view the Premises during business hours in the daytime

#### 4.25 Cost of licences and notices as to breach of covenant

To pay on demand and indemnify the Landlord against all costs charges and expenses (including professional fees) reasonably and properly incurred by the Landlord arising out of or incidental to any application made by the Tenant for any consent or approval of the Landlord and against all costs charges and expenses (including any professional fees) properly incurred by the Landlord arising out of or incidental to any breach or the Tenant's covenants or the preparation and service of a schedule or interim schedule of dilapidations or any notice which the Landlord may serve on the Tenant whether served before or after the determination of this Lease (including a notice under Section 146 of the Law of Property Act 1925) requiring the Tenant to remedy any breach of any of its covenants or arising out of or in connection with any proceedings referred to in Sections 146 or 147 of that

Act notwithstanding that forfeiture may be avoided otherwise than by relief granted by the Court

## 4.26 <u>Indemnity</u>

To be responsible for and to indemnify the Landlord against:

4.26.1 all damage loss or injury occasioned to the Premises or any adjoining premises or to the Accessways or the Landscaped Areas or any Conducting Media or to any person or chattel (whether or not upon the Premises) caused by any act default or negligence of the Tenant or any undertenant or the servants agents licensees or invitees of either of them or by reason of any defect in the Premises and

all losses damages costs expenses claims and proceedings incurred by or made against the Landlord arising out of any breach by the Tenant of any of its obligations arising by virtue of this Lesse

## 4.27 <u>VAT</u>

4.26.2

4.27.1

4.27.2

To pay to the Landlord upon demand any value added tax chargeable upon:

any supply made by the Landlord to the Tenant pursuant to this Lease so that all consideration for any such supply is exclusive of value added tax

any supply (whether made to the Landlord or to a third person) where pursuant to this Lease the Tenant is required to pay to the Landlord any sum in respect of any costs fees expenses or other expenditure or liability (of whatever nature) in connection with that supply except to the extent that any such value added tax may be recoverable by the Landlord from H.M. Customs and Excise

PROVIDED ALWAYS that the Landlord will produce a valid VAT invoice to the Tenant within 14 days of receipt of any payment of VAT from the Tenant

## 4.28 <u>Defects</u>

To inform the Landlord as soon as practicable in writing of any defect in the Premises which might give rise to a duty imposed by common law or statute on the Landlord and to indemnify the Landlord against all actions costs claims and liabilities suffered or incurred by or made against the Landlord in respect of the Premises under the Defective Premises Act 1972

#### 4.29 <u>Costs of party items</u>

In so far as the Tenant is not obliged to contribute to the costs of the same under any other provision of this Lease to pay a fair and proper proportion of the expense (including any professional fees) of repairing rebuilding painting maintaining cleaning and lighting all party structures and all roofs conducting media boundary structures forecourts yards roads ways entrances passages staircases balconies and other amenities or things the use or benefit of which is common to the Premises and any adjoining or neighbouring premises such proportion to be determined by the Landlord's Surveyor whose determination shall (save in the case of manifest error) be final and binding on the Tenant

#### 4.30 <u>Documents affecting title</u>

To perform and observe the provisions of the documents and the other matters referred to in the Fifth Schedule so far as they affect or relate to the Premises

#### . LANDLORD'S COVENANTS

The Landlord covenants with the Tenant:

#### 5.1 Quiet enjoyment

That the Tenant performing and observing the covenants conditions and agreements contained in this Lease shall and may peaceably and quietly hold and enjoy the Premises during the Term without any lawful

interruption or disturbance by the Landlord or any person rightfully claiming through or under it

#### 5.2 <u>Insurance</u>

At all times during the Term to keep the Premises insured for the Landlord's benefit in the Full Reinstatement Value against the Insured Risks and if the Premises are damaged or destroyed by any of the Insured Risks the Landlord will with all convenient and practicable speed repair or reinstate the Premises using such materials as are then appropriate subject to all necessary consents and licences being obtained Provided that:

- 5.2.1 the Landlord's obligations under this covenant shall cease if the insurance shall be rendered void or voidable or the policy moneys withheld in whole or in part by reason of any act or default of the Tenant or any undertenant or any of their respective employees contractors licensees or invitees
- 5.2.2 if the Premises are destroyed or seriously damaged by any Insured Risk as to require (to the opinion of the Landlord's surveyor whose decision shall be final and binding upon the Parties) substantial reconstruction then the Landlord may at any time within six months' notice in writing to determine this Lease and immediately upon the expiry of that notice this demise shall determine but without prejudice to the rights and remedies of any party against any other in respect of any antecedent claim or breach of covenant and all insurance money shall be the absolute property of the Landlord

## 5.3 <u>Estate Roads and Parking etc</u>

Subject to payment by the Tenant of the Tenant's Proportion of the Service Charge in accordance with Part 1 of the Sixth Schedule and any sums payable in accordance with Part 2 of the Sixth Schedule the Landlord shall:

5.3.1 maintain and repair such of the Estate Roads as are within the Estate and use all reasonable endeavours to do so (or to procure that it be done) in respect of the remainder of

the Estate Roads until (in each case) adoption by the highway authority and

5.3.2 maintain and repair the Accessways

# CONDITIONS

6.1.1

6.1.2

6.1.3

Provided always and it is hereby agreed and declared as follows:

#### Repossession on Tenant's default

If at any time during the Term:

the rents reserved by this Lease or any of them or any part of them shall be in arrear for fourteen days after the same shall have become due (whether legally demanded or not) or

the Tenant shall at any time fail or neglect to perform or observe any of the covenants conditions or agreements on its part to be performed and observed contained in this Lease or in any licence approval or consent given by the Landlord to the Tenant in relation to the Premises or in any other deed supplemental to this Lease or by which this Lease may be varied or

the Tenant either shall (being a corporation) have an application made for an administration order (whether or not at its instance) or enter into liquidation whether compulsory or voluntary (not being a voluntary liquidation for the purpose of reconstruction only) or (being an individual) become bankrupt or

6.1.4 the Tenant shall make any arrangement or composition with creditors or suffer any distress or execution to be levied on property of the Tenant or have an encumbrancer take possession or a receiver appointed in respect of the same

then and in any such case it shall be lawful for the Landlord or any person or persons duly authorised by it in that behalf) to re-enter into or upon the Premises and thereupon the Term shall absolutely cease and determine but without prejudice to the rights and remedies of the Landlord in respect of any antecedent breach of any of the covenants conditions or agreements contained in this Lease

#### 6.2 Benefit of insurance and abatement of rent

6.2.2

6.2.1 The benefit of all insurance effected by the Landlord under this Lease or otherwise in respect of the Premises or the Estate shall belong solely to the Landlord but if the Premises or any part of them shall at any time be destroyed or damaged by any of the Insured Risks so as to be unfit for occupation or use then and in every such case (unless the Landlord's policy of insurance in relation to the Premises shall have been rendered void or voidable or the policy moneys withheld in whole or in part by reason of the act default or omission of the Tenant or any undertenant or any of their respective employees contractors licensees or invitees) the rent first reserved by this Lease or a fair and just proportion thereof according to the nature and extent of the damage sustained shall be suspended and cease to be payable until the Building shall have been repaired or reinstated and made fit for occupation or use in accordance with clause 5.2

No account shall be taken of damage in relation to any alteration or improvement to the Premises carried out otherwise than by the

Landlord unless such alteration or improvement has in fact been taken into account in effecting both the insurance of the Premises and the insurance in respect of the Loss of Rent

Any dispute between the Landlord and the Tenant concerning the proportion or duration of the suspension or cesser shall be determined by an arbitrator appointed in default of agreement between the Landlord and the Tenant on the application of either of them by the President of the Royal Institution of Chartered Surveyors and any such reference shall be a submission to arbitration within the Arbitration Acts 1950 and 1979

#### 6.3 Notices

6.4.2

The provisions of Section 196 Law of Property Act 1925 (as amended) shall apply to the giving and service of all notices and documents under or in connection with this Lease

#### 6.4 <u>Repair of Estate Roads etc.</u>

The Landlord shall have no liability to the Tenant:

6.4.1 in relation to any failure to maintain and repair the Estate Roads or the Accessways unless the Tenant has given written notice to the Landlord of the relevant aspect of non maintenance or disrepair or

on the grounds of disrepair of the Estate Roads caused by traffic using the Estate Roads for the purposes of the development of other parts of the Estate or the carrying out of works on the Estate but so that the disrepair shall be made good within a reasonable period after the Estate Roads have ceased to be so used

#### 6.5 Closure of facilities

Subject to the Landlord using all reasonable endeavours to procure alternative access to the Premises the Landlord may temporarily close or

withdraw from use any of the Estate Roads the Accessways to permit the carrying out of any repairs maintenance or works by it or any person authorised by if and in such circumstances the Tenant shall have no claim against the Landlord in connection with any such closure or withdrawal the person carrying out such works endeavouring to keep such closure or withdrawal to the minimum reasonably required

## 7. <u>RENT REVIEW</u>

7.1 In this clause:

"Assumptions"

means the assumptions that:

- 1. the Premises are in good and substantial repair and condition
- 2. the Landlord and the Tenant have complied with all their respective covenants and obligations imposed by this Lease on each of them
- 3. all parts of the Premises are fit and ready for use for the Permitted Use
- 4. that the rent at which the Premises could reasonably be expected to be let is that which would be payable after the expiry of any rent free period or after the receipt of such other rent concession or inducement (in each case for whatever reason) as may be negotiated in the open market between a landlord and a tenant upon a letting of the Premises

5. no work has been carried out on the Premises during the Term which has diminished the rental value of the Premises and
6. any damage to or destruction of the Premises or any means of access to them has been fully reinstated
"Current Rent" means the yearly rent reserved by this Lease (disregarding any suspension of rent under any other provision of this Lease) as varied from time to time pursuant to this clause
"Matters to be Disregarded" means each of the following matters so far as they may affect rental value:
1. the fact that the Tenant has previously been in occupation of the Premises
2. any goodwill attaching to the Premises by reason of the carrying on of the business of the Tenant at the Premises and
3. any improvement to the Premises carried out during the Term by the Tenant or undertenant other than improvements effected at the expense of the Landlord or pursuant to any obligation to the Landlord whether under the provisions of this Lease or any other deed or document
"New Rent" as at any Review Date means the higher of:

1. the Current Rent immediately before that Review Date and

2. the Rental Value as at that Review Date

means the President for the time being of the Royal Institution of Chartered Surveyors any other body reasonably "President"

specified by the Landlord

"Rental Value" as at any Review Date means the open market rental value of the Premises at that Review Date:

1. as agreed by the Landlord and the Tenant or

2. as determined by a Valuer pursuant to the provisions of this clause

means a chartered surveyor who has experience of practice in property of the nature and type of the Premises and who

is acquainted with the market in the area in which the Premises are located

The New Rent shall be payable from and including each Review Date.

If the New Rent has not been agreed by the date which is three months before the relevant Review Date either the Landlord or the Tenant may require the Rental Value to be

determined by a Valuer

"Valuer"

7.2

7.3

7.4

Where the Rental Value is to be determined by a Valuer and the Landlord and the Tenant do not agree as to his appointment within twenty one days of either of them putting

forward a nomination to the other such Valuer shall be appointed at the request of either party by the President

- 7.5 The Valuer shall act as an expert and not as an arbitrator and his decision (including any decision as to the costs of such determination) shall be final and binding on the parties
- 7.6 The Valuer shall upon appointment either by the parties or the President be required upon his determination to provide a reasoned award to the Landlord and the Tenant
- 7.7 Notwithstanding that the Valuer shall act as an expert the Landlord and the Tenant shall each be entitled to make representations and counter-representations to such Valuer a copy of which shall be supplied by the Valuer to the other of them and in making an award as to costs the Valuer shall have regard to the representations and counter-representations made to him
- The Valuer shall determine the Rental Value as the best yearly open market rack rental value at which the Premises might reasonably be expected to be let with vacant possession in the open market by a willing lesser to a willing lessee for a term of years equal in length to the balance unexpired of the Term as at the relevant Review Date and on the terms and conditions of a lease which are otherwise the same as this Lease except as to the actual amount of the Current Rent and the date on which the term commences and making the Assumptions but taking no account of the Matters to be Disregarded
  - If by the relevant Review Date the New Rent has not been ascertained (whether or not negotiations have commenced) the Tenant shall continue to pay the Current Rent on each day appointed by this Lease for payment of Rent until the New Rent has been ascertained and upon such ascertainment of the New Rent the Tenant will pay to the Landlord as arrears of rent an amount equal to the difference between the New Rent and

the Current Rent actually paid for the period since the relevant Review Date together with interest on the difference at 3% below the Prescribed Rate

7.10 In no event shall the yearly rent payable by the Tenant to the Landlord after the relevant Review Date be less than the yearly rent payable by the Tenant to the Landlord immediately before such relevant Review Date

A memorandum in the form set out in the Fourth Schedule of any increased rent determined pursuant to this clause 7 shall as soon as may be after such determination be prepared in duplicate and signed by or on behalf of the Landlord and Tenant

#### TENANT'S OPTION TO DETERMINE

In this clause "Termination Date" means November 2001 or November 2006

Subject to the pre-conditions in clause 8.3 being satisfied on the relevant Termination Date, and subject to clause 4.8 the Tenant may determine the Term on a Termination Date by giving the Landlord not less than six months' written notice, which notice must be expressed to be given under section 24(2) of the Landlord and Tenant Act 1954. The Term will then determine on the relevant Termination Date, but without prejudice to any rights of either party against the other for any antecedent breach of its obligations under this Lease

8.3 The pre-conditions are that:

7.11

8.1

8.2

8.3.1

8.3.2

vacant possession of the whole of the Premises is given to the Landlord; and

all rent and other sums due under this Lease up to the relevant Termination Date have been paid in full and all the Tenants obligations in this Lease up to the Termination Date have been substantially complied with

- 8.4 The Landlord may waive any of the pre-conditions set out in clause 8.3 at any time before the relevant Termination Date by written notice to the Tenant 8.5 The Tenant will cancel any registration it has made in connection with this clause within 15 working days of the relevant Termination Date
- 8.6 Time will be of the essence for the purposes of this clause

IN WITNESS of which this Lease has been executed and is delivered as a deed on the date appearing as the date of this Lease

## FIRST SCHEDULE

#### Description of the Building and Fixtures

The schedule annexed to this Lease headed "The First Schedule"

1.1

1.2

## SECOND SCHEDULE

Part 1

## The Rights

1. The right in common with the Landlord and all other persons now or at any time after the date of this Lease similarly entitled to pass at all times and for all purposes connected with the proper use of the Premises in accordance with this Lease:

with or without vehicles over and along the Estate Roads and the Accessways and (except for that part hatched purple on the Lease Plan) until in each case adoption by the highway authority and

on foot only over and along that part shown hatched purple on the Lease Plan

The right in common with the Landlord and all other persons now or at any subsequent time entitled to a similar right to the free passage and running of water soil gas electricity and other services from and to the Premises through the

Conducting Media in the Estate other than those adopted by the relevant statutory undertaker

The right of support and protection for the Premises from the remainder of Winnersh 500

2.2

4. So far as necessary and in any event subject to any licence required by clause 4.20 the right to enter upon so much of the area shown hatched green on the Lease Plan as lies to the rear of the Land to install and thereafter at all times to maintain repair renew and rebuild an air conditioning plant

#### Part 2

## The Exceptions and Reservations

- 1. To the Landlord and all others authorised by it the free and uninterrupted passage and running of water soil gas electricity and telephone or any other service or supply from the other buildings and land of the Landlord and its tenants adjoining or near the Premises and from the land and premises of others so authorised as aforesaid through the Conducting Media which are now or may hereafter be in through under or over the Premises
  - To the Landlord and all others authorised by it the right at all times to enter the Premises with all necessary equipment for the purposes of:
- 2.1 carrying any repairs maintenance or works to or in relation to the Accessways and (where clause 4.6.5 applies) the Landscaped Areas including the right to use and take water from any external water supply at the Premises for the purposes of maintenance of planting and landscaping at Winnersh 500
  - laying constructing installing replacing repairing maintaining or altering any Conducting Media now or hereafter in through under or over the Premises or any adjoining property or making connections to any such Conducting Media

- 2.3 carrying out inspections of or tests to any such Conducting Media
- doing such other things in relation to any Conducting Media which directly or indirectly serve or are connected to other premises as the Landlord considers proper to ensure that such Conducting Media are in good working order and condition and
- 2.5 exercising any of the rights of the Landlord contained in this Lease.

The Landlord causing as little damage and inconvenience as practicable in the exercise of such rights and as soon as practicable making good all damage caused

- To the Landlord full right and liberty at any time hereafter or from time to time to execute works and erections upon or to alter or rebuild any of the buildings erected on any part of the Estate and to use its Estate and each part of it in such manner as the Landlord may think fit notwithstanding that the access of light and air to the Premises may thereby be interfered with
  - To the Landlord and other the tenants and occupiers of other parts of Winnersh 500 the right of support and protection from the Premises
- To the Landlord the right to install and retain on the Land columns for the provision of lighting security or other services for Winnersh 500 and the right to enter the Premises with all necessary equipment for such purposes or for maintaining altering or replacing such column the Landlord causing as little damage and inconvenience as practicable in the exercise of such rights and as soon as practicable making good all damage caused

#### THIRD SCHEDULE

## Obligations of the Surety

If at any time the Tenant shall not pay any of the rents or other sums payable under this Lease or perform and observe any of the covenants conditions or other

terms of the Lease the Surety shall pay such rents or other sums or observe or perform such covenants conditions or other terms

- By way of separate and additional liability and notwithstanding that the guarantee in paragraph 1 may be unenforceable or invalid for any reason the Surety indemnifies the Landlord against all proper losses damages costs and expenses suffered or incurred by the Landlord arising out of or in connection with any failure by the Tenant to pay any of the rents and sums or to perform and observe any of the covenants conditions or other terms referred to in paragraph 1
- . I

3.2

- 1 the Tenant shall be wound up or (being an individual) become bankrupt and its liquidator or trustee in bankruptcy shall disclaim this Lease or
  - the Tenant shall cease to exist or shall die or 3.3 this Lease shall be forfeited

(the date on which such event occurs being called the "Relevant Date") the Landlord may within three months after the Relevant Date by notice in writing require the Surety to accept a lease of the Premises for a term commencing on the Relevant Date and continuing for the residue then remaining of the Term at the same rents and with the same covenants and conditions as are reserved by and are contained in this Lease and in such case the Surety shall take such lease accordingly and execute a counterpart of it and pay all costs and duties in relation to it

- The Surety undertakes with the Landlord that:
  - its obligations to the Landlord are primary obligations and it is jointly and severally liable with the Tenant (both before or after any disclaimer by a liquidator or trustee in bankruptcy) for the fulfillment of all the Tenant's covenants and obligations

Surety shall remit to the Landlord the proceeds of all judgments and all distributions which the Surety may receive from any liquidator trustee in bankruptcy administrator administrative receiver receiver or supervisor of the Tenant and shall hold for the benefit of the Landlord all security and rights the Surety may have over assets of the Tenant while any liabilities of the Tenant or the Surety to the Landlord remain outstanding and if the Landlord shall not require the Surety to take a new lease of the Premises the Surety shall nevertheless upon demand pay to the Landlord a sum equal to the rent first 4.3 reserved under this Lease and all other sums that would have been payable under this Lease in respect of the period from and including the Relevant Date until the expiry of six months after such Date or until the Landlord shall have granted a lease of the Premises to a third party (whichever shall first occur) in addition and without prejudice to the Surety's other obligations to the Landlord The Surety waives any right to require the Landlord to proceed against the Tenant or to pursue any other remedy of any kind which may be available to the Landlord before proceeding

the Surety shall not claim in any liquidation bankruptcy administration receivership composition or arrangement of the Tenant in competition with the Landlord and that the

- against the Surety
- The liabilities of the Surety under this Schedule shall not be affected by:
  - the granting of time or any other indulgence or concession to the Tenant or any compromise or compounding of the Landlord's rights
- the Tenant being in liquidation or (as the case may be) declared bankrupt 6.2
- 63 any variation in the terms and conditions of this Lease

4.2

6.1

any delay in exercising or failure to exercise or other exercise (including re-entry under clause 6.1) of any of the Landlord's rights against the Tenant

any refusal by the Landlord to accept rent tendered by or on behalf of the Tenant following a breach by the Tenant of its obligations under this Lease

	(including the acceptance by the Tenant of this Lease) may be outside or in excess of the powers of the Tenant or
6.6	any other thing (including the expiration or sooner determination of the Term or any such disclaimer or the death of the Surety (or any of the persons comprising the Surety) or (in relation to one or more of such persons) the discharge of the other person or persons) whereby (but for this provision) the Surety or any of them would be exonerated either wholly or in part from any of the Surety obligations hereunder
	FOURTH SCHEDULE
	Rent Review Memorandum
	Winnersh 545 Winnersh Triangle
	Wokingham Berkshire

Slough Properties Limited (1) and

any legal limitation or any immunity disability or incapacity of the Tenant (whether or not known to the Landlord) or the fact that any dealings with the Landlord by the Tenant

] 1996 between

Lease dated [

July Tollant

#### FIFTH SCHEDULE

#### Documents and matters affecting title

- 1. The covenants matters and stipulations set out or referred to in or contained or referred to in the documents referred to in the Property and Charges Registers of the Landlord's title number BK 167503 so far as the same affect or relate to the Premises other than the various agreements under Section 52 of the Town and Country Planning Act 1971 as varied by the Termination Agreement dated 30th June 1993
- 2. A lease dated 5th November 1996 between Slough Properties Limited (1) and Southern Electric plc (2) relating to an electricity substation to the south-east of the Premises

# SIXTH SCHEDULE

#### Part 1

## Service Charge for the Estate

#### Part A

## Heads of Expenditure

Costs and liabilities which the Landlord (which in this Schedule shall where the context admits include any other company which is a member of the same group of companies as the Landlord) reasonably and properly incurs or becomes liable to pay or discharge in connection with the Estate or occupiers thereon including the costs of:

- 1. repairing maintaining cleaning renewing and resurfacing the Estate Roads (including the renewal of the line markings on the Roads)
- repairing maintaining replacing and operating the lighting of the Estate Roads (including the cost of electricity)
- 3. repairing maintaining decorating and replacing any estate office for the Estate including:

3.2 rates payable in respect of any such office
3.3 the cost of equipment and materials in or for such office to the extent that they are intended to be provided for the purposes of such office
4. repairing maintaining and renewing any Conducting Media in or for any part of the Estate to the extent that they are not the responsibility of any tenant of the Landlord on the Estate or of a statutory undertaker and do not exclusively serve premises occupied by such a tenant

the cost of services (including electricity gas and telephone) supplied to any such office

- . repairing maintaining cleaning and keeping tidy the Common Areas including the tending care and replacement of plants and trees and the maintenance and upkeep of landscaped areas including nature strips in roads or on roundabouts at or at the approaches to Winnersh Triangle
- for repair maintenance and replacement of tanks pumps pipes and other equipment (excluding any that form part of the Premises) forming part of the sprinkler system at the Estate including the costs of inspection and maintenance contracts
  - repair maintenance decoration operation lighting and cleaning of any structures fences walls signs footpaths amenities and things on the Common Areas and benefiting the Estate or part of it including any entrance feature from time to time for the Estate and any equipment associated with it
    - employing staff for the benefit of the Estate or the provision of any services on or for the Estate (including for the purposes of operating an estate office) including the costs of statutory and other insurance health pension welfare and other payments contributions and premiums and the costs incidental to the performance of the duties of any such staff but where engaged also to perform duties not connected with the Estate only a proportion of each of such costs

- 9. rates taxes assessments duties charges burdens impositions and outgoings imposed or charged upon the Common Areas or any part of them (including any estate office) or upon the owner or occupier thereof
- 10. insurance in such sum and against such risks as the Landlord shall consider appropriate in respect of damage to any part of the Common Areas (including the Estate Roads) and the structures buildings walls fences and other things thereon
- 11. public liability insurance in respect of any liability of the Landlord in relation to the Estate and the Estate Roads
- 12. calculating the Service Charge and the Tenant's liability under this Lease including preparation of accounts and certification
- 13. providing such security service for the benefit of the Estate as the Landlord may from time to time consider appropriate
- 14. the management of the Estate including the fees and disbursements of:

14.2

- any managing agents for or in connection with such management (including the collection of rent and other sums payable by tenants of the Estate to the Landlord but excluding the costs of court proceedings in recovering arrears from tenants other than the Tenant) and the performance of any other duties or services in or about the Estate
  - the Landlord's Surveyor for or in connection with the performance of any function for the purposes of this Lease
- 14.3 any other individual firm or company engaged to perform services for the Estate or any part of it
  - the Landlord where it carries out any service or function in such management (including a fee charged by the Landlord for the collection of rent and other sums payable by tenants of the Estate to the Landlord but excluding the costs of court proceedings in recovering arrears from tenants other than the Tenant)

- 2.4.3 calculated according to an estimate of the Service Charge made in accordance with 2.1 and notified in writing to the Tenant
   3. If the Tenant's Proportion of the Service Charge for a Service Charge Period:
   3.1 exceeds any amounts paid by the Tenant to the Landlord as advance payments on account thereof the amount of the excess (or the whole Proportion if no advance payments)
- 3.1 exceeds any amounts paid by the Tenant to the Landlord as advance payments on account thereof the amount of the excess (or the whole Proportion if no advance payments have been made) shall (notwithstanding the expiration or sooner determination of the Term) be paid by the Tenant to the Landlord within twenty-one days of the supply to the Tenant of the account pursuant to paragraph 1 or
- 3.2 is less than such amounts so paid the amount of the difference shall be credited to the Tenant against the next payments of rents due

paid by the Tenant on the date of this Lease and

4. In respect of each of the Service Charge Periods in which occur the Commencement Date and the date of the expiration or sooner determination of the Term the Tenant shall only be obliged to pay the Tenant's Proportion of the Service Charge in respect of that part of the Service Charge for that Period as bears to the whole of that Service Charge the same proportion that the number of days of the Term occurring in the relevant Period bears to 365

#### Part 2

#### Costs of Winnersh 500 facilities

#### Accessways and landscaping

2.4.2

- The Tenant shall pay to the Landlord on written demand the proper proportion of the costs liabilities fees and expenses which the Landlord incurs or becomes liable to pay in connection with:
- 1.1.1 the Accessways and any signs or direction notices on or for them including all sums incurred pursuant to clause 5.3 or otherwise in

# SEVENTH SCHEDULE

# Materials referred to in clause 4.18.2

The schedule annexed to this Lease and headed "The Seventh Schedule"

THE COMMON SEAL of SLOUGH PROPERTIES LIMITED was affixed to this deed in the presence of:

)
)
)
(S E A L]
/s/ [Illegible] Director
/s/ [Illegible] Secretary

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## FIRST SCHEDULE

#### BUILDING NO. 545 ESKDALE ROAD WINNERSH TRIANGLE WINNERSH

A two storey, office/production building measuring approximately, 18.25m (59'10") by 31.52m (103'5") comprising at ground floor, office and production areas and first floor office, the whole providing gross external areas of:-

Production Area	364.96 m <sup>2</sup>	(3,928 sq.ft)
First Floor Office	185.41 m <sup>2</sup>	(1,996 sq. ft.)
Ground Floor Office	185.41 m <sup>2</sup>	(1,996 sq. ft)
Total	735.78 m <sup>2</sup>	(7.920 sq. ft)

## FOUNDATIONS

Mass concrete bases and trench fill foundations, to structural engineer's design and specification.

#### FRAME

Steel frame of columns and beams all to structural engineer's design and specification.

#### DOOE

Roof comprises profiled steel sheeting with light grey coloured plastisol finish and supported on galvanised mild steel purlins and galvanized zed spacers. Internal roof lining of galvanised PVF2 coated profiled lining sheets, cavity between containing 80mm layer of rockwool insulation.

Rainwater is conducted away via insulated, galvanised pressed steel gutters discharging into internal PVCu rainwater pipes connected to the below ground surface water drainage system.

#### <u>EXTERNAL WALLS</u>

Cavity wall construction of 103mm facing bricks and internal skin of 100mm blockwork finished fair faced and emulsion painted within the production area with a partially filled cavity containing 65mm rockwool insulation held against inner skin. Internal faces of the external walls to offices finished with plasterboard drylining with an emulsion paint finish.

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South (front) elevation comprises facing brick piers surmounted by facing brick parapet with PVF2 colour coated, galvanised steel copings and contains 4 No. full height panels of curtain walling and 1 No. recessed full height entrance screen.

The curtain walling/window system has a self-draining thermally broken and pressure equalised aluminum frame with an external coating of black powder coating with silver grey anolok 541 anodised cappings. The internal coatings being matt white polyester powder coat.

Double glazing within the curtain walling and windows consists of 6mm grey anti-sun outer pane, 12mm cavity and 6mm clear inner pane. Insulated look-a-like panels provided where vision not required.

Curtain walling panels each have four top hung opening lights. The curtain walling and entrance canopy are set within recesses and are provided with PVF2 coated galvanised steel brise solier over the ground floor windows.

The full height entrance screen contains two opening lights, a matching three panel door complete with polished stainless steel furniture, mortice lock and concealed bolts at head and foot. The entrance screen also contains PVF2 coated letter plate inset within the glazing units. A stainless steel, tubular toned feature panel is provided over the main entrance between brick piers left ready to receive tenant's signage.

West elevation contains three full height panels of curtain walling. One painted steel Henderson Defender door set including butt hinges and push bar panic latch, one electrically operated insulated sectional up and over loading door approximately 5m x 3.85m.

North elevation comprises cavity brickwork as previously described with feature brick walling. East elevation comprises double block party wall.

#### EXTERNAL AREAS

**South:** - Car parking in concrete block paving for five cars.

- Landscaping incorporating shrubs and semi mature trees.
- Block paving footpaths.

West:
- 2.4m high x 200mm diameter painted mild steel tubular bollards with cranked tops to loading door reveals.

- Two retractable anti ram bollards to loading bay door.
- Remote landscaping incorporating shrubs and semi mature trees.
- Car parking in concrete block paving for fifteen cars.

## INTERNAL

#### WALLS

Internal blockwork walls forming at ground floor level division between office/production areas and staircase, disabled, male and female toilet accommodation and tea room and at first floor level, staircase, male and female toilet accommodation and plant area.

Dividing wall between production and office areas is of two skins of 100mm blockwork, remaining walls generally of 100mm blockwork.

General office areas and staircase are plasterboard drylined with emulsion paint finish. Toilet accommodation and tea room plasterboard drylined with ceramic tile finish. First floor cleaners' cupboard and plant room finished fair faced blockwork. All drylined walls provided with varnished ash skirtings. External windows provided with Durapal laminate faced window boards.

Internal walls contain at ground floor level six and first floor level four flush faced ash veneered semi solid core doors incorporating glazed vision panels to circulation areas. Fire doors glazed with Georgian wired polished plated glass.

Ground and first floor staircase entrances incorporate staircase screen in solid ash with Georgian wired polished plate glass. Doors complete with polished stainless steel door furniture, mortice latches or locks, kicking plates, door signage and door closers as appropriate all set in solid ash frames and architraves with clear varnished finish.

# **Toilet Accommodation Ground Floor: Male**

First Floor:

2 No.

1 No.

WC suites.

WC suite.

2 No.	Hand basins.
2 No.	Urinals.
2 No.	WC suites.
2 No.	Hand basins.
1 No.	Stainless steel single bowl, single drainer sink set in post formed melamine worktop with base units under.
1 No.	WC suite.
1 No.	Hand basin.
3 No.	Fixed grab rails.
1 No.	Retractable grab rail.
1 No.	WC suite.
1 No.	Hand basin.
1 No.	Urinal.
	2 No. 2 No. 2 No. 1 No.

Page 3

#### Female Toilet 1 No Hand basin

All sanitary fittings are white vitreous china (commercial standard) and provided with all taps, plugs, chains and wastes and connected to hot and cold water supplies as necessary and connected to the below ground foul drainage system. Mirrors provided over hand basins.

#### FLOODS

Ground floor to production area comprises of a powerfloated reinforced concrete floor to BRE medium load classification incorporating proprietary anti-dust sealant.

Ground floor office of reinforced concrete floor designed for a uniformly distributed load of 6 KN per m² (120lb per sq. ft) with a raised access floor to PSA medium grade providing 150mm clear void. Raised access floor finished with Esco Pallas Excel or similar carpet tiles.

First floor comprises of precast prestressed concrete planks designed for a superimposed load excluding self weight of 3.5KN per m<sup>2</sup> (70lb per sq. ft.). Office areas complete with PSA medium grade raised access floor with 150mm clear void. Raised access floor finished with Esco Pallas Excel or similar carpet tiles.

Toilet areas to ground and first floors finished with Polyflor Finesse vinyl floor covering.

Staircase and associated lobbies finished with carpet tiles to match general office areas and incorporate non-slip safety nosings.

Matwell and Jaymart grimestopper mat inset provided to the main entrance lobby area.

#### CEILINGS

Ceiling to production area comprises underside of structural soffit to first floor offices.

Ceiling throughout remainder of offices, staircase and toilet accommodation comprises of 600mm x 600mm ceiling tiles, Rachter Systems Rafa Co-ordinate 9 Plain or similar tiles set in a micro look exposed grid.

#### **STAIRCASE**

Staircase of precast reinforced concrete complete with polished stainless steel handrail. The stairs are fitted with solid ash strings and skirtings with clear varnish finish to match remainder of accommodation.

## **ELECTRICAL INSTALLATION**

## Lighting is provided as follows:-

Ground Floor Office: 19 No. Recessed fluorescent luminaires (1200mm x 600mm).

Ground Floor Toilet 5 No. Recessed compact fluorescent downlights.

Accommodation Concealed fluorescent batten luminaires above mirrors and WC's.

Kitchenette & Lobby: 2 No. Circular recessed fluorescent fittings with prism louvres.

Production Area: 9 No. Sodium boxed downlighters.

Disabled Toilets: 1 No. Shallow dome, wall mounted fluorescent fitting.

Staircase & 4 No. Recessed, compact, fluorescent downlights.

Associated Lobbies: 3 No. Wall mounted, feature, fluorescent fittings.

3 No. Wall mounted, feature, fluorescent fittings3 No. Recessed, circular, fluorescent luminaires.

First Floor Toilet 3 No. Compact fluorescent downlights

Accommodation: 2 No. Concealed fluorescent batten luminaires above WC's.

First Floor Office: 22 No. 1200mm x 600mm recessed fluorescent luminaires with V cross blade low brightness louvres.

External: 3 No. Compact fluorescent downlights to canopy over entrance. Tungsten floodlight over rear loading bay door.

Emergency lighting to office and production areas comprises of self contained emergency lighting unit installed to meet fire officers requirements for an open plan office and production area.

## Small power is provided as follows:-

Ground Floor Office: 3 No. 13A switched socket outlet.

Ground Floor Toilet Lobby: 1 No. 13A switched socket outlet.

Kitchenette: 1 No. 13A twin switched socket outlet.

Production Area: 1 No. Surface mounted 13A twin switched socket outlet.

Staircase and Associated 2 No. 13A switched socket outlets.

Lobbies:

First Floor Office: 3 No. 13A switched socket outlets.

Plant Room: 1 No. Surface mounted 13A switched socket outlet.

#### Control and protection is provided by:-

A 200KVA electricity supply is provided complete with all necessary distribution equipment:

1 No. 400A load switch (main incomer)

1 No. Dorman Smith switchgear load bank distribution board provided with two 100A switches, a 32A switch for external lighting, two 25A switches for fire

alarm supply and heating and ventilation control equipment.

1 No. Lighting and power distribution board for offices.

1 No. Distribution board for production area lighting and power.

1 No. External lighting DB stop and control panel.

1 No. Lighting contactors panel.

The installation is wired in PVC cable of reputable manufacture and encased in welded steel screwed conduit and galvanised trunking fully complying with the present day good practise and the regulation of the Institute of Electrical Engineers.

#### HEATING

Heating is provided to the offices, toilets, tea room, staircase and circulation areas by a low pressure hot water system serving pressed metal radiators each complete with thermostatic radiator controls.

A gas fired low pressure hot water boiler complete with twin wall insulated flue and all necessary pumps, valves, thermostats and controls being located on the first floor plant area.

#### **GAS INSTALLATION**

An incoming metered and valved gas supply is provided serving boiler installation.

#### HOT WATER

Hot water is provided to all sanitary accommodation via a wall mounted Heatrae Sadia instantaneous electric water heater. A further Heatrae Sadia 'Handy' water heater is provided within the disabled toilet.

#### **TELECOMMUNICATIONS**

Incoming telephone duct is provided within the ground floor office left ready to receive tenant's installation.

## VENTILATION

Toilet areas are ventilated to provide six air changes per hour.

Thermostatically controlled roof mounted extract fans installed to exhaust air from the first floor office ceiling void to reduce void temperature build up at times of high solar gain through the roof.

#### <u>WATER INSTALLATION</u>

Incoming water main to supply Authority's meter. From the Authority's meter the supply is distributed within the building to serve drinking water points direct and sanitary appliances, from a storage tank.

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#### The Seventh Schedule

# CHEMICALS TO BE USED BY AZUR ENVIRONMENTAL AT ITS UK FACILITY

The solvents which will be used by Azur Environmental for the purposes of research and development will be those used by a typical life sciences laboratory and are most likely to be:

lower alcohols (methanol, ethanol, isopropanol) toluene, xylene and related compounds

hydrochloric, sulphuric and nitric acids.

The maximum quantities of each held at any one time would not exceed two winchesters (2 x 2.5 litres) and all would be stored in compliance with existing fire and Health and Safety legislation, eg. solvents would be stored in an approved fireproof cabinet.

A variety of dry chemicals will be held but it is impossible to specify these except that they are unlikely to differ significantly from those found in a standard life science laboratory. These will be stored and used in accordance with current Health and Safety legislation.

No hazardous or unusual chemicals will be used in Manufacturing.

All chemicals will be disposed of in accordance with recommended practice.

A safety adviser with many years experience is being appointed to ensure compliance with current legislation.

# AZUR ENVIRONMENTAL LIMITED

- and -

# MICROSCIENCE LIMITED

# ASSIGNMENT OF LEASE

545 Eskdale Road Winnersh Triangle Wokingham Berkshire

> SHADBOLT & CO Reigate

THIS ASSIGNMENT is made the 27th of September 2001

#### BETWEEN

- (1) AZUR ENVIRONMENTAL LIMITED (Company Registration No 2538199) whose Registered Office is at 540/545 Eskdale Road Winnersh Triangle Wokingham Berkshire RG41 5TU ('The Assignor');
- (2) MICROSCIENCE LIMITED (Company Registration No 03270465) whose Registered Office is at 545 Eskdale Road Winnersh Triangle Wokingham RG41 5TU ('The Assignee')

#### WHEREAS

#### (1) Lease or underlease

By a lease particulars of which are set out in the first schedule ('the Lease') the property more particularly described in the Lease the postal address of which is set out in the second schedule ('the Property') was demised to the Assignor for the term of years and at the yearly rent set out in the first schedule subject to the performance and observance of the covenants on the part of the Assignor and the conditions contained in the Lease and subject to and with the benefit of the document particulars of which are set out in the Third Schedule ("the documents").

#### (2) Agreement for sale

The Assignor has agreed with the Assignee in consideration of the covenant on the part of the Assignee contained below for the assignment to the Assignee of the Property for the residue of the term granted by the Lease subject to and with the benefit of the documents.

#### NOW THIS DEED WITNESSES as follows:

#### 1 Assignment

In pursuance of the above agreement and in consideration of the covenant on the part of the Assignee contained below the Assignor with full title guarantee assigns to the Assignee ALL THAT the Property TO HOLD the Property to the Assignee for the residue now unexpired of the term of years granted by the Lease SUBJECT henceforth to the payment of the rent reserved by and the performance and observance of the covenants and agreements on the part of the lessee and the conditions contained in the Lease and the documents.

#### Covenant for indemnity

The Assignee covenants with the Assignor that it and its successors in title to the Property will during the continuance of the term granted by the Lease

pay the rent reserved by and perform and observe covenants restrictions conditions stipulations and other matters contained or referred to in the Lease and the documents and will keep the Assignor indemnified against all proceedings costs claims and expenses whatsoever on account of any omission to pay the rent reserved by or any breach of any of the covenants agreements and conditions contained in the Lease and in the documents.

#### 3. Covenants for title

It is hereby agreed and declared between the Assignor and the Assignee that the covenants implied by section 4 of the Law of Property (Miscellaneous Provisions) Act 1994 shall be varied so that the Assignor shall be under no liability for any failure to carry out any works of repair renewal or decoration to the Property or for any other works required under the lease when ever those works are due to be carried out.

#### . Matters of Public Record

It is further agreed and declared between the Assignor and the Assignee that for the purposes of section 6(2) Law of Property (Miscellaneous Provisions) Act 1994, all matters now recorded in registers open to public inspection are to be considered with in the actual knowledge of the Assignee.

#### . Contracts (Rights of Third Parties) Act 1999

It is not intended that any term of this deed shall be enforceable pursuant to the Contracts (Rights of Third Parties) Act 1999.

#### 6. Certificate of value

It is hereby certified that the transaction hereby effected does not form part of a larger transaction or of a series of transactions in respect of which the amount or value of the aggregate amount or value of the consideration exceeds the sum of £60,000.

IN WITNESS of which this assignment has been executed as a deed and has been delivered on the date first written above

#### FIRST SCHEDULE

#### Particulars of the Lease

13 December 1996: Slough Properties Limited (1) and the Assignor (2)

# SECOND SCHEDULE

# Postal address of the Property

545 Eskdale Road Winnersh Wokingham Berkshire

# THIRD SCHEDULE

# The documents

DateDocumentParties13 December 1996Licence for AlterationsSlough Estates Limited (1) and the Assignor (2)

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EXECUTED as a deed by  AZUR ENVIRONMENTAL LIMITED  Acting by two directors or a director and the company secretary	) ) ) )	
		Director /s/ [Illegible]
		Secretary /s/ [Illegible]
		For and on behalf of MAWLAW SECRETARIES LTD
EXECUTED as a deed by  MICROSCIENCE LIMITED  Acting by two directors or a director and the company secretary	) ) ) )	
MICROSCIENCE LIMITED Acting by two directors or a director	) ) ) )	Director [Illegible]
MICROSCIENCE LIMITED Acting by two directors or a director	) ) ) )	Director [Illegible] Director/Secretary /s/ Jonathan RHH Pockson

#### AMENDED AND RESTATED LOAN AGREEMENT

THIS AMENDED AND RESTATED LOAN AGREEMENT is made as of <u>July 29th</u>, 2005, by and between **BIOPORT CORPORATION**, a Michigan corporation, of Lansing, Michigan ("Borrower"), and FIFTH THIRD BANK, a Michigan banking corporation, of East Lansing, Michigan ("Lender").

Borrower and Lender are parties to Loan Agreements dated as of July 30, 2004 and October 8, 2004, under which Bank agreed to extend to Borrower revolving credit loans of up to \$10 million in the aggregate at any time outstanding. This Amended and Restated Loan Agreement amends and restates the Loan Agreements of June 25, 2003, July 30, 2004 and October 8, 2004, in their entirety, to read as follows:

Lender and Borrower agree as follows:

#### SECTION 1. DEFINITIONS.

In this Agreement:

- "Affiliate" of a Person means a Person that now or in the future controls, is controlled by, or is under common control with, the Person.
- "Agreement" means this Amended and Restated Loan Agreement as amended, including the schedules attached to this Loan Agreement.
- "Capitalized Lease Obligation" means any obligation of Borrower to pay future rentals under a lease that, in accordance with GAAP, is required to be shown as a liability on Borrower's balance sheet.
  - "Collateral" means the proceeds of the Government Contracts.
- "Collateral Document" means each security agreement, mortgage, pledge agreement, assignment, guaranty and every other agreement and document that has been or in the future is, or is required to be, given by Borrower or any third party to secure any Lender Indebtedness.
- "Contamination" or "Contaminated" means, when used with reference to any real or personal property, that a Hazardous Substance is present on or in the property in any amount or level that exceeds any legal limit set forth under Environmental Law. "Contamination or "Contaminated" shall not include latent, unexposed asbestos in any building located on any of the real property unless and until exposure that exceeds the foregoing legal limit occurs due to renovation or otherwise.

A Person "controls" another Person if the Person has, directly or indirectly, the power to direct or cause the direction of the management or policies of the other Person.

- "Default" means an event, condition or circumstance that, with the lapse of time or giving of notice (absent any permitted cure), would be an Event of Default.
- "DOD Contract" means Contract No. W9113M-04-D-0002, dated January 3, 2004, between U.S. Army Space and Missile Defense Command and Borrower, as it has been and in the future is amended.
  - "Eligible Account" means, as of the relevant date of determination, an account receivable of Borrower arising in the ordinary course of business:
    - (a) that is not more than 90 days old from the earlier of the original invoice date or the date of shipment of the goods or performance of the services that gave rise to the account receivable;
    - (b) that arises from Borrower's sale and shipment of goods or Borrower's performance of services, in the ordinary course of Borrower's business;
    - (c) that is the valid, binding and enforceable obligation of the account debtor and is not subject to any offset, counterclaim or defense;
    - (d) that is evidenced by an invoice that is dated not later than the 15th day post the date of shipment of the goods or performance of the services and payable in full no more than 90 days after the invoice date and that is not evidenced by an instrument or chattel paper;
      - (e) that is owned by Borrower and is not subject to any security interest, lien, encumbrance, assignment or trust, except in favor of Lender;
      - (f) in which Lender holds a valid and perfected security interest;
      - (g) that is owing by the federal government under a Government Contract;
      - (h) that does not arise from a sale of goods on consignment or on a sale-or-return basis;
    - (i) that is owing by an account debtor to whom Borrower does not have any maintenance obligation with respect to the goods or services the sale of which gave rise to the account receivable;
      - (j) that is not subject to retainage; and
      - (k) as to which Lender has not notified Borrower is, in Lender's good faith judgment, uncollectible, in whole or in part, within 60 days.

**"Environmental Law"** means at any time any applicable federal, state, local or foreign law (including common law), ordinance, rule, regulation, permit, order or other requirement that then (1) regulates the quality of air, water, soil or other environmental media, (2) regulates the generation, management, transportation, treatment, storage, recycling or disposal of any waste, (3) protects public health, occupational safety and health, natural resources or the environment or (4) establishes liability for the investigation, removal or remediation of, or harm caused by, Contamination.

- "ERISA" means the Employee Retirement Income Security Act of 1974, as now and in the future amended, together with all regulations issued under it.
- "Event of Default" has the meaning specified in Section 9 of this Agreement.
- "FDA" means the U.S. Food and Drug Administration.
- "GAAP" means generally accepted accounting principles as consistently applied by Borrower.
- "Government Contracts" means the HHS Contract and the DOD Contract.
- "Guarantor" means each Person who has guaranteed or in the future guarantees payment of all or part of the Lender Indebtedness.
- "Hazardous Substance" means at any time any substance or waste that is then regulated by or subject to any Environmental Law.
- "HHS Contract" means Contract No, 200-2005-11811, dated May 5, 2005, between Department of Health and Human Services ('HHS') and Borrower, which provides for Borrower to sell to HHS, and for HHS to purchase from Borrower, anthrax vaccine, as that Contract is amended in the future.

"Indebtedness" means indebtedness for borrowed money, indebtedness representing the deferred purchase price of property (excluding indebtedness under normal trade credit for property or services purchased in the normal course of operations), any obligation under a note payable or draft accepted representing an extension of credit, indebtedness (whether or not assumed) secured by a mortgage, security interest or other lien on property, and any Capitalized Lease Obligation. By way of clarification, for the avoidance of doubt, and without limiting the foregoing, "Indebtedness" shall not include deferred revenue, deferred tax liabilities or any indebtedness for borrowed money or representing the deferred purchase price of property, whether or not secured, that is Subordinated Indebtedness.

"Intangible Collateral" means the Collateral described in Sections 5.1 and 5.2 of this Agreement.

- "Intellectual Property" means all patents, trademarks, service marks, trade names, copyrights, licenses and similar rights.
- "Leader Indebtedness" means any indebtedness, obligation or liability, of whatever type or nature, that Borrower now or in the future owes to Lender under this Agreement.
- "Loan" means any loan that Lender makes to Borrower under this Agreement.
- "Loan Document" means this Agreement, the Revolving Credit Note and every other promissory note that Borrower has given or in the future gives to Lender under this Agreement, each renewal, extension and replacement of the Revolving Credit Note, each Collateral Document and every other agreement, instrument and document that has been or in the future is signed or delivered in connection with this Agreement or in connection with any Lender indebtedness.
- "Material Adverse Effect" means any material adverse effect upon (1) the validity, performance or enforceability of any Loan Document, (2) the Borrower's properties taken as a whole, (3) a Government Contract or any other material contract, (4) business operations, profits or financial condition of Borrower, (5) the ability of Borrower or any Guarantor to fulfill any material obligation under any Loan Document or (6) the ability of Lender to take possession of, collect or otherwise realize upon any Collateral or other security for the Lender Indebtedness.
  - "Maturity" of an indebtedness or obligation means the time when that indebtedness or obligation has become due and payable, for whatever reason.
  - "Non Disclosure Agreement" means that Nondisclosure Agreement, dated November 18, 2002, between Borrower and Lender.
- "Note" means the Revolving Credit Note and any other promissory note that Borrower has signed or in the future signs and that now or in the future evidences any Lender Indebtedness, including any renewals, extensions or modifications.
- "Permitted Lien" means (1) a security interest, mortgage or other lien in favor of Lender, (2) a lien for taxes that are not delinquent or, in a jurisdiction where payment of taxes is abated during the period of any contest, being contested in good faith by appropriate proceedings, if adequate reserves for it have been set aside on Borrower's books, in accordance with GAAP, (3) a lien or encumbrance that is described on Borrower's balance sheet dated December 31, 2004, that Borrower has delivered to Lender and (4) an inchoate materialmen's, mechanics', workmen's, repairmen's or other like lien arising in the ordinary course of business, if the obligation secured is not delinquent or is being contested in good faith by appropriate proceedings, if adequate reserves for it have been set aside upon Borrower books in accordance with GAAP and if the lien does not jeopardize any Collateral and does not have a Material Adverse Effect.

- "Person" means an individual and a corporation, partnership, limited liability company, trust, association and any other entity.
- "Plan" means an "employee pension benefit plan" with respect to which Borrower or any Affiliate is an "employer" or "party in interest," as ERISA defines those terms.
- "Revolving Credit Commitment" means the lesser of 75% of Borrower's Eligible Accounts or \$10,000,000.
- "Revolving Credit Loans" has the meaning specified in Section 3.1 of this Agreement.
- "Revolving Credit Note" has the meaning specified in Section 3.3 of this Agreement.
- "Schedule" means a schedule attached to this Agreement.
- "Subordinated Indebtedness" means, at any time, all Indebtedness that Borrower owes to any Person or Persons to the extent that its repayment is subordinated to payment of the Lender Indebtedness in form and manner satisfactory to Lender.
  - "Subsidiary" means a corporation or a limited liability company all of the capital stock, membership interests and other equity interests of and in which are owned by Borrower.
  - "Term Loan" has the meaning specified in Section 4 of this Agreement.
  - "Term Loan Note" has the meaning specified in Section 4 of this Agreement.

#### SECTION 2. WARRANTIES AND REPRESENTATIONS.

Borrower represents and warrants to Lender, and agrees, as follows:

- 2.1 Borrower is a corporation that is duly organized, validly existing and in good standing under the laws of the state of Michigan. Borrower is duly qualified and authorized to do business, and is in good standing as a foreign corporation, in each jurisdiction in which the failure to be so qualified or authorized to do business would have a Material Adverse Effect.
- 2.2 Borrower has all requisite corporate power and authority and all necessary licenses and permits to own and operate its properties and to carry on its business as it now conducts it and as it contemplates that it will conduct it in the future. Borrower is in compliance with all laws, rules and regulations that apply to Borrower, its operations or its properties, except where any noncompliance could not have a Material Adverse Effect.
- 2.3 The audited balance sheets of Borrower as of December 31, 2001 and December 31, 2002, and December 31, 2003, and the unaudited balance sheets of Borrower as of December 31, 2004 and March 31, 2005, and the related statements, if applicable, of income, of retained earnings and of changes in financial position for the periods then ended, copies of all of which

have been delivered to Lender, have been prepared in accordance with GAAP and present fairly the financial position of Borrower as of those dates and the results of its operations for those periods. Since the date of the most recent of those financial statements, there has not been any change in Borrower's financial condition or operations that has not been disclosed to Lender in writing and could have a Material Adverse Effect.

- 2.4 Neither this Agreement nor any financial statement that Section 2.3 above refers to nor any other written statement that Borrower has furnished to Lender in connection with the negotiation of any Loan, contains any untrue statement of a material fact or omits a material fact necessary to make the statements contained in this Agreement, the financial statement or other written statement not misleading.
- 2.5 Except as previously disclosed to Lender in writing, there is not any proceeding pending or, to the knowledge of the officers and directors of Borrower, threatened, before any court, governmental authority or arbitration board or tribunal, against Borrower, that, if determined adversely to Borrower, could reasonably be expected to have a Material Adverse Effect. Borrower is not in default with respect to any order, judgment or decree of any court, governmental authority or arbitration board or tribunal.
- 2.6 All of the issued and outstanding shares of capital stock of Borrower are owned by Emergent BioSolutions Inc., a Delaware corporation. There are not any outstanding options, warrants or rights to purchase, and there is not any agreement for the subscription, purchase or acquisition of, any such shares of Borrower's capital stock.
- 2.7 Borrower has good and marketable title to all of the intangible assets that it purports to own, including the intangible assets reflected in the financial statements referred to in Section 2.3 of this Agreement, free and clear of all liens, encumbrances, security interests, claims, charges and restrictions, except Permitted Liens.
- 2.8 (a) Borrower owns, jointly owns, or has been licensed the right to use pursuant to licenses that remain in full force and effect, Intellectual Property sufficient to operate its business as it is presently being conducted.
- (b) Except as previously disclosed to Lender in writing, there is no action, suit or proceeding pending against or, to the knowledge of Borrower, threatened against Borrower (1) challenging the rights of Borrower in any Intellectual Property owned or used by Borrower or (2) alleging that products manufactured, used, imported or sold by Borrower conflict with, misappropriate, infringe or violate the Intellectual Property rights of any third party, except in each case for actions, suits or proceedings the outcome of which individually or in the aggregate would not have a Material Adverse Effect
- 2.9 Borrower has full power and authority to sign, deliver and perform the Loan Documents. The signing, delivery and performance of the Loan Documents: (1) have been duly authorized by appropriate corporate action of Borrower, (2) will not violate the provisions of Borrower's articles of incorporation or bylaws or of any law, rule, judgment, order, agreement or

instrument to which Borrower is a party or by which it is bound and (3) do not require any approval or consent of any public authority or other third party, except for (a) consents and approvals that have been obtained prior to the date of this Agreement; or (b) approvals or consents the failure of which to obtain, individually or in the aggregate, do not have a Material Adverse Effect and do not materially impair the ability of Borrower to perform its obligations under the Loan Documents. Borrower has properly signed and delivered the Loan Documents, and the Loan Documents are the valid and binding obligations of Borrower and are enforceable against Borrower in accordance with their terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors and the rules of law governing specific performance, injunctive relief and other equitable remedies.

- 2.10 Borrower has filed each tax return that it is required (after taking account of any properly-filed and valid and effective extensions) to file in any jurisdiction, and Borrower has paid each tax, assessment, fee and other governmental charge upon it or upon its assets, income or franchises before the time when its nonpayment could give rise to a lien that could have a Material Adverse Effect. Borrower does not know of any proposed additional tax assessment against it.
- 2.11 Borrower does not have any investments in the securities of any Person. Borrower does not intend to carry or purchase any "margin security" within the meaning of Regulation U of the Board of Governors of the Federal Reserve System, 12 C.F.R. Chapter II.
- 2.12 Attached to this Agreement as **Schedule 2.12** is a list of all Plans. No Plan has been terminated since the effective date of ERISA. No Plan is a "multi-employer plan" within the meaning of Section 3(37)(A) of ERISA. An "accumulated deficiency" (within the meaning of Section 412 of the Internal Revenue Code, as amended) or a "reportable event" (as defined in Title IV of ERISA) has not occurred with respect to any Plan. Neither Borrower nor any Affiliate has incurred any material liability to the Pension Benefit Guaranty Corporation ("**PBGC**") or otherwise under ERISA. The PBGC has not started or, to the knowledge of Borrower, threatened to start a proceeding against Borrower or any Affiliate under ERISA.
- 2.13 Borrower is not, and no person, firm or corporation that has "control" of Borrower is, an "executive officer," "director" or "person who directly or indirectly, or in concert with one or more persons owns, controls or has the power to vote more than 10 percent of any class of voting securities" (within the meaning of 12 U.S.C. Section 375(b) and regulations issued under that section), of Lender, Fifth Third Bancorp or any subsidiary of Fifth Third Bancorp.
  - 2.14 With such exceptions as do not have, individually or in the aggregate, a Material Adverse Effect:
- (a) No written notice, demand, citation, or order has been received, no penalty has been assessed, and no action, suit or proceeding is pending or, to the knowledge of the Borrower, is threatened by any governmental agency pursuant to or arising out of any Environmental Laws; and

- (b) There are no liabilities of the Borrower not recorded on the Borrower's financial statements in accordance with GAAP arising as a result of Borrower's real or personal property (a) being Contaminated; (b) being the source of any Contamination of any adjacent property or any groundwater or surface water; or (c) being the source of any air emissions in excess of any legal limit or standard under Environmental Laws
  - 2.15 Borrower has furnished to Lender a complete and correct copy of each Government Contract, including all amendments.
  - 2.16 Schedule 2.16 lists each Affiliate and describes Borrower's relationship to it, including ownership of capital stock.

#### SECTION 3. REVOLVING LINE OF CREDIT.

- 3.1 Subject to satisfaction of the conditions precedent set forth in Section 10 of this Agreement and as long as there shall not have occurred any Default or Event of Default, that in each case has not been cured or waived, Lender shall extend to Borrower from time to time loans in amounts ("Revolving Credit Loans") that shall not at any time in the aggregate exceed the Revolving Credit Commitment.
- 3.2 If the aggregate principal amount of the Revolving Credit Loans outstanding at any time exceeds the Revolving Credit Commitment, then Borrower shall immediately repay the amount of the Revolving Credit Loans that is required to eliminate the excess.
- 3.3 All Revolving Credit Loans shall be evidenced by and payable with interest in accordance with the terms of a promissory note in the form attached to this Agreement as **Schedule 3.3** ("**Revolving Credit Loan Note**"), which Borrower shall sign and deliver to Lender.
  - 3.4 Each Revolving Credit Loan shall be in the amount \$1,000 or a whole multiple of that amount and shall be made upon Borrower's request.
- 3.5 Borrower shall have the right to prepay all Revolving Credit Loans, in whole or in part, at any time without penalty or any other premium or charge. Borrower may reborrow amounts that it prepays, subject to the other provisions of this Agreement.
- 3.6 Unless it is sooner terminated or Lender extends it in writing, Lender's obligation to make or to renew Revolving Credit Loans shall expire on May 1, 2006. If Lender extends it, then Lender's obligation to make or renew Revolving Credit Loans shall expire on the date stated in the extension. If Lender's obligation to make or renew Revolving Credit Loans expires, then the aggregate unpaid principal balance of all outstanding Revolving Credit Loans, together with all accrued interest on them, shall be due and payable in full on the expiration date.

### **SECTION 4. TERM LOAN**

- 4.1 On August 10, 2004, Lender made a term loan to Borrower in the principal amount of \$2,400,000 ("Term Loan").
- 4.2 The Term Loan is evidenced by and payable in accordance with a Term Note dated August 10, 2004, payable to Lender, that Borrower executed and delivered to Lender ("Term Loan Note").
- 4.3 Nothing in this Agreement amends or modifies the Term Loan or the Term Loan Note.

#### SECTION 5. SECURITY.

- 5.1 Simultaneously with the signing and delivery of this Agreement, Borrower is signing and delivering to Lender an Amended and Restated Security Agreement granting to Lender a valid first security interest in the Collateral, and in all proceeds to secure payment and performance of all Lender Indebtedness.
- 5.2 Simultaneously with the signing and delivery of this Agreement, Borrower is assigning to Lender, as security, all payments that are now or in the future owing to Borrower under each Government Contract, to secure payment and performance of all Lender Indebtedness.
- 5.3 Borrower has signed and delivered to Lender two mortgages, dated July 30, 2004, that grant to Lender valid first liens on the real property located in Ingham County, Michigan and Clinton County, Michigan, described in them, to secure the Lender Indebtedness described in them. If at any time after July 31, 2005, Borrower gives to Lender a written request that Lender discharge either or both of the mortgages and if at that time (a) neither a Default nor an Event of Default shall have occurred and be continuing, (b) Borrower is not indebted to Lender, other than in respect of the Term Loan or one or more Revolving Credit Loans and (c) Lender is not obligated to extend any loan or other credit facility to Borrower, then Lender shall, within 30 days after it receives the request, comply with the request.
- 5.4 Borrower shall sign and deliver to Lender all financing statements, assignments, documents of title and other documents, agreements and instruments in connection with the perfection or priority of the security provided for above, and shall take all further actions that Lender reasonably requests in connection with the perfection or priority of the security provided for above.

### SECTION 6. AFFIRMATIVE COVENANTS.

From the date of this Agreement and until all Lender Indebtedness is fully paid and Lender does not have any obligation to extend loans or other credit facilities to Borrower hereunder, Borrower shall:

- 6.1 Furnish to Lender, within 120 days after the end of each of Borrower's fiscal years, beginning with its fiscal year ending December 31, 2005, an audited financial report prepared in accordance with GAAP by independent certified public accountants that are satisfactory to Lender (it being understood that Borrower's current auditors are satisfactory to Lender), containing (1) Borrower's balance sheet as of the end of that year, its related statements of operations for that year and its statement of cash flows for that year, (2) any management letters that those certified public accountants prepare in conjunction with such audits, (3) all notes and other financial schedules that are customarily included in the audited financial statements and (4) the unqualified opinion of the certified public accountants stating that the financial statements for the fiscal year present fairly the financial position, results of operations and cash flows in conformity with GAAP.
- 6.2 Furnish to Lender within 20 days after the end of each month, beginning with the month of May, 2005, an unaudited financial report, the accuracy of which is certified to by the President or chief financial officer of Borrower, prepared in accordance with GAAP, containing Borrower's balance sheet as of the end of the period and its income statement showing the results of its operations for the portion of its fiscal year then elapsed.
- 6.3 Furnish to Lender within 20 days after the end of each month, beginning with the month of May, 2005, a detailed aging of all of Borrower's accounts receivable that are in excess of \$100,000, in form reasonably satisfactory to Lender.
- 6.4 (1) Promptly inform Lender of any occurrence that is a Default or an Event of Default and of any other occurrence that has had, could reasonably be expected to have, a Material Adverse Effect; (2) grant to Lender or its representatives the right to examine its books and records during normal business hours no more frequently than once per calendar quarter; (3) maintain complete and accurate books and records of its transactions in accordance with Borrower's current accounting practices; and (4) furnish to Lender any information that it reasonably requests concerning Borrower's financial condition and results of operations within 45 days after Lender makes the request.
- 6.5 (1) Maintain insurance, including, but not limited to, fire and extended coverage insurance, workers' compensation insurance and commercial and general liability insurance with responsible insurance companies on its properties and against the risks and in the amounts and in a manner consistent with Borrower's current practice; (2) furnish to Lender upon its request the details with respect to that insurance and satisfactory evidence of that insurance coverage. Each insurance policy that this Section requires shall be written or endorsed in a manner that makes losses, if any, payable to Borrower and Lender as their respective interests appear and shall include, where appropriate, a mortgage clause or lender's loss payable endorsement in favor of Lender in form and substance reasonably satisfactory to Lender.
- 6.6 Pay and discharge, as often as they are due and payable, all taxes and assessments of whatever nature that are levied or assessed against it or any of its properties, unless and to the extent only that (1) in a jurisdiction where payment of taxes and assessments is abated during the

period of any contest, those taxes or assessments are being contested in good faith by appropriate proceedings and (2) Borrower shall have set aside on its books adequate reserves with respect to those taxes and assessments.

- 6.7 Maintain its existence as a corporation in good standing in the State of Michigan and its qualification in good standing in every other jurisdiction in which the failure to be qualified or authorized to do business could have a Material Adverse Effect; continue to conduct and operate its business substantially as it presently conducts and operates it subject to Borrower's right, subject to Section 7.5, upon prior written notice to Lender, to expand its business, make acquisitions, enter joint ventures and similar arrangements and enter into new, but related, business lines; and comply with all governmental laws, rules, regulations and orders that apply to it, the failure to comply with which could have a Material Adverse Effect.
- 6.8 Keep in good working order and condition, ordinary wear and tear excepted, all of its material assets and properties that are necessary to the conduct of its business, in a manner consistent with industry practice, other than machinery and equipment that Borrower disposes of as permitted by Section 7.2.
  - 6.9 Maintain its principal commercial deposit accounts with Lender.
- 6.10 (1) Comply in all material respects with the applicable requirements of ERISA and the Internal Revenue Code with respect to each Plan, including, without limitation, all provisions regarding minimum funding requirements and requirements as to plan termination insurance; (2) within 30 days after it is filed, furnish to Lender a copy of each annual report and annual return, with all schedules and attachments, that ERISA requires Borrower to file with the Department of Labor or the Internal Revenue Service pursuant to ERISA in connection with each Plan for each Plan year; (3) notify Lender immediately of any fact or circumstance, including, but not limited to, any "reportable event" (as defined in Title IV of ERISA), that might be grounds for termination of a Plan by the Pension Benefit Guaranty Corporation or for the appropriate United States District Court of a trustee to administer the Plan, together with a statement, if Lender requests it, as to the reason the fact or circumstance has occurred and the action, if any, that Borrower proposes to take to avoid termination of the Plan; and furnish to Lender, upon its request, any additional information concerning any Plan that Lender reasonably requests.
- 6.11 Notify Lender in writing within 10 days after Borrower receives any notice of the beginning of (1) any proceeding or investigation by a federal or state environmental agency against Borrower regarding Borrower's compliance with Environmental Laws or (2) any other judicial or administrative proceeding or litigation by or against Borrower in each case that would result in a Material Adverse Effect.

### SECTION 7. NEGATIVE COVENANTS.

From the date of this Agreement and until all Lender Indebtedness is fully paid and Lender does not have any obligation to extend loans or other credit facilities to Borrower, Borrower shall not, without the prior written consent of Lender:

- 7.1 Create or permit to exist any lien, security interest, mortgage, pledge, attachment, garnishment, execution or other legal process or encumbrance on any Collateral, other than liens created under the Loan Documents and Permitted Liens.
- 7.2 Sell, lease or otherwise dispose of any of its assets with a value in excess of \$250,000, except for (1) the sale of inventory in the ordinary course of business (as Borrower conducts its business on the date of this Agreement) and (2) the disposition, in the ordinary course of business, of machinery and equipment that has become obsolete, damaged, unsuitable or unnecessary for its business.
- 7.3 Make loans or advances to any Person, except for (1) loans and advances to Affiliates or Subsidiaries and (2) loans and advances to Persons that are not Affiliates or Subsidiaries as long as the aggregate loans and advances outstanding to all Persons that are not Affiliates or Subsidiaries does not at any time exceed \$250,000.
- 7.4 Guarantee, endorse, assume or otherwise incur or suffer to exist any contingent liability in respect of any obligation of any other Person, other than an Affiliate or Subsidiary, except by the endorsement of negotiable instruments for deposit or collection in the ordinary course of business and except for guarantees under which the maximum possible liability of Borrower does not at any time exceed \$500,000 in the aggregate.
- 7.5 Enter into any merger, consolidation, reorganization or recapitalization, or purchase or otherwise acquire all, or substantially all, of the assets, obligations or capital stock of or any other interest in any Person if either (1) a Default or an Event of Default shall have occurred and is then continuing or (2) the merger, consolidation, reorganization, recapitalization, purchase or acquisition would result in or cause a Default or an Event of Default.
  - 7.6 Subordinate any indebtedness that any Person other than an Affiliate or Subsidiary owes to Borrower to Indebtedness that that Person owes to any other Person.
- 7.7 Engage in any transaction with any Affiliate on terms that are less favorable to Borrower than Borrower could obtain at the time in a comparable transaction in an arm's-length dealing with a Person other than an Affiliate; except that this Section 7.7 shall not prevent Borrower from continuing any transaction with an Affiliate in existence on October 8, 2004.
- 7.8 Issue, incur, assume or permit to remain outstanding any Indebtedness that is not Subordinated Indebtedness, other than (1) Lender Indebtedness, (2) Indebtedness the proceeds of which are used to pay the purchase price of real property acquired by Borrower, and (3) other Indebtedness that does not exceed \$500,000 in the aggregate at any time outstanding.
- 7.9 Become a contributing employer with respect to a multi-employer employee benefit plan within the meaning of Section 3(37)(A) of ERISA (29 U.S.C. 1002), as amended by Section 302 of the Multi-Employer Pension Plan Amendments Act of 1980 (other than any Plans described on **Schedule 2.12** as being multi-employer plans); or establish for any of its employees

any employee benefit plan that has, or may in the future incur, any unfunded past service liability.

- 7.10 Change its name, fiscal year or method of accounting, except as GAAP requires, and except that Borrower may change its name if Borrower gives Lender 60 days' prior written notice of the name change and takes any action that Lender reasonably considers necessary to continue the perfection of the security interests and liens that the Collateral Documents grant to Lender.
- 7.11 Enter into any amendment to or modification of, or terminate all or any part of, any Government Contract that in any way materially adversely affects the payments due to the Borrower under such Government Contracts without Lender's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed.

# SECTION 8. APPLICATION OF PROCEEDS.

Borrower shall apply the proceeds of the Revolving Credit Loans for any proper business purpose, including without limitation for working capital.

### SECTION 9. EVENTS OF DEFAULT AND REMEDIES.

- 9.1 Each of the following is an "Event of Default" under this Agreement not cured within 30 days (unless some other cure period is provided below) from written notice of default:
- A. If Borrower defaults in the payment of the principal or interest of any Lender Indebtedness, when and as it is due and payable, whether by acceleration or otherwise and does not cure the default within ten (10) business days after Lender gives Borrower notice of the default.
- B. If Borrower fails to perform any of its other obligations under, or to comply with any of the terms, conditions and covenants that are contained in, this Agreement or any other Loan Document or other agreement, document or instrument that Borrower or any third party has given or in the future gives to Lender to secure any Lender Indebtedness, if, in the case of a failure that can be cured, Borrower does not cure the failure within thirty (30) days after Lender gives Borrower notice of it.
- C. If Borrower defaults in the payment of any other Indebtedness and does not cure the default within thirty (30) days after Lender gives Borrower notice of the default, if the default results in a right of the holder of the Indebtedness to accelerate the maturity of such Indebtedness in an amount in excess of \$500,000.
- D. If any warranty or representation that Borrower makes in this Agreement or any statement, warranty or representation that Borrower or any third party has made or in the future makes in any other Loan Document, certificate, report or other document, instrument or agreement that is delivered under this Agreement or in

connection with any Lender Indebtedness is false or inaccurate in any material respect when made.

- E. If any guaranty that now or in the future secures payment of all or any part of the Lender Indebtedness is, other than by its terms, terminated or limited for any reason without the written consent of Lender
- F. If Borrower fails to perform any of its obligations under any Government Contract within any cure period so provided or if a Government Contract is terminated for any reason other than by expiration in accordance with its terms.
- G. If, as a result of any order, judgment or other action of the FDA, a court or any other governmental agency or entity, Borrower is required to stop selling all or any of the anthrax vaccine that it has agreed to sell under a Government Contract.
- H. If Borrower (1) applies for or consents to the appointment of, or the taking of possession by, a receiver, custodian, trustee or liquidator of itself or of all or a substantial part of its property, (2) is generally unable to pay its debts as they become due, (3) makes a general assignment for the benefit of its creditors, (4) starts a voluntary case under the federal Bankruptcy Code (as now or in the future in effect), (5) files a petition that seeks to take advantage of any other law that provides for the relief of debtors, (6) fails to controvert in a timely or appropriate manner, or acquiesces in writing to, any petition that is filed against Borrower in any involuntary case under the Bankruptcy Code or (7) takes any action for the purpose of effecting any of the foregoing.
- I. If a proceeding or case is started in any court of competent jurisdiction and is not dismissed within 60 days, seeking (1) the liquidation, reorganization, dissolution, winding up or composition or readjustment of Borrower or its assets or the appointment of a trustee, receiver, custodian, liquidator or the like of Borrower or of all or any substantial part of the assets of Borrower or (2) similar relief in respect of Borrower under any law that provides for the relief of debtors; or if an order for relief against Borrower is entered in an involuntary case under the Bankruptcy Code.
- 9.2 If an Event of Default that is described in *subsections 9.1A* through 9.1G above occurs, then, at the option of Lender, Lender's obligation to make or renew Revolving Credit Loans shall terminate, and all or any part of the unpaid principal balance of and accrued interest on all Lender Indebtedness shall become immediately due and payable, without presentment, demand or notice of any kind, all of which Borrower waives.
- 9.3 If an Event of Default that is described in *subsection 9.1H* or *9.11* above occurs, then Lender's obligation to make or renew Revolving Credit Loans shall immediately terminate, and the entire unpaid principal balance of and accrued interest on all outstanding Lender Indebtedness shall automatically become due and payable without presentment, demand or notice of any kind, all of which Borrower waives.

### SECTION 10. CONDITIONS PRECEDENT.

The obligation of Lender to make the initial Revolving Credit Loan is subject to the following conditions precedent:

- 10.1 Lender shall have received copies of resolutions of the Board of Directors of Borrower, certified by the Secretary of Borrower as being in full force and effect on the date of making the loans, authorizing Borrower's signing, delivery and performance of this Agreement and all other Loan Documents.
- 10.2 Lender shall have received a copy of Borrower's bylaws, including all amendments to them, certified by the Secretary of Borrower as being in full force and effect on the date of making the Loans
- 10.3 Lender shall have received copies of the articles of incorporation of Borrower, including all amendments to them, certified by the Michigan Department of Labor and Economic Growth not more than 30 days before the initial extension of loans under this Agreement.
- 10.4 Lender shall have received a good standing certificate with respect to Borrower from the Michigan Department of Labor and Economic Growth dated not more than 30 days before the initial extension of loans under this Agreement.
  - 10.5 Borrower shall have signed and delivered to Lender all Loan Documents.
  - 10.6 Borrower shall have delivered to Lender evidence satisfactory to Lender that Borrower has obtained the insurance policies that this Agreement and any Collateral Documents require.
  - 10.7 There shall not have occurred and be continuing any Default or Event of Default.
  - 10.8 Borrower shall have paid to Lender a processing fee in the amount of \$425 as required by Section 11.2.

## SECTION 11. MISCELLANEOUS.

11.1 Borrower shall pay, or reimburse Lender for, all out-of-pocket expenses that Lender incurs (including, but not limited to, recording and filing fees and taxes, search fees, title insurance premiums and actual fees and expenses of legal counsel, other professional advisers, consultants and experts) in connection with (1) the negotiation, preparation and signing of the Loan Documents, any amendments to, or waivers of any provisions of, the Loan Documents and any refinancing or restructuring of any Lender Indebtedness, (2) the administration of this Agreement and the other Loan Documents, including, without limitation, making filings and recordings in public offices to perfect or give notice of liens in favor of Lender, obtaining policies of title insurance, title searches, financing statement searches, tax lien searches,

appraisals and environmental inspections, audits and assessments, (3) obtaining advice of counsel or other professional advisers, consultants and experts regarding any aspect of the Loan Documents or any Lender Indebtedness, (4) the enforcement of any of the provisions of the Loan Documents, (5) the collection of any Lender Indebtedness and (6) the foreclosure of any security interests, mortgages, or other liens that at any time secure any Lender Indebtedness.

- 11.2 Upon signing of this Agreement, Borrower shall pay to Lender a nonrefundable processing fee in the amount of \$425.
- 11.3 Borrower acknowledges that Lender has and shall have the right to set off any indebtedness that Lender from time to time owes to Borrower, including, without limitation, any indebtedness that is represented by any deposit account that Borrower maintains with Lender, against any indebtedness that is at any time due and payable by Borrower to Lender.
- 11.4 Each right and remedy that this Agreement or any other Loan Document grants to Lender or that the law allows to Lender shall be cumulative, and Lender may exercise it from time to time. Lender's failure to exercise, and Lender's delay in exercising, any right or remedy shall not be a waiver of that right or remedy or a waiver of any other right or remedy. This Agreement may not be amended and a provision of it may not be waived except by a writing that Lender signs.
- 11.5 The relationship between Borrower and Lender under this Agreement and the other Loan Documents is solely that of debtor and creditor. Lender does not have any fiduciary responsibilities to Borrower. Lender does not and shall not have any responsibility to review, or to inform Borrower of any matter in connection with, any aspect of Borrower's business, operations or properties. Borrower shall rely entirely upon its own judgment with respect to its business and properties. Any review, appraisal, audit, survey, inspection, report or other information that Lender obtains, whether or not Borrower pays for it or Lender furnishes it to Borrower ("Lender Information"), is solely for the benefit of Lender. Neither Borrower nor any third party is entitled to rely on any Lender Information. Lender does not have any duty to Borrower with respect to any Lender Information, including, without limitation, any duty to assure that any review, audit, survey, inspection, appraisal is performed properly or any duty to disclose to Borrower any facts, information, opinions, conclusions or statements that any review, audit, survey, inspection, appraisal or other Lender Information contain
- 11.6 Any and all information provided to Lender by Borrower or any of its Affiliates shall be subject to the non-disclosure and other obligations of Lender under the terms of the Nondisclosure Agreement. Borrower authorizes Lender to furnish to any Affiliate of Lender and to any prospective transferee of, or participant in, any Loan or Loans any or all information about Borrower, including, without limitation, financial statements and information regarding the operations, assets and properties, finances, strategies, plans, activities, transactions, owners, directors, officers, employees and customers of Borrower and its Affiliates, if, in each case, the Affiliate or any other prospective transferee or participant acknowledges in writing that it shall be subject to the Nondisclosure Agreement as though an original party named in it and such obligations shall be enforceable by Borrower directly against such Person.

11.7 This Agreement and the rights and obligations of the parties under it shall be governed by and interpreted in accordance with the internal laws of the State of Michigan.

11.8 Any notice or other communication that this Agreement requires or permits shall be in writing and shall be served either personally or by certified United States mail with postage fully prepaid, or by a nationally-recognized, overnight courier service, addressed to Borrower as:

# BIOPORT CORPORATION

3500 North Martin Luther King, Jr. Blvd. Lansing, Michigan 48906

Attention: Robert Kramer, President With a copy to: Jose Ochoa, General Counsel

and to Lender as:

## FIFTH THIRD BANK

2501 Coolidge Road East Lansing, Michigan 48813

Attention: Michael Debri

or to any other place that either party designates by written notice to the other party.

11.9 This Agreement shall be binding upon and shall inure to the benefit of Borrower and Lender and their respective successors and assigns. No Person is a third party beneficiary of this Agreement.

11.10 This Agreement amends and restates in its entirety the Loan Agreements between the parties dated July 25, 2003, July 30, 2004 and October 8, 2004.

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LENDER AND BORROWER EACH IRREVOCABLY AND UNCONDITIONALLY WAIVES ITS RIGHT TO A TRIAL BY JURY IN ANY ACTION, INCLUDING ANY CLAIM, COUNTERCLAIM, CROSS-CLAIM OR THIRD-PARTY CLAIM ("CLAIM") THAT IS BASED UPON, ARISES OUT OF OR RELATES TO THIS LOAN AGREEMENT OR THE LENDER INDEBTEDNESS, INCLUDING, WITHOUT LIMITATION, AND CLAIM THAT IS BASED UPON, ARISES OUT OF OR RELATES TO ANY ACTION OR INACTION OF LENDER IN CONNECTION WITH ANY ACCELERATION OF THE INDEBTEDNESS OR ANY ENFORCEMENT OF ANY SECURITY THAT LENDER AT ANY TIME HAS FOR ANY LENDER INDEBTEDNESS.

Borrower and Lender have signed this Agreement as of the date stated on the first page of this Agreement.

ATTEST:

BIOPORT CORPORATION

By /s/ Robert G. Kramer

Its President & CEO

And by /s/ Ronald S. Huben

Its Associate Director of Finance

FIFTH THIRD BANK

By /s/ Michael Debri
Its Vice President

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Schedule 2.12
Plans
[Unavailable]

Schedule 2.16 Affiliates [Unavailable] Patrick Saam, Controller Bioport Corporation 3500 North Martin Luther King Jr. Blvd. Lansing, MI 48906

Dear Mr. Saam,

This letter is to inform you that the bank has extended your ten million dollar line of credit for 90 days to expire August 1, 2006. All terms and conditions remain the same. If you have any questions, please feel free to call me at (517) 351-5204.

Sincerely,

/s/ David S. Flower

David S. Flower Vice President Fifth Third Bank

### AMENDMENT TO AMENDED AND RESTATED LOAN AGREEMENT

THIS AMENDMENT TO AMENDED AND RESATED LOAN AGREEMENT is made as of August 1, 2006, by and between BIOPORT CORPORATION, a Michigan corporation, of Lansing, Michigan ("Borrower"), and FIFTH THIRD BANK, a Michigan banking corporation, which has an office in East Lansing, Michigan ("Lender").

Borrower and Lender are parties to an Amended and Restated Loan Agreement dated as of July 29, 2005, under which Lender agreed to extend to Borrower revolving credit loans of up to \$10 million in the aggregate at any time outstanding ("Loan Agreement").

Lender and Borrower agree to amend the Loan Agreement and, among other things, add a financial ratio provided under a prior agreement as follows:

- 1. Each capitalized term that this Amendment uses but does not define has the meaning that the Loan Agreement gives it.
- 2. Borrower adopts and restates all of the warranties and representations set forth in the Loan Agreement and the other Loan Documents, other than the warranties and representations contained in Sections 2.5, 2.12 and 2.16 of the Loan Agreement, as fully as though Borrower had made them on the date of this Amendment.
  - 3. Lender shall discharge the two mortgages referred to in Section 5.3 of the Loan Agreement.
  - 4. Section 1 of the Loan Agreement shall be and is amended, effective immediately, by adding the following definitions:
    - "'Liabilities' means all liabilities that GAAP requires to be classified as liabilities on a balance sheet of Borrower."
    - "Stockholders' Equity' means, at any time, the sum of the following accounts set forth in a balance sheet of Borrower, prepared in accordance with GAAP: (1) the par or stated value of all outstanding capital stock, (2) capital surplus and (3) retained earnings."
    - "Tangible Net Worth' means, at any time, Stockholders' Equity, less the sum of (1) goodwill, including any amounts, however designated on a balance sheet of Borrower, representing the excess of the purchase price that Borrower paid for assets or stock acquired over the value assigned to the stock or assets on Borrower's books, (2) patents, trademarks, trade names and copyrights, (3) treasury stock, (4) loans and advances to shareholders, directors, officers or employees, (5) prepaid expenses and, (6) other intangible assets."
  - 5. Section 3.6 of the Loan Agreement shall be and is amended, effective immediately, to read as follows:

- "3.6 Unless it is sooner terminated or Lender extends it in writing, Lender's obligation to make or to renew Revolving Credit Loans shall expire on October 1, 2006. If Lender extends it, then Lender's obligation to make or renew Revolving Credit Loans shall expire on the date stated in the extension. If Lender's obligation to make or renew Revolving Credit Loans expires, then the aggregate unpaid principal balance of all outstanding Revolving Credit Loans, together with all accrued interest on them, shall be due and payable in full on the expiration date."
- 6. Section 6.4 of the Loan Agreement shall be and is amended, effective immediately, to read as follows:
  - "6.4 Furnish to Lender within 45 days after the end of each fiscal quarter of Borrower, beginning with the quarter ended June 30, 2006, an unaudited financial report, the accuracy of which is certified to by the President or chief financial officer of Borrower, prepared in accordance with GAAP, containing Borrower's balance sheet as of the end of the period and its income statement showing the results of its operations for the portion of its fiscal year then elapsed."
- 7. The Loan Agreement is amended, effective immediately, by adding a new Section 6.12 reading as follows:
  - "6.12 Maintain a ratio of total Liabilities to Tangible Net Worth of not more than 2.5 to 1.0."
- 8. Except as expressly amended by this Amendment, all of the provisions of the Loan Agreement are ratified and confirmed.

Borrower and Lender have executed this Amendment as of the date stated in the first paragraph.

## BIOPORT CORPORATION

By /s/ Robert G. Kramer

Its President and CEO

And by Patricia D. Saam

Its Controller

FIFTH THIRD BANK

By /s/ Mark Conn

Its Vice President

### LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (this "Agreement") dated this 14th day of October, 2004, by and among ADVANCED BIOSOLUTIONS, INC., a Maryland corporation, which maintains its chief executive office at c/o Antex Biologics Inc., 300 Professional Drive, Suite 100, Gaithersburg, Maryland 20879 (the "Borrower" which term shall mean the "Debtor" as defined under the Maryland Uniform Commercial Code), ANTEX BIOLOGICS INC., a Delaware corporation, BIOPORT CORPORATION, a Michigan corporation and EMERGENT BIOSOLUTIONS INC., a Delaware corporation (individually or collectively, the "Guarantor") and MERCANTILE POTOMAC BANK (the "Bank" which term shall mean the "Secured Party" as defined in the Maryland Uniform Commercial Code).

WHEREAS, the Borrower has applied to the Bank for a term loan of SEVEN MILLION and No/100 Dollars (\$7,000,000.00) (the "Term Loan") and the issuance of a letter of credit not exceeding ONE MILLION TWO HUNDRED FIFTY THOUSAND and No/100 Dollars (\$1,250,000.00) (the "Letter of Credit") (the Term Loan and the Letter of Credit are collectively referred to herein as the "Facilities"); and

WHEREAS, the Facilities will be of benefit to the Guarantor and the Guarantor desires to induce the Bank to make the Term Loan and issue the Letter of Credit by guaranteeing the payment of the Term Loan and the reimbursement of the payment under the Letter of Credit; and

WHEREAS, the Bank is willing to make the Term Loan to the Borrower and issue the Letter of Credit upon the terms and subject to the conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the foregoing and of the agreements, covenants and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

### SECTION 1. DEFINITIONS

As used herein, the following terms, when initial capital letters are used, shall have the respective meanings set forth below. In addition, all terms defined in the Maryland Uniform Commercial Code (including revised Article 9 thereof) shall have the meanings given therein unless otherwise defined herein.

1.01 <u>Defined Terms</u>. As used in this Agreement, the following terms shall have the following meanings, unless the context otherwise requires:

"Affiliate" shall mean (a) any entity in which the Borrower legally or beneficially owns or holds, directly or indirectly, any capital stock, membership interest or other equity interest; (b) any person or entity that is a partner in or member of the Borrower or a partnership or limited liability company in which the Borrower is a partner; (c) any person that is a director, officer, employee, member, stockholder (legally or beneficially) or other affiliate of any of the foregoing or of the

Borrower, and (d) any person or entity that directly or indirectly controls, is under the control of, or is under common control with, the Borrower, including, without limitation, any person or entity that directly or indirectly has the right or power to direct the management or policies of the Borrower and any person or entity whose management or policies the Borrower directly or indirectly has the right or power to direct.

"Certificate of Deposit" shall mean that certain certificate of deposit number 5018577 dated October 14, 2004 issued in the name of the Borrower by the Bank, and all replacements, modifications, rollovers, renewals and restatements thereof.

"Collateral" shall mean the Property and the Certificate of Deposit.

"DBED Loan" shall mean that certain loan in the amount of Two Million Five Hundred Thousand and No/100 Dollars (\$2,500,000.00) from the Maryland Department of Business and Economic Development to the Borrower, and any refinancing, replacement, or amendment thereof.

"DBED Loan Documents" shall mean any and all loan documents evidencing and securing the DBED Loan executed and delivered by the Borrower and the Guarantor to the Maryland Department of Business and Economic Development.

"Deed of Trust" shall mean the Purchase Money Deed of Trust, Assignment of Rents and Leases and Security Agreement, in form and content satisfactory to the Bank, made and executed by the Borrower for the benefit of the Bank, as amended, supplemented, restated or modified from time to time, to secure the Term Note, which Deed of Trust, when recorded, shall create a first lien on the Property.

"Environmental Laws" shall mean all federal, State and local laws, whether now or hereafter enacted, and as amended from time to time, relating to pollution or protection of the environment and the handling of Hazardous Materials, including, without limitation, laws relating to emissions, discharges, releases or threatened releases of Hazardous Materials into the environment (including, without limitation, ambient air, surface water, ground water or land), or otherwise relating to the manufacture, generation, production, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, and any and all regulations, codes, plans, orders, decrees, judgments, injunctions, notices or demand letters issued, entered, promulgated or approved thereunder

"ERISA" shall mean the Employee Retirement Income Security Act of 1974, as amended from time to time, and any successor legislation, and all regulations, codes, orders, decrees, judgments, injunctions, notices or demand letters issued, entered, promulgated or approved thereunder.

"Event of Default" shall mean any of the events specified in Section 10 hereof, provided that any requirement for the giving of notice, the lapse of time, or both have been satisfied.

"Fifth Third Loan" shall mean that certain (1) Ten Million and No/100 Dollars (\$10,000,000.00) loan to BioPort Corporation from Fifth Third Bank dated October 8, 2004 and any refinancing replacement, amendment or enlargement thereof, and (2) Two Million Four Hundred Thousand No/100 Dollars (\$2,400,000.00) term loan to BioPort Corporation from Fifth Third Bank dated August 10, 2004 and any refinancing replacement, amendment or enlargement thereof.

"Fifth Third Loan Documents" shall mean any and all loan documents evidencing and securing the Fifth Third Loan.

"GAAP" shall mean generally accepted accounting principles.

"Guaranty" shall mean the Guaranty, in form and content satisfactory to the Bank, made and executed by each Guarantor for the benefit of the Bank, as amended, supplemented, restated or modified from time to time.

"Hazardous Materials" shall mean any (i) hazardous, regulated and/or toxic chemicals, materials, substances or wastes occurring in the air, water, soil or ground water or noise in, on, over or under the Property or the improvements thereon, as defined by the Comprehensive Environmental Response, Compensation, and Liability Act (Superfund or CERCLA), and the Superfund Amendments and the Reauthorization Act of 1986 (SARA), 42 U.S.C. § 9601 et seq., the Emergency Planning and Community Right-to-Know Act, 42 U.S.C. § 11001 et seq., the Resource Conservation and Recovery Act (the Solid Waste Disposal Act or RCRA), 42 U.S.C. § 6901 et seq., the Federal Water Pollution Control Act, (CWA), 33 U.S.C. § 1251 et seq., the Clean Air Act (CAA), 42 U.S.C. § 7401 et seq., the Hazardous Materials Transportation Act, 49 U.S.C. § 1801 et seq., the Federal Water Pollution Control Act, 33 U.S.C. § 1251 et seq., the Safe Drinking Water Act, 42 U.S.C. § 300f et seq. and the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C.A. § 136 et seq., the Uranium Mill Tailings Radiation Control Act, 42 U.S.C. § 7901 et seq., or comparable state statutes, as each such statute may be amended from time to time, and/or as defined in regulations promulgated thereunder; (ii) oil, petroleum products, and their by-products; (iii) any substance, the presence of which is prohibited or controlled by any other applicable federal or state or local laws, regulations, statutes or ordinances now in force or hereafter enacted relating to waste disposal or environmental protection with respect to hazardous, toxic or other substances generated, produced, leaked, released, spilled or disposed of at or from the Property, (iv) any other substance which by law requires special handling in its collection, storage, treatment or disposal including, but not limited to, asbestos or asbestos-containing material in any form that could be friable, polychlorinated biphenyls (PCBs), urea formaldehyde foam insulation and lead-based paints, but not including small qu

"hazardous material," hazardous waste," "toxic substance." "toxic pollutant," "contaminant," or "pollutant" within the meaning of any Environmental Laws. "Microbial Matter" shall mean the presence of fungi or bacterial matter which reproduces through the release of spores or the splitting of cells, including, but not limited to, mold, mildew and viruses, whether or not such Microbial Matter is living.

"Letter of Credit" shall mean the letter of credit in form and substance satisfactory to the Bank, issued by the Bank for the benefit of the Maryland Department of Business and Economic Development at the request of the Borrower in the amount of One Million Two Hundred Fifty Thousand and No/100 Dollars (\$1,250,000.00).

"Lien" shall mean any mortgage, pledge, deed of trust, assignment, security interest, encumbrance, hypothecation, lien, or charge of any kind (including any conditional sale or other title retention agreement, any financing lease having substantially the same economic effect as any of the foregoing, and the filing of, or agreement to give, any financing statement under the Uniform Commercial Code or comparable law of any jurisdiction).

"Loan Documents" shall mean the Note, this Agreement, the Guaranty, the Deed of Trust, the LOC Deed of Trust, the Pledge Agreement, or any other agreement or document referred to herein or now or hereafter delivered in connection with the transactions contemplated hereby, together with any and all revisions, amendments, restatements and modifications to, replacements of and substitutions for, any of the foregoing.

"LOC Deed of Trust" shall mean the Deed of Trust, Assignment of Rents of Leases and Security Agreement in form and content satisfactory to the Bank, made and executed by the Borrower or to be executed by the Borrower subsequent to the date hereto, for the benefit of the Bank, as amended, supplemented, restated or modified from time to time, which Deed of Trust secures the LOC Note.

"LOC Note" shall mean the promissory note of even date herewith executed by the Borrower and consented to by the Guarantor to evidence the obligation of the Borrower to reimburse the Bank for the payment under the Letter of Credit, as amended, supplemented, restated, replaced or modified from time to time.

"Note" shall mean the Term Note and the LOC Note, as amended, supplemented, restated, replaced or modified from time to time.

"Park" shall mean the Dudrow Business Park, Frederick, Maryland.

"Permitted Liens" shall mean: (a) Liens, if any, for taxes, front foot benefit charges, assessments and other charges enumerated in Section 1.03(a) of the Deed of Trust, not yet due or payable; (b) applicable building and zoning laws and regulations; (c) any mechanic's, artisan's, materialman's, landlord's, carrier's or other like Lien arising in the ordinary course of business with respect to obligations which are not due; (d) any and all municipal and public utility easements of record; (e) any Lien arising out of a judgment, order or award with respect to which the Borrower

shall in good faith be prosecuting diligently an appeal or proceeding for review, provided appropriate reserves therefor are established by the Borrower in accordance with GAAP and provided such Lien is subordinate to any security interest of the Bank in the property encumbered by such Lien; (f) the DBED Loan; (g) any deposit of funds made in the ordinary course of business to secure obligations of the Borrower under worker's compensation laws, unemployment insurance laws or similar legislation, to secure public or statutory obligations of the Borrower, to secure surety, appeal or customs bonds in proceedings to which the Borrower is a party, or to secure the Borrower's performance in connection with bids, tenders, contracts (other than contracts for the payment of money), leases or subleases made by the Borrower in the ordinary course of business; (h) any Lien set forth in the Commitment for Title Insurance No. CTCI-04107 issued by Chicago Title Insurance Company, as updated to the date of this Agreement; (i) any lease, sublease or agreement for occupancy or use for any part of the Property, so long as those leases, subleases or agreements are subordinate to the Deed of Trust and the LOC Deed of Trust and have been approved by the Bank pursuant to Section 1.19(g) of the Deed of Trust and LOC Deed of Trust; (j) any routine utility, access or similar easements granted in connection with the use of the Property; (k) any easement granted to Frederick County, Maryland; (l) a Lien in favor of the Bank; and (m) a Lien, (i) which is subordinate to the lien of this Deed of Trust and the LOC Deed of Trust, (ii) is required in connection with the purchase, improvement, renovation, conversion or maintenance of the Property and the entire proceeds of the refinancing are used for such purposes, (iii) provides for notice to the Bank of an event of default under such financing, and (iv) is approved in writing by the Bank, which approval shall not be unreasonably withheld, delayed or conditioned.

"Pledge Agreement" shall mean the Pledge Agreement, in form and content satisfactory to the Bank, made and executed by the Borrower for the benefit of the Bank, as amended, supplemented, restated or modified from time to time, pursuant to which the Borrower grants to the Bank a first lien security interest in the Certificate of Deposit.

"Property" shall mean that certain real property and improvements thereof owned by the Borrower and located at 7114 Geoffrey Way, Frederick, Building 1, Unit 1, Maryland 21703, as more particularly described in the Deed of Trust.

"Term Note" shall mean the promissory note of even date herewith executed by the Borrower and consented to by the Guarantor to evidence the Term Loan, as amended, supplemented, restated, replaced or modified from time to time.

"Secured Obligations" shall have the meaning ascribed to such term in Section 4 hereof.

"Subsidiary" shall mean any corporation at least a majority of the outstanding voting stock of which, now or in the future, is owned or controlled by the Borrower, directly or indirectly, or through one or more intermediaries.

1.02 Accounting Terms. As used in this Agreement and any of the other Loan Documents, as well as in any certificate, report or other document made or delivered pursuant to or

in connection with this Agreement, accounting terms not defined herein and accounting terms only partly defined herein shall have the respective meanings given to them under GAAP.

1.03 <u>Use of Defined Terms</u>. All terms defined in this Agreement shall have the defined meanings when used in any of the other Loan Documents or in any certificate, report or other document made or delivered pursuant to or in connection with this Agreement, unless the context shall require otherwise.

### SECTION 2. LOAN AND REPAYMENT

- 2.01 <u>Term Loan</u>. Subject to the terms and conditions set forth herein, the Bank agrees to lend to the Borrower, in a single advance to be made on or about the date hereof, the sum of Seven Million and No/100 Dollars (\$7,000,000.00).
- 2.03 Note. The Borrower's indebtedness to the Bank for the Term Loan together with interest accrued thereon, shall be evidenced by the Term Note and the Borrower's obligation to reimburse the Bank for the payment under the Letter of Credit, together with interest accrued thereon, shall be evidenced by the LOC Note.
- 2.04 Repayment of Term Loan; Letter of Credit. The Borrower shall repay the Term Loan and reimburse the Bank for the payment of the Letter of Credit, along with interest accrued thereon, in accordance with the terms of the Note.
- 2.05 <u>Issuance of Letter of Credit</u>. Subject to the terms and conditions of this Agreement, the Bank will issue a Letter of Credit to the Maryland Department of Business and Economic Development in the amount of One Million Two Hundred Fifty Thousand and No/100 Dollars (\$1,250,000.00) as requested by the Borrower upon the execution by the Borrower and delivery of an application for Letter of Credit, indemnity agreement and promissory note in the form acceptable to the Bank.
- 2.06 Fees. The Borrower shall pay to the Bank a fee equal to one percent (1.0%) of the face amount of the Letter of Credit upon the issuance of the Letter of Credit, and pay to the Bank annual fees equal to one percent (1.0%) of the face amount of the Letter of Credit (the "Annual Fee") which fee shall be due and payable on the date on which the Letter of Credit is reissued or renewed. In the event the Letter of Credit is terminated before its expiration date, the Annual Fee shall be prorated based upon such portion of the time from the termination date until the expiration date. As of the date hereof, the Borrower has paid the commitment fee of Seventy Thousand and No/100 Dollars (\$70,000.00) for the Term Loan.

# SECTION 3. CONDITIONS PRECEDENT.

The Bank's obligations under the Loan Documents are subject (a) to the accuracy, as of the date hereof and as of the date that any future advance of money is made to or requested by the Borrower under the Loan Documents, of the representations and warranties contained herein and in the Loan Documents and is further subject to (b) the satisfaction of the Bank, on or before the date of each advance of money under the Loan Documents, of the following conditions precedent, except to the extent that they may be waived or deemed satisfied by the Bank:

- 3.01 Advance. The advance under the Term Note and the issuance of the Letter of Credit shall be conditioned upon:
- 3.01 (a) Delivery of Documents. The Borrower shall have delivered to the Bank the following:
  - (i) a certificate of good standing for the Borrower certified by the Secretary of State, or other appropriate governmental authority, of the state of incorporation of the Borrower;
- (ii) a copy, certified as of the date hereof by the Secretary or an Assistant Secretary of the Borrower, of the resolutions of its Board of Directors authorizing (a) the execution, delivery and performance of the Loan Documents to which the Borrower is a party, (b) the borrowings by the Borrower hereunder, and (c) the granting of the liens contemplated by the Loan Documents to which the Borrower is a party;
- (iii) a certificate from the Borrower, signed by a duly authorized officer of the Borrower, dated as of the date hereof, as to the incumbency, authority and signatures of the officers of the Borrower authorized to sign on behalf of the Borrower the Loan Documents to which the Borrower is a party;
- (iv) a certificate of good standing for each Guarantor certified by the Secretary of State, or other appropriate governmental authority, of the state of incorporation of each Guarantor and such Guarantor's principal place of business;
- (v) a copy, certified as of the date hereof by the Secretary or an Assistant Secretary of each Guarantor, of the resolutions of its Board of Directors authorizing (a) the execution, delivery and performance of the Loan Documents to which each Guarantor is a party, and (b) the guaranties by the Guarantor hereunder;
- (vi) a certificate from each Guarantor, signed by a duly authorized officer of each Guarantor, dated as of the date hereof, as to the incumbency, authority and signatures of the officers of the Guarantor authorized to sign on behalf of the Guarantor the Loan Documents to which the Guarantor is a party;

- (vii) the original Agreement executed by the Borrower and the Guarantor;
- (viii) the original Note executed by the Borrower and consented to by the Guarantor;
- (ix) the original Guaranty executed by each Guarantor;
- (x) the original Pledge Agreement executed by the Borrower;
- (xi) the original Deed of Trust executed by the Borrower;
- (xii) a written opinion of counsel to the Borrower and the Guarantor dated as of the date of this Agreement and addressed to the Bank, which opinion must be, in form and content, satisfactory to the Bank;
- (xiii) such financing statements or other documents which the Bank may request in connection with the Collateral; evidence satisfactory to the Bank that all filings under the Uniform Commercial Code or with any federal or state agency or department that the Bank or its counsel deems necessary or desirable in connection with the creation and perfection of the security interest granted hereunder have been effected; and such other evidence as the Bank may require that confirms that, as a result of such filings, the Bank's security interest in the Collateral is consistent with the representation contained in this Agreement relating thereto;
  - (xiv) the insurance policies evidencing the insurance coverages required by the Deed of Trust and this Agreement, together with proof of payment of the premiums for such insurance;
  - (xv) all fees payable to the Bank, including legal fees, commitment fees, administration fees, etc.;
- (xvi) such executed agreements, notices or other documents in form and substance satisfactory to the Bank in connection with the Bank's control of any rights in any deposit accounts, electronic chattel paper, investment property or letter of credit.
- (xvii) such other loan documents, agreements, consents, approvals, certificates, resolutions, instruments, opinions and other documents and materials as listed on any closing checklist or as the Bank may reasonably request.
- 3.01 (b) Compliance. The Borrower and the Guarantor shall have complied and shall then be in compliance in all material respects with all material terms, covenants and conditions of this Agreement
  - 3.01 (c) No Default. There shall exist no Event of Default (as hereinafter defined) and no event which, upon notice or lapse of time or both, would constitute an Event of Default.

- 3.01 (d) Representations True. The representations and warranties contained in this Agreement shall be true and correct in all material respects.
- 3.01 (e) No Material Adverse Change. There shall be no materially adverse change in the total financial condition of the Borrower or the Guarantor, taken as a whole, from the financial condition of the Borrower or the Guarantor, as the case may be, as set forth in the financial statements furnished to the Bank pursuant to this Agreement or from the financial condition of the Borrower or any Guarantor previously disclosed to the Bank in any other manner.
  - 3.02 (f) Closing of DBED Loan. The Borrower shall have executed and delivered the DBED Loan Documents and funding under the DBED Loan has occurred.

## SECTION 4. SECURITY INTEREST

In order to secure the payment of the Note, the performance of all of the Borrower's obligations under the Note, this Agreement, and the other Loan Documents, as such Loan Documents may be amended, restated, substituted, renewed, extended, supplemented or modified from time to time, the payment of all other existing and future non-consumer liabilities, of whatever type whether or not contemplated by the parties hereto, payable by the Borrower to the Bank, and liability for overdrafts of the Borrower and advances by the Bank to the Borrower in excess of the amount of the Loan ("administrative overlines") and as indorser, guarantor or surety plus all reasonable costs, expenses, advances and reasonable attorneys' fees which may be made or incurred by the Bank in the collection or the enforcement of any of the Bank's rights and remedies hereunder (collectively, the "Secured Obligations"), the Borrower hereby assigns to the Bank, and grants to the Bank a first lien security interest in the Collateral.

# SECTION 5. REPRESENTATIONS AND WARRANTIES

To induce the Bank to enter into this Agreement, the Borrower, as to itself, and each Guarantor, as to itself, represent, warrant and agree as of the date hereof, and continuing so long as any obligation of the Borrower and/or the Guarantor exists to the Bank under the Loan Documents as follows:

5.01 <u>Corporate Status; Subsidiaries</u>. The Borrower is a corporation, duly organized and validly existing in the jurisdiction in which it is organized, has the power and authority to own its properties and to carry on its business as currently conducted, and is duly qualified to do business and is in good standing in each jurisdiction in which the transaction of its business makes such qualification necessary. The Borrower has no subsidiaries other than those previously disclosed to the Bank in writing.

- 5.02 Mergers and Consolidations. Except as previously disclosed to the Bank in writing, no entity has merged into the Borrower or been consolidated with the Borrower, and the business of the Borrower has not ever been conducted as a partnership or proprietorship in the past.
- 5.03 <u>Purchase of Assets</u>. Except as previously disclosed to the Bank in writing, no entity has sold substantially all of its assets to the Borrower or sold assets to the Borrower outside the ordinary course of such seller's business or in a transaction subject to the bulk transfer laws at any time in the past.
- 5.04 Borrower's and Guarantor's Authority and Capacity. The Borrower and the Guarantor have the full legal right, authority and capacity to execute, deliver and perform the Loan Documents and to incur the obligations provided for therein. The execution, delivery and performance of the Loan Documents and the obligations provided for therein have been duly and validly authorized by all necessary corporate actions on the part of the Borrower (all of which actions are in full force and effect), and do not and will not require any consent or approval of the stockholders of the Borrower which has not been obtained.
- 5.05 <u>Binding Agreement of Borrower and the Guarantor</u>. The Loan Documents are the valid and legally binding obligations and agreements of the Borrower and of the Guarantor, enforceable in accordance with their respective terms.
- 5.06 No Conflicting Law and Agreements. The execution, delivery and performance by the Borrower of the Loan Documents will not violate any provision of law, any order of any court or government instrumentality or agency, any indenture, any loan or credit agreement or any other material agreement, commitment, lease, contract, deed of trust, mortgage, note or other instrument binding on the Borrower or affecting its property, or be in conflict with, result in a breach of, in any material respect, or constitute (with due notice, lapse of time, or both) a default (as defined therein) under any such indenture, agreement, commitment, lease, contract, deed of trust, mortgage, note or other instrument, or result in the creation or imposition of any Lien of any nature whatsoever upon any of the property or assets of the Borrower, or result in or require the acceleration of any indebtedness of the Borrower.
- 5.07 Compliance with Laws. The Borrower is in compliance in all material respects with any federal, State and local laws, rules and regulations including, but not limited to Environmental Laws and the Fair Labor Standards Act. The Borrower and the Guarantor maintain all of the necessary permits, licenses and certifications necessary for the operation of the their businesses. All of the foregoing are in full force and effect and not in known conflict with the rights of others. The Borrower is not in breach of or default (as defined therein) under the provisions of any of the foregoing, nor is there any event, fact, condition or circumstance which, with notice or passage of time or both, would constitute or result in a conflict, breach, default or event of default (as defined therein) under, any of the foregoing which, if not remedied within any applicable grace or cure period could reasonably be expected to have a material adverse effect on the Borrower.

- 5.08 Taxes. The Borrower has filed or caused to be filed all Federal, state and local income, excise, property and other tax returns which are required to be filed. All such returns are true and correct in all material respects and the Borrower has paid or caused to be paid all taxes, assessments, interest and penalties as shown on such returns or on any assessment received by them, to the extent that such taxes have become due, including, but not limited to, all F.I.C.A. payments and withholding taxes. The amounts reserved as a liability for income and other taxes payable in the most recent financial statements of the Borrower provided to the Bank pursuant to this Agreement are sufficient for the payment of all unpaid Federal, state, county and local income, excise, property and other taxes, whether or not disputed, of the Borrower and the Guarantor accrued for or applicable to the period and on the dates of such financial statements and all years and periods prior thereto and for which the Borrower, any existing Subsidiary or the Guarantor may be liable in its or their own right or as a transferee of the assets of, or as successor to, any other person or entity.
- 5.09 <u>Financial Condition</u>. The financial statements of the Borrower and the Guarantor and other related information previously submitted to the Bank are true, complete and correct in all material respects, fairly represent the financial condition of the Borrower and the Guarantor and the result of their respective operations and transactions as of the dates and for the periods of such statements and have been prepared in accordance with GAAP applied on a consistent basis throughout the period involved. There are no liabilities, direct or indirect, fixed or contingent, matured or unmatured, known to the Borrower or the Guarantor which are not reflected therein. There has been no material adverse change in the business, operations, prospects, assets, properties or condition (financial or otherwise) of the Borrower or the Guarantor, taken as a whole since the date of said financial statements.
- 5.10 <u>Title To Properties</u>. The Borrower has good, valid, insurable (in the case of real property) and marketable title to all of their properties and assets including the Collateral (whether real or personal, tangible) reflected on the financial statements referred to in this Agreement, except for such properties and assets as have been disposed of since the date of such financial statements as no longer used or useful in the conduct of their business or as have been disposed of in the ordinary course of business, and all such properties and assets are free and clear of all Liens except for Permitted Liens. None of the real property included in such properties of the Borrower is subject to any covenant or other restriction preventing or limiting the right of the record owner to convey or use it, all such real property has adequate rights of ingress and egress, and all such real property has direct and unobstructed access to electric, gas, water, sewer and telephone lines, all of which are adequate for the uses to which such property is currently devoted.
- 5.11 <u>Litigation</u>. Except as previously disclosed to the Bank in writing, there are no actions, claims, suits or proceedings pending, or, to the knowledge of the Borrower, threatened or reasonably anticipated against or affecting the Borrower at law or in equity including, without limitation, under ERISA or any Environmental Laws or before or by any governmental instrumentality or agency (domestic or foreign), commission, board, bureau, arbitrator or arbitration panel, and there is no probable judgment, liability or award which may reasonably be expected to result in any material adverse change in the business, operations, prospects, properties or assets or condition, financial or otherwise, of the Borrower or the Guarantor. The Borrower is

not in default with respect to any judgment, order, writ, injunction, decree, rule, award or regulation of any court, governmental instrumentality or agency, commission, board, bureau, or arbitrator or arbitration panel.

- 5.12 No Other Defaults. Except as previously disclosed to the Bank in writing, the Borrower is not in default under any contract, agreement, commitment or other instrument which default would have a material adverse effect on the business, properties or condition, financial or otherwise, of the Borrower, or in the performance of any covenants or conditions respecting any of their indebtedness. No holder of any indebtedness of the Borrower has given notice of any asserted default thereunder. No liquidation or dissolution of the Borrower or the Guarantor and no receivership, insolvency, bankruptcy, reorganization or other similar proceeding relative to the Borrower or the Guarantor or their properties is pending or, to the knowledge of the Borrower or the Guarantor, is threatened against them or any of them.
- 5.13 ERISA. (a) The pension, profit sharing, savings, stock bonus and other deferred compensation plans established and maintained by the Borrower, the Guarantor and any Commonly Controlled Entity (as defined below) which are subject to the requirements of ERISA, if any, were stated in their inception or have, since ERISA became effective with respect to such plans, been amended and restated in a manner designed to qualify under the applicable requirements of ERISA and the Internal Revenue Service Code of 1986, as amended (the "Code"); and subsequent to such statement, or restatement, those plans and their related trusts have received favorable determinations from the Internal Revenue Service holding that such plans and trusts so qualify; (b) to the knowledge of the Borrower and the Guarantor, there is no current matter which would materially adversely affect the qualified tax-exempt status of any pension, profit-sharing, savings, stock bonus or other deferred compensation plan and their related trusts of either of the Borrower or any Commonly Controlled Entity under the Code; (c) neither the Borrower, the Guarantor, nor any Commonly Controlled Entity has incurred in connection with any such plan any "accumulated funding deficiency" (as defined in Section 302 of ERISA or Section 412(a) of the Code) whether or not waived; (d) there has been no "prohibited transaction" (within the meaning of Section 4975 of the Code or Section 406 of ERISA) involving any such plan of the Borrower, the Guarantor, or any Commonly Controlled Entity; (e) no "reportable event," as defined by Title IV of ERISA, has occurred with respect to any plan subject to the minimum funding requirements of Section 412 of the Code maintained for employees of the Borrower or any Commonly Controlled Entity; (f) no "multi-employer plan" (as defined in ERISA) to which either of the Borrower, the Guarantor or any Commonly Controlled Entity has an obligation to contribute, has "terminated," as that term is defined in ERISA; (g) neither the Borrower, the Guarantor, nor any Commonly Controlled Entity has withdrawn, in a "complete withdrawal" (as defined in ERISA), from any "multi-employer plan" to which either the Borrower or such Commonly Controlled Entity had an obligation to contribute; (h) neither the Borrower, the Guarantor nor any Commonly Controlled Entity has withdrawn, in a "partial withdrawal" (as defined in ERISA), from any "multi-employer plan" to which either the Borrower, the Guarantor or such Commonly Controlled Entity had an obligation to contribute; and (i) no "multi-employer plan" to which either the Borrower, the Guarantor or any Commonly Controlled Entity had an obligation to contribute is in "reorganization" (as defined in ERISA and the Code) nor has notice been received from the administrator of any "multi-employer plan" to which either the Borrower.

the Guarantor, or any Commonly Controlled Entity has an obligation to contribute that any such plan will be placed in "reorganization." For purposes of this Section, the term "Commonly Controlled Entity" means any corporation which is a member of a controlled group of corporations (as defined for purposes of Section 414(b) of the Code) of which the Borrower is a member and any trade or business (whether or not incorporated) which is under "common control" (as defined for purposes of Section 414(c) of the Code) with the Borrower.

- 5.14 Other Security Interests. The Borrower is the owner of the Collateral, free from any Lien except a Permitted Lien.
- 5.15 <u>Franchises, Patents, Etc.</u> Except as previously disclosed to the Bank in writing, no franchises, licenses, trademarks, trade names, copyrights or patents are owned or licensed by, or registered in the name of, or have been applied for by, the Borrower, and no such rights or agreements are necessary to the conduct of the present business of the Borrower. The Borrower has no knowledge of and has not received any notice to the effect that any product it manufactures or sells, or any service it renders, or any process, method, know-how, trade secret, part or material it employs in the manufacture of any product it makes or sells or any service it renders, or the marketing or use by it or another of any such product or service, may infringe any trademark, trade name, copyright, patent, trade secret or legally protectable right of any other person or entity.
- 5.16 Approvals. No approval, consent or other action by any governmental instrumentality or agency or any other person or entity, which approval, consent, or other action has not been obtained or taken or which does not remain in effect as of the date hereof, is or will be necessary to permit the valid execution, delivery and performance by the Borrower and the Guarantor of the Loan Documents.
- 5.17 <u>Tradenames; Name Changes</u>. The Borrower utilizes no tradenames in the conduct of its business, except as stated above or previously disclosed to the Bank in writing and has not changed its name.
- 5.18 <u>Labor Relations</u>. There are no strikes, work stoppages, material grievance proceedings or other material controversies pending or, to the best of Borrower's knowledge, threatened between the Borrower and any employees engaged in the business of the Borrower or any union or other collective bargaining unit representing such employees. The Borrower has complied and is in compliance with all laws relating to the employment of labor, including, without limitation, provisions relating to wages, hours, collective bargaining, occupational safety and health, equal employment opportunities and the withholding of income taxes and social security contributions, the non-compliance with which might materially adversely affect its business, operations, prospects, assets, properties or condition (financial or otherwise).

#### SECTION 6. AFFIRMATIVE COVENANTS

The Borrower, as to itself and each Guarantor, as to itself, covenant and agree that, so long as any of the Loan Documents shall remain in effect, or unless the Bank shall otherwise consent in writing, they will:

- 6.01 Payment of Loan. Comply with the terms and conditions for repayment of the Loan in accordance with the terms of the Note and Guaranty.
- 6.02 Financial Statements. Furnish to the Bank:
- (a) as soon as available but in no event more than one hundred twenty (120) days after the last day of each fiscal year of the Borrower and the Guarantor, consolidated financial statements of the Borrower and the Guarantor containing a balance sheet, a statement of income and expenses and a statement of changes in financial condition as of the close of such period, prepared in accordance with GAAP applied on a basis consistent with prior periods, showing the financial condition of the Borrower and the Guarantor at the close of such year in form reasonably satisfactory to the Bank and prepared and audited by Ernst & Young, or another independent certified public accountant reasonably satisfactory to the Bank.
- (b) as soon as available but in no event more than thirty (30) days after the last day of each quarter of each fiscal year of the Borrower and the Guarantor, consolidated financial statements of the Borrower and the Guarantor containing a balance sheet, a statement of income and expenses and a statement of changes in financial condition as of the close of such period, prepared in accordance with GAAP applied on a basis consistent with prior periods, showing the financial condition of the Borrower and the Guarantor at the close of such period, in form reasonably satisfactory to the Bank
- (c) promptly, and from time to time, such other information regarding the operation, business, affairs and financial condition of the Borrower and the Guarantor as the Bank may request, including, but not limited to interim financial statements including an income statement, balance sheet, aging of accounts receivable and/or accounts payable.
- (d) within thirty (30) days after the last day of each of the quarters of each fiscal year of the Borrower, a certificate of the chief financial officer of the Borrower (a) certifying that to the best of his knowledge no Event of Default has occurred and is continuing or, if an Event of Default has occurred and is continuing, a statement as to the nature thereof and the action which is proposed to be taken with respect thereto and (b) with computation demonstrating compliance with the covenants contained in Sections 6.18 and 6.19.
- (e) Borrower and Guarantor will use commercially reasonable efforts to cause its independent certified public accountant who audited its financial statements to provide simultaneously with the delivery of the annual financial statements a certificate acceptable to the Bank in its reasonable discretion to the effect that, in making the examination necessary for the

audit of such statements, they have obtained no knowledge of any condition or event which constitutes a failure to comply with the covenants contained in Sections 6.18 and 6.19 of this Agreement, or if such accountants shall have obtained knowledge of any such condition or event, specify in such certificate each such condition or event of which they have knowledge and the nature and status thereof

The financial statements of the Borrower and the Guarantor delivered to the Bank pursuant to this Section shall each be certified by the president or chief financial officer of the Borrower and the Guarantor as to the authenticity, accuracy of integrity of the representation contained therein and as having been prepared in accordance with GAAP applied on a basis consistent with prior periods. Any such financial information provided to the Bank shall be maintained by the Bank as confidential proprietary records.

- 6.03 Maintaining Records; Access to Properties and Inspections. Maintain financial records in accordance with GAAP consistently applied and permit any authorized representative designated by the Bank to visit and inspect any of the properties of the Borrower or the Guarantor (including, without limitation, their books of account, records, correspondence and other papers and to make extracts therefrom) and to discuss their affairs, finances and accounts (in the case of the Borrower) with their respective officers and their respective independent certified public accountants or other parties preparing statements for or on behalf of the Borrower or the Guarantor, subject to advance notice and subject to safety limitations and legal limits of general applicability.
- 6.04 <u>Place of Business</u>; <u>Location of Records</u>; <u>Notices</u>. Maintain their executive offices and their records at their current locations. The Bank shall be entitled to rely upon the foregoing unless it receives fourteen (14) days advance written notice of a change in such executive offices or in such office where such records are kept.
- 6.05 <u>Maintenance of Business</u>. (a) Maintain the corporate existence of the Borrower and the Guarantor in good standing and in existence in the State of its original formation; and (b) maintain and keep in full force and effect all licenses and permits necessary to the proper conduct of the Borrower's and the Guarantor's business.
- 6.06 Insurance. The Borrower shall maintain and pay for insurance covering such risks and in such amounts and with such insurance companies as shall be satisfactory to the Bank, and deliver the policies or certificates of all such insurance to the Bank with satisfactory lender's loss payable endorsements naming the Bank as loss payee; and maintain, with financially sound and reputable insurers, insurance with respect to their properties and business against such casualties and contingencies of such types (including personal injury and property damage liability insurance, automobile liability insurance, product liability insurance, biomedical insurance, worker's compensation insurance, business interruption insurance, employee dishonesty insurance, and directors' and officers' liability insurance) and in such amounts as is customary in the case of persons or entities in the same or similar business. Each policy or insurance required hereunder shall require the insurer to give not less than thirty (30) days prior written notice to the Bank in the event of cancellation of such policy for any reason whatsoever, and shall provide that the interest

of the Bank thereunder shall not be impaired or invalidated by any act or neglect of the Borrower or the owner of any of the insured property or by the occupation of the premises wherein such property is located for purposes more hazardous than are permitted by such policy. If the Borrower fails to provide and pay for such insurance, the Bank may, at the Borrower's expense, procure the same, but shall not be required to do so. The Borrower agrees to deliver to the Bank, promptly as rendered, true copies of any reports made to any insurance company.

- 6.07 Execution of Documents. At the request of the Bank, execute and deliver such financing statements, documents and instruments including, but not limited to, written acknowledgments from any third party holding all or any portion of the Collateral that it does so for the Bank's benefit and any control agreements with respect to any investment property, letter-of-credit rights, deposit accounts or electronic chattel paper, and perform all other acts as the Bank deems necessary or desirable, and pay, upon demand, all reasonable costs and expenses (including reasonable attorneys' fees and disbursements) incurred by the Bank in connection therewith.
- 6.08 Obligations and Taxes. Pay all indebtedness and obligations promptly and in accordance with their terms, and pay and discharge promptly all taxes, assessments and governmental charges or levies imposed upon them or in respect of their property and the Collateral, including, but not limited to, all F.I.C.A. payments and withholding taxes, before the same shall become in default, as well as all claims for labor, materials, and supplies or otherwise which, if unpaid, might become a Lien upon such properties or any part thereof; provided, however, that the Borrower and the Guarantor are not required hereby to pay and discharge or to cause to be paid and discharged any such indebtedness, obligation, tax, assessment, charge, levy or claim so long as the validity thereof shall be contested in good faith by appropriate proceedings and the Borrower and the Guarantor shall set aside on their books reserves which are in conformity with generally accepted accounting principles and which the Bank deems adequate with respect to any such tax, assessment, charge, levy or claim so contested.
- 6.09 <u>Litigation Notice</u>. Give the Bank prompt notice of any action, suit or proceeding at law or in equity or by or before any governmental instrumentality or agency (domestic or foreign), commission, board, bureau, arbitrator or arbitration panel which, if adversely determined, could materially impair or affect the right of the Borrower to carry on its business substantially as now conducted or could materially affect its respective business, operations, prospects, properties, assets (including the Collateral) or condition, financial or otherwise, in each case if in excess of \$500,000,00
- 6.10 Notification Relating to Hazardous Materials. Immediately advise the Bank in writing of (a) any and all enforcement, cleanup, remediation or removal, pursuant to any governmental or regulatory actions instituted, completed or threatened pursuant to any applicable federal, state, or local laws, ordinances or regulations relating to any Hazardous Materials affecting the Property or the business operations of the Borrower; and (b) all claims made or threatened by any third party against the Borrower relating to damages, contribution, cost recovery compensation, loss or injury resulting from any Hazardous Materials. The Borrower shall immediately notify the Bank of any remedial action taken by the Borrower with respect to the Property or the business operations of the Borrower.

- 6.11 Access Onto Property. Grant hereby an easement to enter and to authorize appropriate agents and contractors of the Bank to enter upon the Property for the purposes of conducting environmental investigations and audits (including taking physical samples) and such other action deemed necessary by the Bank to insure compliance by the Borrower with all Environmental Laws, subject to advance notice and subject to safety limitations and legal limits of general applicability. The Borrower acknowledges that no adequate remedy at law exists for a violation of the easement granted herein and agrees that the Bank is entitled to specific performance of its rights under this easement, subject to advance notice and subject to safety limitations and legal limits of general applicability. The easement granted herein shall continue until this Agreement is terminated.
- 6.12 Notice of Default; Adverse Change. Promptly notify the Bank of any condition or event that constitutes, or with the running of time, the giving of notice, or both, would constitute, an Event of Default, and promptly inform the Bank of any material adverse change in the financial condition of the Borrower or of the Guarantor.
- 6.13 Borrower's Claims. Promptly notify the Bank in writing of any action or omission of the Bank which the Borrower claims caused or may cause injury, loss or damage to the Borrower. Failure of the Borrower to so notify the Bank of such claim within one hundred eighty (180) days after the Borrower determines that it has such claim shall constitute a waiver of such claim.
- 6.14 <u>Defense of Collateral</u>. Defend the Collateral, and the Bank's first and prior security interest therein, against all claims and demands of all persons at any time claiming the same or any interest therein and pay, upon demand, all reasonable costs and expenses (including reasonable attorneys' fees and disbursements) incurred by the Bank in connection therewith.
- 6.15 <u>Use of Proceeds</u>. Use the proceeds of the Term Loan solely for the purchase of the Property or for any commercial purpose not violative of or inconsistent with any provision of this Agreement or the Loan Documents.
- 6.16 <u>Compliance with Laws</u>. Comply, in all material respects, with all federal, State and local laws, rules and regulations including, but not limited to Environmental Laws and the Fair Labor Standards Act applicable to its business, whether now in effect or hereafter enacted, and upon request of the Bank, the Borrower will provide the Bank with such evidence of compliance as the Bank may reasonably request.
- 6.17 <u>Hazardous Materials</u>. With respect to all property owned, subleased, operated or occupied by the Borrower, maintain and cause all operators, tenants, subtenants, licensees and occupants of all such property to maintain such property free of all Hazardous Materials, other than those Hazardous Materials used in compliance with all Environmental Laws and prevent all such property from being used for the manufacture, generation, production, processing, distribution, use, treatment, storage, disposal, transport or handling of any Hazardous Materials other than those Hazardous Materials used in compliance with all Environmental Laws; and deliver to the Bank

copies of all reports prepared by any governmental authority, any environmental auditor or engineer, or any other person, relating to or in connection with the Borrower's compliance with any Environmental Laws, unless the Borrower cannot obtain such reports or copies thereof.

- 6.18 Minimum Tangible Net Worth. Collectively, on a consolidated basis, maintain at all times, a minimum tangible net worth of not less than Five Million and No/100 Dollars (\$5,000,000.00).
- 6.19 <u>Debt Coverage Ratio</u>. Collectively, on a consolidated basis, maintain at all times a debt coverage ratio of no less than 1.1 to 1. For purposes of this Agreement, the debt coverage ratio shall be calculated as follows: earnings before interest, taxes, depreciation and amortization divided by the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed monies, in each case due and payable within the following twelve (12) months.

### SECTION 7. INTENTIONALLY OMITTED

## SECTION 8. RELEASE OF COLLATERAL

8.01 Certificate of Deposit. Upon the request of the Borrower, the Bank will release and terminate any security interest in the Certificate of Deposit granted hereby, provided: (a) no Event of Default or any matter with which the passage of time would constitute an Event of Default has occurred and remains outstanding; (b) (i) in the event the LOC Deed of Trust is in a second lien priority position, subject only to a first deed of trust in favor of the Bank, and the outstanding principal balance due and owing under the Term Loan plus the face amount of the Letter of Credit totals less than seventy percent (70%) of the fair market value of the Property; or (ii) in the event the LOC Deed of Trust is in a third lien priority position, subject only to a first deed of trust in favor of the Bank and the second deed of trust in favor of DBED, and the outstanding principal balance due and owing under the Term Loan and the DBED Loan totals less than seventy percent (70%) of the fair market value of the Property; and (c) the Bank is provided with a current title insurance policy or endorsement to an existing title insurance policy insuring that the priority of the LOC Deed of Trust is as required in clause (b)(i) or (b)(ii) above. For purposes hereof, the fair market value will be determined by an appraisal satisfactory to the Bank, paid for by the Borrower, and prepared by an appraiser approved in advance by the Bank in writing (which approval shall not be unreasonable withheld or delayed).

### SECTION 9. EVENTS OF DEFAULT

The occurrence of any one or more of the following events shall constitute an Event of Default hereunder:

- 9.01 Payments. Default shall be made in the payment of the principal of, or any installment of principal of, or interest on, the Note, whether at the due date thereof, at a date fixed for prepayment thereof, upon acceleration thereof or otherwise.
- 9.02 <u>Representations</u>. Any representation or warranty made in or in connection with any of the Loan Documents shall prove to have been false or misleading in any material respect when made or deemed to have been made.
- 9.03 Covenants. Default shall be made in the due observance or performance of any covenant, condition or agreement on the part of the Borrower or any Guarantor pursuant to the terms of any of the Loan Documents, and not already subject to a grace or cure period, and such default shall continue unremedied for fifteen (15) business days after notice to the Borrower and the Guarantor thereof.
- 9.04 (a) Voluntary Bankruptcy, Etc. The Borrower: (i) voluntarily is adjudicated as bankrupt or insolvent, (ii) seeks or consents to the appointment of a receiver or trustee for itself or for all or any part of its property, (iii) files a petition seeking relief under the bankruptcy or similar laws of the United States or any other competent jurisdiction, (iv) makes a general assignment for the benefit of creditors, or (v) admits in writing its inability to pay its debts as they mature.
- (b) <u>Involuntary Bankruptcy</u>, <u>Etc</u>. A court of competent jurisdiction enters an order, judgment or decree appointing, without the consent of Borrower, a receiver or trustee for Borrower, for all or any part of its property or approving a petition filed against it or him seeking relief under the bankruptcy or other similar laws of the United States or any state or other competent jurisdiction, and such order, judgment or decree shall remain in force undischarged or unstayed for a period of 60 calendar days.
  - 9.05 Attachment. The issuance of any attachment or garnishment against the Borrower, if the Borrower is the debtor.
- 9.06 Cross Default. The occurrence of an event of default (as defined therein) under any of the Loan Documents, any default (as defined therein) under the terms of any other mortgage, deed of trust or other lien or encumbrance on the Collateral, including, without limitation, the DBED Loan, or under any promissory note payable to the Bank under which the Borrower is an obligor, and the expiration of any applicable cure period, or the occurrence of an event of default (as defined therein) under any other indebtedness or liability for borrowed money of the Borrower in an amount in excess of \$500,000.00, including, without limitation, the Fifth Third Loan, if the effect of such default is to accelerate the maturity of such evidence of indebtedness or liability or to permit the holder thereof to cause any indebtedness to become due prior to its stated maturity and the Bank determines, in its discretion, that such default impairs or prevents the Borrower from performing its obligations under the Loan Documents.

- 9.07 <u>Judgment</u>. Unless in the opinion of the Bank, adequately covered by insurance, the entry of one or more final judgments, decrees or orders for the payment of money involving more than \$500,000.00 in the aggregate against the Borrower and all applicable periods for appeal have terminated and such judgment or decree is not satisfied within forty-five (45) days thereafter and the Bank determines in its discretion, that such judgment or decree impairs or prevents the Borrower from performing its obligations under the Loan Documents.
- 9.08 Loss, Damage to Collateral. Loss, theft, damage, or destruction of any material portion of the Collateral for which there is either no insurance coverage or for which, in the opinion of the Bank, there is insufficient insurance coverage.
- 9.09 Guaranty. The Guaranty shall, at any time after its execution and delivery and for any reason, cease to be in full force and effect or shall be declared null and void, or the validity or enforceability thereof shall be contested by any Guarantor or any Guarantor shall deny it has any further liability or obligation under the Guaranty.
- 9.10 Payments to Subordinated Creditors. The Borrower makes any payment on account of indebtedness that has been subordinated to any of the Secured Obligations, other than payments specifically permitted by the terms of such subordination.
  - 9.11 Adverse Change. There shall be no materially adverse change in the total financial condition of the Borrower or the Guarantor, taken as a whole.

#### SECTION 10. RIGHTS AND REMEDIES

- 10.01 Remedies. If any one or more Events of Default shall occur, then in each and every such case, the Bank may at any time thereafter exercise and/or enforce any of the following rights and remedies:
  - (a) No Further Advances. Make no further advances under the Facilities.
- (b) <u>Acceleration</u>. Declare the Note to be immediately due and payable, together with accrued interest thereon, without presentment, demand, protest or notice of dishonor, all of which the Borrower and the Guarantor hereby waive.
- (c) <u>Possession and Collection</u>. (i) Take possession or control of, sell or otherwise dispose of all of any part of the Collateral; (ii) endorse as the agent of the Borrower any chattel paper, documents, or instruments forming all or any part of the Collateral; (iii) pay, purchase, contest, or compromise any encumbrance, charge, or lien that, in the opinion of the Bank, appears to be prior or superior to its Lien and pay all reasonable expenses incurred in connection therewith; (iv) take any other action which the Bank deems necessary or desirable to protect and realize upon its security interest in the Collateral; and (v) in addition to the foregoing, and not in substitution therefor, exercise any one or more of the rights and remedies exercisable by the Bank under other provisions of this Agreement, under the Note, under any of the other Loan

Documents, or provided by applicable law (including, without limitation, the Uniform Commercial Code as in effect in Maryland) and may specifically disclaim any warranties of title or the like. In taking possession of the Collateral the Bank may proceed without legal process, if this can be done without breach of the peace. The Borrower waives any right it may have to require the Bank to pursue any third person for payment of the Secured Obligations.

- (d) <u>Receiver</u>. Obtain appointment of a receiver for all or any of the Collateral, the Borrower and the Guarantor hereby consenting to the appointment of such a receiver and each agreeing not to oppose any such appointment. Any receiver so appointed shall have such powers as may be conferred by the appointing authority including any or all of the powers, rights and remedies which the Bank is authorized to exercise by the Loan Documents, and shall have the right to incur such obligations and to issue such certificates therefor as the appointing authority shall authorize.
- (e) <u>Performance by Bank</u>. Make such payment or perform any of the conditions, covenants, terms, stipulations or agreements contained in this Agreement or any of the other Loan Documents for the account and at the expense of the Borrower.
- 10.02 <u>Sales on Credit</u>. If the Bank sells any of the Collateral upon credit, the Borrower will be credited only with payments actually made by the purchaser, received by the Bank and applied to the indebtedness of the purchaser. In the event the purchaser fails to pay for the Collateral, the Bank may resell the Collateral and the Borrower shall be credited with the proceeds of the sale.
- 10.03 <u>Proceeds</u>. Any proceeds of the collection of the Secured Obligations or of the sale or other disposition of the Collateral will be applied by the Bank to the payment of fees and costs, and any balance of such proceeds (if any) will be applied by the Bank to the payment of the remaining Secured Obligations (whether then due or not), at such time or times and in such order and manner of application as the Bank may from time to time in its sole discretion determine. If the sale or other disposition of the Collateral fails to satisfy all of the Secured Obligations, the Borrower and the Guarantor shall remain jointly and severally liable to the Bank for any deficiency.
- 10.04 Notices. Any notices required under the Maryland Uniform Commercial Code with respect to the sale or other disposition of the Collateral shall be deemed reasonable if mailed by the Bank to the persons entitled thereto at their last known address at least ten (10) days prior to disposition of the Collateral.

10.05 Waiver of Jury Trial. THE BORROWER, THE GUARANTOR AND THE BANK HEREBY VOLUNTARILY AND KNOWINGLY WAIVE ANY RIGHT THEY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION, PROCEEDING, OR COUNTERCLAIM BROUGHT BY ANY PARTY AGAINST THE OTHER ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREIN. THE BORROWER AND THE

GUARANTOR ACKNOWLEDGE THAT THEY HAVE BEEN INFORMED BY THE BANK THAT THE PROVISIONS OF THIS PARAGRAPH CONSTITUTE A MATERIAL INDUCEMENT UPON WHICH THE BANK HAS RELIED, IS RELYING AND WILL RELY IN MAKING THE TERM LOANN AND ISSUING THE LETTER OF CREDIT. THE BORROWER AND THE GUARANTOR HEREBY CERTIFY THAT NO REPRESENTATIVE OR AGENT OF THE BANK (INCLUDING ITS COUNSEL) HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT THE BANK WOULD NOT, IN THE EVENT OF LITIGATION, ENFORCE THIS WAIVER OF RIGHT TO JURY TRIAL. THE BORROWER AND THE GUARANTOR ACKNOWLEDGE THAT THEY HAVE CONSULTED WITH AN ATTORNEY AND FULLY UNDERSTANDS THE LEGAL EFFECT OF THE PROVISIONS OF THIS PARAGRAPH.

10.06 <u>Cumulative Remedies</u>. Each right, power and remedy of the Bank as provided for in the Loan Documents, or now or hereafter existing at law or in equity or by statute or otherwise shall be cumulative and concurrent and shall be in addition to every other such right, power or remedy, and the exercise or beginning of the exercise by the Bank of any one or more of such rights, powers or remedies shall not preclude the simultaneous or later exercise by the Bank of any or all other such rights, powers or remedies. The Bank may comply with any applicable state or federal law requirements in connection with a disposition of the Collateral and compliance will not be considered to adversely affect the commercial reasonableness of any sale of the Collateral.

10.07 No Waiver. No failure or delay by the Bank in insisting upon the strict performance of any term, condition, or covenant of the Loan Documents or in exercising any right, power or remedy consequent upon an Event of Default shall constitute a waiver of any such term, condition or covenant or of any such breach, or preclude the Bank from exercising any such right, power or remedy at any later time or times. By accepting payment after the due date of any amount payable under the Loan Documents, the Bank shall not be deemed to waive the right either to require prompt payment when due of all other amounts payable under the Loan Documents, or to declare a default for failure to effect such prompt payment of any such other amount.

# SECTION 11. MISCELLANEOUS

11.01 <u>Survival</u>. All covenants, agreements, representations and warranties made in this Agreement and the Loan Documents shall survive the execution and delivery of the Note and shall continue in full force and effect so long as the Note, or any of the other Secured Obligations, or any renewal or extensions of the Note, is outstanding and unpaid.

11.02 Notices. All notices, demands, instructions and other communications required or permitted to be given to or made upon any party hereto shall be in writing, personally delivered or sent by postage prepaid first class certified mail, return receipt requested, overnight courier or by facsimile machine, and shall be deemed to be given on the day that such writing is delivered or sent by facsimile machine or one (1) business day after such notice is sent by overnight courier or three (3) business days after said notice is sent by certified mail. Unless otherwise specified in a notice

sent or delivered in accordance with the foregoing provisions of this paragraph, notices, demands, instructions and other communications in writing shall be given to or made upon the respective parties hereto at their respective addresses indicated for such party below:

Bank: Mercantile Potomac Bank

702 Russell Avenue, Suite 200 Gaithersburg, Maryland 20877

Attention: Brett W. Kaplowitz, Senior Vice President

Facsimile Number: (301) 963-7683

Lerch, Early & Brewer, Chartered With Copy to:

3 Bethesda Metro Center, Suite 460 Bethesda, Maryland 20814

Attn: Lawrence G. Lerman, Esquire Facsimile Number: (301) 347-1776

Borrower

and Guarantor: Advanced BioSolutions, Inc.

Emergent BioSolutions Inc. Bioport Corporation Antex Biologics Inc. c/o Antex Biologics Inc.

300 Professional Drive, Suite 100

Gaithersburg, MD 20879

Attn: President

Facsimile Number: (301) 529-1252

With Copy to: Thelen Reid & Priest LLP

701 Pennsylvania Avenue, NW, Ste 800

Washington, DC 20004 Attn: Carl A. Valenstein, Esq. Facsimile Number: (202) 654-1836

or at such other address as the parties may have furnished to each other in writing, and shall be deemed to be given on delivery or upon mailing.

11.03 Costs and Expenses. The Borrower and the Guarantor shall bear any and all reasonable fees, costs and expenses, of whatever kind and nature, including any taxes of any kind and reasonable attorneys' fees and disbursements, which the Bank may incur: (a) in connection with the closing of the Loan, including, without limitation, the filing of public notices, the preparation of the Loan Documents, the recording of the UCC financing statements, and the making of title examinations; (b) in maintaining, preserving, enforcing or foreclosing any pledge, lien, encumbrance or security interest granted hereunder or in connection herewith, whether through judicial proceedings or otherwise; (c) in conducting audits of the Borrower's business and with respect to the Collateral; and (d) in successfully defending or prosecuting any actions or

proceedings arising out of or relating to transactions with any one or more of the Borrower and the Guarantor. All such fees, costs and expenses until paid shall be included in the Secured Obligations or deducted from any amount due the Borrower or the Guarantor. The Borrower and the Guarantor agree that the attorneys retained by the Bank shall represent only the interests of the Bank.

11.04 <u>Indemnification of Bank</u>. The Borrower shall protect and indemnify the Bank from and against any and all demands, suits, losses, assessments, fines, claims, damages, penalties causes of action, costs or other expenses (including, without limitation, reasonable attorneys' fees and disbursements), imposed upon or incurred by or asserted against the Bank or the directors, officers, agents or employees of the Bank, except those arising out of the willful misconduct or gross negligence of the Bank, by reason of and including but not limited to liability or damage resulting from:

(a) any failure on the part of the Borrower to perform or comply with any of the terms of this Agreement; (b) any action brought against the Bank attacking the validity of this Agreement or any other Loan Document; and/or (c) actual or threatened damage to the environment, agency costs of investigation, personal injury or death, or property damage, due to a release or alleged release or Hazardous Materials, on or under the Property or arising from the Borrower's business operations, or gaseous emissions from the Property or arising from the Borrower's business operations, or gaseous emissions from the Property or arising from the Borrower's business operations resulting from the use or existence of Hazardous Materials, whether such claim proves to be true or false. The term "property damage" as used in this Section includes, but is not limited to, damage of any real or personal property of the Borrower, the Bank, and of any third parties. Any amounts payable to the Bank under this Section which are not paid within twenty (20) days after written demand therefor by the Bank shall bear interest at the rate of interest in effect under the Note from the date of such demand. In the event any action, suit or proceeding is brought against the Bank or the directors, officers, agents or employees of the Bank by reason of any such occurrence, the Borrower, upon the request of the Bank and at the Borrower's expense, shall resist and defend such

11.05 Reinstatement of Liens. If, at any time after payment in full by the Borrower of all Secured Obligations and termination of the Bank's Liens, any payments on the Secured Obligations previously made by the Borrower or any other person must be disgorged by the Bank for any reason whatsoever (including, without limitation, the insolvency, bankruptcy, or reorganization of the Borrower or such other person), this Agreement and the Bank's Liens granted hereunder shall be reinstated as to all disgorged payments as though such payments had not been made, and the Borrower shall sign and deliver to the Bank all documents and things necessary to reperfect all terminated Liens.

11.06 <u>Bank Disclosures</u>. Upon the prior written consent of the Borrower (such consent not to be unreasonable withheld or delayed), the Bank may issue press releases concerning, and otherwise publicly announce or publicize, financings provided by the Bank to the Borrower or Subsidiaries. The Borrower hereby authorizes the Bank to disclose to any subsidiary or affiliate of

the Bank, to any fiduciary institution (as "fiduciary institution" is defined in Subtitle 3 of Title 1 of the Financial Institutions Article of the Annotated Code of Maryland, or any successor legislation) or to any banking institution, credit union or savings and loan association organized under the laws of any State, and hereby authorizes all subsidiaries and affiliates of the Bank, to disclose to the Bank, the financial record of the Borrower (as "financial record" is defined in Subtitle 3 of Title 1 of the Financial Institutions Article of the Annotated Code of Maryland, or any successor legislation).

- 11.07 <u>Participations</u>. The Bank shall have the right to grant participations in the Loan held by it to others at any time and from time to time, and the Bank may divulge to any such participant or potential participant all information, reports, financial statements and documents obtained in connection with this Agreement, the Note and any of the other Loan Documents or otherwise.
- 11.08 Change, etc. Neither this Agreement nor any term, condition, representation, warranty, covenant or agreement contained herein may be changed, waived, discharged or terminated orally, but only by an instrument in writing signed by the party against whom such change, waiver, discharge or termination is sought.
  - 11.09 Governing Law. This Agreement and the Note shall be governed and construed in accordance with the laws of the State of Maryland (but not including the choice of law rules thereof).
- 11.10 Terms Binding. All of the terms, conditions, stipulations, warranties, representations and covenants of this Agreement shall apply to and be binding upon and shall inure to the benefit of the Borrower, the Guarantor and the Bank and each of their respective heirs, executors, personal representatives, successors and assigns and all persons or entities who become bound as a debtor under this Agreement, but neither the Borrower nor the Guarantor shall have the right to assign this Agreement to any person or entity without the prior written consent of the Bank. The Guarantor hereby acknowledges and agrees that all of its obligations under this Agreement, the Guaranty and the other Loan Documents shall be joint and several.
- 11.11 Invalidity of Certain Provisions. If any term or provision of this Agreement or the application thereof to any person or circumstances shall, to any extent, be invalid or unenforceable, the remainder of such term or provision or the application thereof to persons or circumstances other than those as to which it is held invalid or unenforceable shall not be affected thereby and shall be valid and enforceable to the fullest extent permitted by law.
- 11.12 Merger, Integration and Interpretation. The Loan Documents contain the entire agreement of the parties with respect to the matters covered and the transactions contemplated hereby and thereby, and no other agreement, statement or promise made by any such party, or by any employee, officer, agent or attorney of any such party, which is not contained herein or therein, shall be valid or binding. Neither this Agreement nor any uncertainty or ambiguity herein shall be construed or resolved against the Bank or the Borrower, whether under any rule of construction or otherwise. On the contrary, this Agreement has been reviewed by each of the parties and its

counsel and shall be construed and interpreted according to the ordinary meaning of the words used so as to accomplish the purposes and intentions of all parties hereto fairly.

11.13 No Partnership — Control — Third Parties. This Agreement contemplates the extension of credit by the Bank, in its capacity as a lender, to the Borrower, in its capacity as a borrower, and for the payment of interest and repayment of principal by the Borrower to the Bank. The relationship between the Bank and the Borrower is limited to that of creditor/secured party, and debtor. The provisions herein for compliance with financial covenants, delivery of financial statements, and other covenants are intended solely for the benefit of the Bank to protect its interests as lender in assuring payments of interest and repayment of principal, and nothing contained in this Agreement shall be construed as permitting or obligating the Bank to act as financial or business advisor or consultant to the Borrower, as permitting or obligating the Bank to control the Borrower, or to conduct the Borrower's operations, as creating any fiduciary obligation on the part of the Bank to the Borrower, as creating any joint venture, agency, or other relationship between the parties other than as explicitly and specifically stated in this Agreement. The Borrower acknowledges that it has had the opportunity to obtain the advice of experienced counsel of its own choosing in connection with the negotiation and execution of this Agreement and to obtain the advice of such counsel with respect to all matters contained herein, including, without limitation, the provision herein relative to the waiver of trial by jury. The Borrower further acknowledges that it is experienced with respect to financial and credit matters and has made its own independent decision to apply to the Bank for credit and to execute and deliver this Agreement. The terms and provisions of the Note and the Loan Documents are for the benefit of the Borrower and the Bank, their respective successors, assigns, endorsees and transferees and all persons claiming under or through them and no other person shall have any right or cause of action or account thereof.

11.14 Electronic Transmission of Data. The Bank, the Borrower and the Guarantor agree that certain data related to the Loan (including confidential information documents, applications and reports) may be transmitted electronically, including transmission over the Internet. This data may be transmitted to, received from or circulated among agents and representatives of the Borrower, the Guarantor and/or the Bank and their affiliates and other persons involved with the subject matter of this Agreement. The Borrower and the Guarantor acknowledge and agree that (a) there are risks associated with the use of electronic transmission and that the Bank does not control the method of transmittal or service providers, (b) the Bank has no obligation or responsibility whatsoever and assumes no duty or obligation for the security, receipt or third party interception of any such transmission, and (c) the Borrower and the Guarantor will release, hold harmless and indemnify the Bank from any claim, damage or loss, including that

arising in whole or part from the Bank's strict liability or sole, comparative or contributory negligence, which is related to the electronic transmission of data.

- 11.15 Gender, etc. Whenever used herein, the singular shall include the plural, the plural shall include the singular, and the use of the masculine, feminine or neuter gender shall include all genders.
- 11.16 <u>Authority to File Financing Statements and Amendments</u>. The Borrower hereby authorizes the Bank to file a Financing Statement describing the Collateral without the Borrower's signature thereon. After notice to the Borrower, the Bank is authorized to file amendments without the Borrower's signature thereon to any financing statements naming the Bank as a secured party in order to add collateral or a debtor. The Borrower is not authorized to file correction statements to financing statements.
  - 11.17 Headings. The section and subsection headings of this Agreement are for convenience only, and shall not limit or otherwise affect any of the terms hereof.
- 11.18 Counterparts. To facilitate execution, this Agreement may be executed in any number of counterparts as may be required; and it shall not be necessary that the signatures of, or on behalf of, each party, or that the signatures of all persons required to bind any party, appear on each counterpart; but it shall be sufficient that the signature of, or on behalf of, each party, or that the signatures of the persons required to bind any party, appear on one or more counterparts. All counterparts shall collectively constitute a single agreement. It shall not be necessary in making proof of this Agreement to produce or account for more than a number of counterparts containing the respective signatures of, or on behalf of, all of the parties hereto.

IN WITNESS WHEREOF, each of the parties hereto have caused this Agreement to be executed, sealed and attested the day and year first above mentioned.

ATTEST:	ADVANCED BIOSOLUTIONS, INC.	
/s/ Jose Ochoa	By: /s/ Fuad El-Hibri Name: Fuad El-Hibri Title: President	(SEAL)
ATTEST:	MERCANTILE POTOMAC BANK	
/s/ [Illegible]	By: /s/ Brett W. Kaplowitz  Name: Brett W. Kaplowitz  Title: Senior Vice President	(SEAL)
	[signature page continues]	
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Al IESI:	ANTEX BIOLOGICS INC.	
/s/ [Illegible]	By: /s/ Robert G. Kramer	(SEAL)
	Name: Robert G. Kramer Title: President	
	BIOPORT CORPORATION	
/s/ Jose Ochoa	By: /s/ Fuad El-Hibri Name: Title: CEO	(SEAL)
	EMERGENT BIOSOLUTIONS INC.	
/s/ Jose Ochoa	By: <u>/s/ Fuad El-Hibri</u> Name: Title: CEO	(SEAL)

# PROMISSORY NOTE

\$7,000,000,00 October 14, 2004

FOR VALUE RECEIVED, ADVANCED BIOSOLUTIONS, INC. (the "Borrower") promises to pay to the order of MERCANTILE POTOMAC BANK (hereinafter referred to as the "Bank") at its office at 702 Russell Avenue, Suite 200, Gaithersburg, Maryland 20877, or at such other place as the Bank may from time to time direct, the sum of SEVEN MILLION and No/100 Dollars (\$7,000,000.00), with interest computed daily on the unpaid principal balance at the Interest Rate (as such term is hereinafter defined), and payable according to the repayment schedule set forth herein (the "Loan").

From and after the date hereof through and including October 14, 2009 (the "Adjustment Date"), interest shall be computed at the annual rate of interest equal to Six and Five-Eighths percent (6.625%) per annum (the "Initial Interest Rate"). Effective on the Adjustment Date, interest on the outstanding principal balance of this Note shall be computed at a fixed annual rate of interest that equals three hundred twenty (320) basis points over the yield on actively traded U.S. Government securities issues adjusted to a constant maturity of two (2) years, as published in the Federal Reserve Statistical Release H.15 (519) under the heading "U.S. Government Securities Treasury Constant Maturities 2 years" on the last business day that is one (1) week prior to the Adjustment Date, and rounded up to the nearest one-eighth of one percent (1/8 of 1%) (the "Adjusted Interest Rate", and together with the Initial Interest Rate, the "Interest Rate"). On or before the Adjustment Date, the Bank shall provide notice to the Borrower of any change in the interest rate and any change in the monthly payments of principal and interest.

Interest only shall be payable monthly on the 14th day of each month beginning November 14th, 2004 and shall continue on the 14th day of each month thereafter through and including October 14, 2006

From the 14th day of November, 2006 and continuing on the 14th day of each and every month thereafter, through and including October 14, 2009, equal monthly payments of principal and interest in the amount of Sixty-One Thousand Eight Hundred Thirty-Four and 87/100 Dollars (\$61,834.87) (based upon a 15 year amortization) shall be due and payable.

From the 14th day of November, 2009 and continuing on the 14th day of each and every month thereafter until the Maturity Date (hereinafter defined), principal and interest payments equal to an amount sufficient to repay this Note at the Adjusted Interest Rate (based upon a 12 year amortization) shall be due and payable. On October 14th, 2011, the outstanding principal balance and all accrued and unpaid interest shall be due and payable in full (the "Maturity Date").

The rate of interest chargeable under this Note: (1) will not exceed applicable legal limits, and in the event a payment is made by the Borrower or received by the Bank in excess of the applicable legal limits, such excess payment shall be credited as a payment of principal; and (2) shall be computed on the basis of 360-day year and charged for the actual number of days elapsed in each interest calculation period.

In the event the Borrower fails to make a payment of principal and/or interest in fully collected funds within fifteen (15) days after such payment is due, the Borrower shall pay a late charge to the Bank. The late charge will be equal to five percent (5%) of the overdue installment.

Upon an Event of Default (as such term is hereinafter defined) and until such Event of Default is cured or this Note is paid in full, this Note shall bear interest at a rate equal to three percent (3%) above the Interest Rate in effect on the date of such Event of Default.

The Borrower hereby waives demand, presentment for payment, protest, and notice of dishonor, and agrees that at any time and from time to time and with or without consideration, the Bank may, without notice to or further consent of the Borrower and without in any manner releasing, lessening or affecting the obligations of the Borrower: (1) release, surrender, waive, add, substitute, settle, exchange, compromise, modify, extend or grant indulgences with respect to: (a) this Note; and (b) all or any part of any collateral or security for this Note; and (2) grant any extension or other postponements of the time of payment hereof.

Upon five (5) business days' written notice from the Borrower to the Bank, the Borrower may prepay the outstanding principal balance of this Note, in whole or in part, subject to the following terms and conditions:

- (1) any prepayment must include payment of all interest accrued and unpaid on the amount so prepaid as of the date of such prepayment;
- (2) partial prepayment shall not postpone the due date of any subsequent payment, nor shall it change the amount of any monthly payment otherwise required to be made under this Note, unless the Bank otherwise agrees in writing and in advance of receipt of such partial prepayment;
  - (3) The Borrower shall pay to the Bank a prepayment fee to be determined as follows:
- (a) In the event that any such prepayment shall be made during the first year after the date hereof, the prepayment fee shall be equal to one-half of one percent (1/2%) of the principal amount so prepaid;
- (b) In the event that any such prepayment shall be made during the second year after the date hereof, the prepayment fee shall be equal to one quarter of one percent (1/4%) of the principal amount so prepaid.
- (c) Notwithstanding the foregoing, the Borrower shall be entitled to prepay up to the aggregate amount of One Million and No/100 Dollars (\$1,000,000.00) during the first two (2) years of this Note without being subject to any prepayment fee. Furthermore, after the second anniversary of this Note, the Borrower may prepay the outstanding principal balance of this Note, in whole or in part, without being subject to any prepayment fee.

Each of the following shall constitute a default ("Event of Default") under this Note:

- a. A failure to make a payment of any sum when due under this Note.
- b. A failure to perform or observe any of the covenants, conditions or terms of this Note or any deed of trust, loan agreement, guaranty or any other agreement or document in connection with the Loan (collectively, the "Loan Documents") executed by the Borrower or any person or entity who or which has guaranteed repayment of this Note or has granted a lien or security interest in any property as collateral for the repayment of this Note (individually or collectively, the "Obligor"), and the expiration of any applicable notice or cure period provided in the Loan Documents.

Upon the occurrence of an Event of Default or failure to pay the balance hereof when otherwise due, and notwithstanding the payment of any late charges: (1) all remaining payments under this Note shall become due and payable together with interest accrued to the date of payment without notice, at the option of the Bank; (2) the Borrower shall reimburse the Bank for any reasonable expenses, costs and attorneys' fees which the Bank may incur in connection with the collection of any monies due under this Note or in connection with the enforcement of any right under this Note or under any of the Loan Documents; (3) the Borrower hereby authorizes any attorney or Clerk of any Court of Record in Maryland or elsewhere to enter judgment by confession against the Borrower in favor of the holder of this Note for the full amount of the indebtedness due hereunder, interest and costs, including attorneys' fees of 5% of the outstanding indebtedness due under this Note, expressly waiving summons and other process, and does further consent to the immediate execution of said judgment, expressly waiving the benefit of any homestead or other exemption laws; and (4) the Bank may exercise any or all of the other rights, powers and remedies provided for in any of the Loan Documents, or now or hereafter existing at law or in equity or by statute or otherwise.

Each right, power and remedy of the Bank as provided for in this Note, or now or hereafter existing at law or in equity or by statute or otherwise, shall be cumulative and concurrent and shall be in addition to every other right, power or remedy, and the exercise or beginning of the exercise by the Bank of any one or more of such rights, powers or remedies shall not preclude the simultaneous or later exercise by the Bank of any or all of such other rights, powers or remedies.

No failure or delay by the Bank to insist upon the strict performance of any term, condition or covenant of this Note, or to exercise any right, power or remedy upon a breach hereof, shall constitute a waiver of any such term, condition or covenant or of any such breach, nor shall it preclude the Bank from exercising any such right, power or remedy at any later time or times, unless in writing signed by an authorized representative of the Bank. If the Bank accepts any payment after its due date, this does not constitute a waiver of the Bank's right to receive timely payment of all other subsequent amounts or to declare a default for the failure to make any other subsequent payment when due.

Any payment on this Note coming due on a day on which the Bank is not open to conduct full banking business shall be due on the next succeeding business day. Each payment hereunder may be applied to pay interest, principal, late fees or costs as the Bank, in its sole discretion, may determine.

All notices, demands, instructions and other communications required or permitted to be given to or made upon any party hereto shall be in writing, personally delivered or sent by postage prepaid first class certified mail, return receipt requested, overnight courier or by facsimile machine, and shall be deemed to be given on the day that such writing is delivered or sent by facsimile machine or one (1) business day after such notice is sent by overnight courier or three (3) business days after said notice is sent by certified mail. Unless otherwise specified in a notice sent or delivered in accordance with the foregoing provisions of this paragraph, notices, demands, instructions and other communications in writing shall be given to or made upon the respective parties hereto at their respective addresses indicated for such party below:

Bank: Mercantile Potomac Bank

702 Russell Avenue, Suite 200 Gaithersburg, Maryland 20877

Attention: Brett W. Kaplowitz, Senior Vice President

Facsimile Number: (301) 963-7683

With Copy to: Lerch, Early & Brewer, Chartered

3 Bethesda Metro Center, Suite 460

Bethesda, Maryland 20814

Attn: Lawrence G. Lerman, Esquire Facsimile Number: (301) 347-1776

Borrower: Advanced BioSolutions, Inc.

c/o Antex Biologies Inc. 300 Professional Drive Gaithersburg, MD 20879

Attn: President

Facsimile Number: (301) 590-1252

With Copy to: Thelen Reid & Priest LLP

701 Pennsylvania Avenue, NW, Ste 800

Washington, DC 20004 Attn: Carl A. Valenstein, Esq. Facsimile Number: (202) 654-1836

or at such other address as the parties may have furnished to each other in writing, and shall be deemed to be given on delivery or upon mailing.

The Borrower authorizes the Bank to disburse funds represented by this Note to the Borrower and agrees that such disbursement shall be deemed to be full and absolute consideration for the undertaking to make payment hereunder. The Borrower hereby authorizes

the Bank to disclose to any subsidiary or affiliate of the Bank, to any fiduciary institution (as "fiduciary institution" is defined in Subtitle 3 of Title 1 of the Financial Institutions Article of the Annotated Code of Maryland, or any successor legislation) or to any banking institution, credit union or savings and loan association organized under the laws of any State, and hereby authorizes all subsidiaries and affiliates of the Bank, to disclose to the Bank, the financial record of the Borrower (as "financial record" is defined in Subtitle 3 of Title 1 of the Financial Institutions Article of the Annotated Code of Maryland, or any successor legislation).

THE BORROWER AND THE BANK HEREBY VOLUNTARILY AND KNOWINGLY WAIVE ANY RIGHT THEY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION, PROCEEDING, OR COUNTERCLAIM BROUGHT BY EITHER PARTY AGAINST THE OTHER ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS NOTE AND THE TRANSACTIONS CONTEMPLATED HEREIN. THE BORROWER ACKNOWLEDGES THAT IT HAS BEEN INFORMED BY THE BANK THAT THE PROVISIONS OF THIS PARAGRAPH CONSTITUTE A MATERIAL INDUCEMENT UPON WHICH THE BANK HAS RELIED, IS RELYING AND WILL RELY IN MAKING THE LOAN. THE BORROWER HEREBY CERTIFIES THAT NO REPRESENTATIVE OR AGENT OF THE BANK (INCLUDING ITS COUNSEL) HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT THE BANK WOULD NOT, IN THE EVENT OF LITIGATION, ENFORCE THIS WAIVER OF RIGHT TO JURY TRIAL. THE BORROWER ACKNOWLEDGES THAT IT HAS CONSULTED WITH AN ATTORNEY AND FULLY UNDERSTANDS THE LEGAL EFFECT OF THE PROVISIONS OF THIS PARAGRAPH.

This Note shall be governed by and construed under and in accordance with the laws of the State of Maryland (but not including the choice of law rules thereof). The Borrower hereby submits to the non-exclusive jurisdiction of any State of Maryland court or Federal court sitting in the State of Maryland in any action or proceeding arising out of or relating to this Note, and hereby waives any objection it may have to the laying of venue of any such action or proceeding in any of said courts and any claim that it may have that any such action or proceeding has been brought in an inconvenient forum. A final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

Whenever used herein, the word "Borrower" or "Bank" shall be deemed to include, as appropriate, its/his/her respective heirs, personal representatives, successors and assigns. All words used herein shall be deemed to refer to the singular, plural, masculine, feminine or neuter as the identity of the person or entity or the context may require.

[signature page follows]

IN WITNESS WHEREOF, the Borrower has duly executed this Note under seal as of the date a	and year first	nereinabove set forth. This instrument may be signed in multiple co	ounterparts.
WITNESS/ATTEST:		ADVANCED BIOSOLUTIONS, INC.	
/s/ Jose Ochoa		By: /s/ Fuad El-Hibri Fuad El-Hibri, President	(SEAL)
	6		

# CONSENT OF THE GUARANTOR

The undersigned do hereby acknowledge that this Note is one of two (2) notes for which the undersigned's guaranty is made, pursuant to the terms of those certain guaranties executed by the undersigned of even date herewith (individually and collectively, the "Guaranties").

WITNESS/ATTEST:	BIOPORT CORPORATION	
/s/ Jose Ochoa	By: /s/ Fuad El-Hibri	(SEAL)
	Its: CEO	
/s/ Jose Ochoa	EMERGENT BIOSOLUTIONS INC.	
	By: /s/ Fuad El-Hibri	(SEAL)
	Its: CEO	
	ANTEX BIOLOGICS INC.	
	Ву:	(SEAL)
	Its:	
SUBSCRIBED AND SWORN TO before me this 14th day of October, 2004.		
	/s/ Sheila J. Glick Notary Public	
My Commission Expires: March 1, 2006		
	7	

# CONSENT OF THE GUARANTOR

The undersigned do hereby acknowledge that this Note is one of two (2) notes for which the undersigned's guaranty is made, pursuant to the terms of those certain guaranties executed by the undersigned of even date herewith (individually and collectively, the "Guaranties").

WITNESS/ATTEST:	BIOPORT CORPORATION	
	Ву:	(SEAL)
	Its:	
	EMERGENT BIOSOLUTIONS INC.	
	Ву:	(SEAL)
	Its:	
/s/ Michael Zamaria	ANTEX BIOLOGICS INC.	
	By: /s/ Robert G. Kramer	(SEAL)
	Its: President	
SUBSCRIBED AND SWORN TO before me this 14th day of October, 2004.		
	/s/ Evelyn I. Heald Notary Public	

My Commission Expires: March 1, 2007

# LOAN AGREEMENT

THIS LOAN AGREEMENT (as it may be amended, this "Agreement") is made as of this \_\_\_ day of \_\_\_\_\_\_, 2004, between ADVANCED BIOSOLUTIONS, INC., a Maryland corporation (the "Borrower"), and the DEPARTMENT OF BUSINESS AND ECONOMIC DEVELOPMENT, a principal department of the State of Maryland (the "Lender").

# RECITALS

- 1. The Borrower is indebted to the Lender in the principal amount not to exceed \$2,500,000, plus interest thereon (the "Loan"), which will be advanced to the Borrower pursuant to this Agreement. The Loan is evidenced by a Promissory Note dated the date hereof in the original principal amount of \$2,500,000 made by the Borrower and payable to the Lender (as it may be amended or replaced, the "Note").
- 2. The Loan was made pursuant to the provisions of the Maryland Economic Development Assistance Authority and Fund ("MEDAAF"), codified as Sections 5-1401 through 5-1411 of Article 83A of the Annotated Code of Maryland (as amended, the "Act").
- 3. The Loan proceeds will be used by the Borrower to finance a portion of the costs to acquire a facility located at 7114 Geoffrey Way, Frederick, Maryland, known as Unit 1 under the terms of that certain condominium regime burdening that property ("Building 1").
- 4. The activities to be financed with the proceeds of the Loan are part of a larger project to be carried out by, or on behalf of, the Borrower consisting of some combination of the following activities: (1) the acquisition of Building 1, (2) the acquisition or lease of either or both of the remaining two buildings located on Lot 3 Dudrow Industrial Park (the "Remaining Buildings"), (3) the construction of improvements to Building 1 and/or the Remaining Buildings, (4) the acquisition of furniture, fixtures, machinery and equipment for installation in Building 1 and/or the Remaining Buildings, (5) FDA validation of Building 1 and/or the Remaining Buildings, and (6) the operation of Building 1 and/or the Remaining Buildings as a bio-pharmaceutical research, development, and manufacturing facility for the production of vaccines (collectively, the "Project").
  - 5. In addition to the Project, the Borrower shall employ Permanent, Full-time Employees as provided in this Agreement.

NOW, THEREFORE, for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

# ARTICLE I DEFINITIONS

All accounting terms not specifically defined herein shall have the meanings determined by generally accepted accounting principles, consistently applied. All terms previously defined are incorporated in this Agreement by reference. Capitalized terms used in this Agreement have the meanings defined below.

- "Antex" means Antex Biologies, Inc., a Delaware corporation and an affiliate of the Borrower.
- "Application" means the Application from the Borrower to the Lender dated April 30, 2004, as it may be amended.
- "BioPort" means BioPort Corporation, a Michigan corporation and an affiliate of the Borrower.

"Borrower's Contribution" means the provision by the members of the Corporate Group of at least \$42,900,000 towards the costs of the Project, including the amount of the Loan, the Mercantile Senior Loan, the Local Contribution, or funds derived from financing commitments, lines of credit, and/or funds generated by a member of the Corporate Group from operations, government contracts, or otherwise. The Borrower's Contribution shall consist of both expended funds and the amounts owed by a member of the Corporate Group under the terms of binding purchase order or invoice.

- "Calculation Dates" means collectively and individually December 31, 2009, December 31, 2010, December 31, 2011, and December 31, 2012.
- "Claim" means any action or other claim for liability, loss, expense, or other cost, including fees, costs and expenses of attorneys, consultants, contractors, and experts.
- "Commitment Letter" means the conditional commitment letter issued by the Lender in connection with the Loan dated October 4, 2004, as it may be amended.
- "Completion Date" means December 31, 2009.

"Complex" means Building 1 and, if leased or owned by a member of the Corporate Group, either or both of the Remaining Buildings. In addition, the term "Complex" shall include facilities leased or owned by a member of the Corporate Group located within the jurisdiction of the Local Government and a Priority Funding Area and approved by the Lender, so long as the operations at such future facility are ancillary to, or in substitution of, the operations of the Corporate Group at Building 1 and/or the Remaining Buildings.

"Corporate Group" means collectively the Borrower, each Guarantor, and any other entity under common control which becomes a guarantor of the Loan and the Obligations on terms substantially similar to the terms of the Guaranties. For purposes of this Agreement, control means the ownership, either directly or indirectly, of at least 80% of the voting and economic interests by Emergent or the persons who, as of the date of this Agreement, control Emergent, or any other entity approved by the Lender in writing.

"Deed of Trust" means the Deed of Trust and Assignment of Leases and Rents made by the Borrower to James G. Davis and James Henry, as trustees, dated the date of this Agreement, and to be recorded in the Land Records of Frederick County, Maryland.

"Default" means any default under Article IV of this Agreement.

"Eligible Project Costs" means costs to acquire Building 1, as approved by the Lender.

"Emergent" means Emergent BioSolutions, Inc. a Delaware corporation and, as of the date of this Agreement, the parent corporation of the Borrower.

"Employee Report" means a report prepared by the Borrower which consists of (a) a list of the names of all of the Permanent, Full-time Employees employed by the members of the Corporate Group at the Complex as of the date(s) required in Section 6.05 below, and (b) the social security number, the average hours worked, or expected to be worked, for the year, the hourly or annual pay rate, and a general description of available benefits for each listed Permanent, Full-time Employees. An officer of the Borrower shall certify that (i) the list is true and accurate, (ii) the employees listed meet the definition of Permanent, Full-time Employees, and (iii) each of the employees listed is employed at the Complex.

"Expenses" means all costs and expenses incurred by the Lender (whether before or after a Default) in connection with, or in exercising or enforcing any rights, powers and remedies provided in, any of the Financing Documents.

"Final Report" means a completed and executed final report in substantially the form of Exhibit B attached to this Agreement.

"Financing Documents" means all documents executed and delivered in connection with the Loan and the Obligations, including this Agreement, the Note, the Guaranties, the Letter of Credit, the Deed of Trust, and any other document, evidencing or securing the Loan, as any of them may be amended.

"Forgiveness Date" means December 31, 2012.

"Full-time Equivalent Employee" means an employee position of a member of the Corporate Group filled by not more than two part-time employees who in the aggregate work, or are expected to work, at least 1800 hours per year and who otherwise meet the definition of a Permanent, Full-time Employee, provided, however, that the amount of any company subsidy for benefits may be reduced on a pro rata basis based upon hours worked.

"Governmental Authority" means the United States, the State, or any of their political subdivisions, agencies, or instrumentalities, including any local authority having jurisdiction over any aspect of the Project.

"Guaranties" means collectively the Guaranty (Antex), the Guaranty (BioPort), and the Guaranty (Emergent), as any of them may be amended.

"Guarantor" means Antex, BioPort, or Emergent.

- "Guaranty (Antex)" means the guaranty agreement executed by Antex guarantying payment of the Loan, as it may be amended.
- "Guaranty (BioPort)" means the guaranty agreement executed by BioPort guarantying payment of the Loan, as it may be amended.
- "Guaranty (Emergent)" means the guaranty agreement executed by Emergent guarantying payment of the Loan, as it may be amended.
- "Laws" means any current or future federal, state and local laws, statutes, rules, ordinances, regulations, codes, decisions, interpretations, orders, or decrees of any court or other Governmental Authority having jurisdiction.
- "Letter of Credit" means an irrevocable standby letter of credit in the amount of \$1,250,000, issued by Mercantile Potomac Bank, by a financial institution the long-term debt of which is rated at least A by Moody's or at least A by S&P or other comparable ratings if the indicated ratings are no longer in use, or by another commercial lender acceptable to the Lender, for the benefit of the Lender as security for repayment of the Loan, with an initial term of not less than one (1) year from the date of issuance, renewable upon the terms of this Agreement, and in substantially the form of Exhibit D attached hereto.
- "Local Contribution" means the provision of at least \$250,000 towards the costs of the Project by the Local Government, which is expected to be in the form of a Tax Increment Financing package, but may the take the form of any other type of direct assistance to the Borrower from the Local Government.
  - "Local Government" means the County Commissioners of Frederick County, a political subdivision of the State.
- "Mercantile Senior Loan" means a \$7,000,000 loan made by Mercantile Potomac Bank, or its successors and assigns, to the Borrower in connection with the acquisition of Building 1, and any replacement or refinancing of such loan up to the original principal amount of \$7,000,000.
- "Mercantile Senior Loan Documents" means any document executed by the Borrower or any Guarantor in connection with the Mercantile Senior Loan, including any note, loan agreement, deed of trust, security agreement, or guaranty, and further including any such document executed in connection with a replacement or refinancing of the Mercantile Senior Loan up to the original principal amount of \$7,000,000.
- "Mercantile Subordinate Loan" means a loan in the principal amount of \$1,250,000 made by Mercantile Potomac Bank, or its successors and assigns, to the Borrower in connection with the acquisition of Building 1, and any replacement or refinancing of such loan.

"Mercantile Subordinate Loan Documents" means any document executed by the Borrower or any Guarantor in connection with the Mercantile Subordinate Loan, including any note, loan agreement, deed of trust, security agreement, or guaranty, and further including any such document executed in connection with a replacement or refinancing of the Mercantile Subordinate Loan.

"MIDFA" means the Maryland Industrial Development Financing Authority, a body politic and corporate and a public instrumentality and public body of the State.

"MITP" means the Maryland Industrial Training Program.

"MITP Documents" means the documents to be entered into by the Lender and the Borrower in connection with any MITP grant to the Borrower.

"Obligations" means all duties of payment, performance, and completion owed by the Borrower to the Lender under the Financing Documents and by law, including the obligations to:

- (a) Pay all sums of money owed in connection with the Loan and any of the Financing Documents, including all funds and all sums of principal, interest, and premium, if any, due or to become due, and past, present, and future advances under any of the Financing Documents, all money advanced or expended by the Lender as provided for in any of the Financing Documents, and all Expenses; and
  - (b) Strictly observe and perform all of the provisions of the Financing Documents, time being of the essence.

"Permanent Full-time Employees" means employees who (a) are employed by the Corporate Group at the Complex for at least 1800 hours per year, without a fixed term of employment, (b) are eligible for an employer subsidized health care benefits package, (c) are eligible for similar other benefits as other employees of the Corporate Group at a similar pay grade at the Complex, and (d) make an hourly wage of at least 150% of the federal minimum wage. A Permanent, Full-time Employee shall not include (i) an employee of a company acquired by the Corporate Group after the date hereof, if the employee's place of employment immediately prior to the acquisition was in the State or (ii) an employee of the Corporate Group who is transferred to the Complex, if the employee's place of employment immediately prior to the transfer was in the State. In determining the number of Permanent, Full-time Employees employed by the Corporate Group, the Borrower may include up to 28 Full-time Equivalent Employees.

"Regulations" means the regulations in COMAR 24.05.02.01 through 24.05.02.16, as they may be amended.

"State" means the State of Maryland.

"Taxes" means all taxes, water rents, sewer rents, assessments, utility charges (whether public or private), and other governmental or municipal or public dues, charges, and levies.

# ARTICLE II TERMS OF THE LOAN AND DISBURSEMENT

# Section 2.01. The Loan.

Subject to the terms and conditions of all of the Financing Documents, the Lender agrees to extend the Loan to the Borrower.

# Section 2.02. Repayment and Interest.

All sums advanced under the Loan shall be evidenced by the Note and shall be repaid with interest in accordance with the provisions of the Note.

# Section 2.03. Disbursement.

- (a) <u>In General</u>. Subject to the Borrower's compliance with all of the terms of all of the Financing Documents, the satisfaction of all conditions precedent to disbursing Loan proceeds under this Agreement, and the non-existence of a Default or any event, circumstance, act or omission which with the giving of notice, the passage of time, or both, would constitute a Default, the Lender shall advance to the Borrower the full amount of the Loan pursuant to a completed Request for Disbursement, the form of which is attached hereto as <u>Exhibit A</u>.
  - (b) Disbursement. The Request for Disbursement shall be made to the Lender at the address specified in Section 5.01, or at any other place that the Lender designates
- (c) <u>Disbursement to the Borrower</u>. The disbursement shall be made directly to the Borrower by check. The Lender shall only disburse Loan proceeds upon presentation by the Borrower of a final settlement statement for the Facility.
- (d) Conditions for Disbursement. The obligation of the Lender to disburse the proceeds of the Loan is subject to the satisfaction of the following conditions as of the date the disbursement is made:
  - (i) Receipt of Request for Disbursement. The Lender shall have received a completed Request for Disbursement.
  - (ii) Representations True. No representation or warranty of the Borrower contained in this Agreement shall be or have become materially incorrect or inaccurate.
- (iii) No Defaults. There shall be no breach, default, or event of default (including a Default) under the terms of any of the Financing Documents, and no event, circumstance, act, or omission shall exist which with the giving of notice, the passage of time, or both, would constitute breach, default, or event of default (including a Default) under any of the Financing Documents.

# BioSolutions MEDAAF Loan Agreement

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- (iv) Solvency Certifications. If requested by the Lender, the Borrower shall deliver to the Lender satisfactory evidence that no (1) petition in bankruptcy, voluntary or otherwise, (2) assignment for the benefit of creditors, (3) petition seeking reorganization or arrangement under bankruptcy laws of the United States or of any state, or (4) other action brought under any bankruptcy laws, is pending against the Borrower or any Guarantor. The Lender may request such a certification at any time during the Loan term.
- (v) No Adverse Change. There has been no materially adverse change in the Borrower's or any Guarantor's financial condition from that reflected in the Borrower's or a Guarantor's (as the case may be) financial statements most recently submitted to the Lender prior to the closing.
  - (e) The Borrower's right to borrow under this Agreement shall terminate six months after the date of this Agreement.
  - (f) Availability of Funds. Disbursement of Loan proceeds is subject to the continuing availability of funds for such purpose and compliance with all applicable Laws.

# Section 2.04. Conditions Precedent to Disbursement.

Before disbursing any Loan proceeds, the Lender shall receive all of the items set forth on the Pre-Closing and Closing Checklist attached hereto as Exhibit C, in form and substance acceptable to the Lender, except to the extent any of the foregoing may be waived or deemed satisfied by the Lender.

# Section 2.05. Completion.

Within 90 days after the Completion Date, the Borrower shall submit to the Lender the following:

- (a) Evidence that the Project is completed; and
- (b) A Final Report, together with any additional information required by the Lender.

# ARTICLE III REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE BORROWER

# Section 3.01. Representations and Warranties.

The Borrower represents and warrants as follows:

- (a) Organization. The Borrower:
  - (i) Is a corporation duly organized, validly existing, and in good standing under the laws of the State;

- (ii) Has the power to own its property and to carry on its business as now being conducted;
- (iii) Is duly qualified to do business in each jurisdiction in which the character of properties owned by it or the transaction of its business makes qualification necessary; and
- (iv) Has delivered a complete copy of its articles of incorporation and by-laws, together with all amendments, to the Lender.
- (b) <u>Due Authorization</u>. The Borrower has the full corporate power and authority to enter into this Agreement, to borrow the Loan as contemplated by the Financing Documents, to execute and deliver all of the Financing Documents to which it is a party, and to comply with the terms set forth in all of the Financing Documents, all of which have been duly authorized by all necessary corporate action of the Borrower. No approval of any other person or public authority or regulatory body is required as a condition to the validity of any of the Financing Documents, or, if required, the approval has been obtained.
  - (c) Validity of Financing Documents. All of the Financing Documents have been properly executed by the Borrower and will:
    - (i) Not violate any Laws, or any provision of the Borrower's articles of incorporation or by-laws;
    - (ii) Not violate any provision, or result in a breach, of any document or agreement binding on the Borrower or affecting its property; or
    - (iii) Constitute the valid and legally binding obligations of the Borrower, fully enforceable against the Borrower in accordance with their terms.
- (d) Legal Actions. There is no (1) Claim pending or, to the best of the Borrower's knowledge, threatened in any court or before any governmental agency, and (2) investigation by or before any Governmental Authority, that:
  - (i) Questions the validity or enforceability of any of the Financing Documents, or any action taken, or to be taken, under any of them;
- (ii) Is likely to result in any material adverse change in the authority, properties, assets, liabilities, or conditions (financial or otherwise) of the Borrower that would materially impair the Borrower's ability to perform any of its obligations under all of the Financing Documents; or
  - (iii) Affects Building 1 or the Project.
- (e) <u>Taxes</u>. All Taxes imposed upon the Borrower and its properties have been paid prior to the date when any interest or penalty would accrue for nonpayment, except for those Taxes being contested in good faith and by appropriate proceedings by the Borrower.

- (f) <u>Accuracy of Statements</u>. All information contained in any financial statement, report, or other document given by the Borrower or by any other person in connection with the Loan is true and accurate in all respects, and the Borrower and each other person has not omitted to state any material fact or any fact necessary to make the information not misleading.
- (g) <u>Application</u>. All information in the Application was true and complete in all material respects as of the date of the Application. The Borrower is aware of no event that would require any amendment to the Application in order to make any information in the Application true and complete in all material respects and not misleading in any material respect as of the date of this Agreement, and the Borrower is aware of no event or other fact that should have been, and has not been, reported in the Application as material information.
- (h) Financing Document Defaults. There is no event of default or default (including a Default) on the part of the Borrower under any of the Financing Documents to which the Borrower is a party, and no event has occurred or is continuing that, with notice, or the passage of time, or both, would constitute an event of default or default (including a Default) under any of the Financing Documents to which the Borrower is a party.
  - (i) Compliance With Laws. The Borrower has complied with all Laws.
  - (j) State Drug Policy. The Borrower is in compliance with the State's policy concerning drug and alcohol free workplaces, as set forth in COMAR 01.01.1989.18 and 21.11.08.

#### Section 3.02. Borrower's Covenants

The Borrower covenants as follows:

- (a) Repayment and Performance. The Borrower shall promptly pay and perform all of the Obligations in the manner provided in the Financing Documents.
- (b) Use of Loan Proceeds. The Borrower shall use the Loan proceeds for Eligible Project Costs.
- (c) Financial Information. The Borrower shall cause Emergent to furnish the Lender with:
- (i) As soon as available, but in no event more than 90 calendar days after the close of each of Emergent's fiscal years, a copy of the Emergent's consolidated annual financial statement in reasonable detail satisfactory to the Lender, prepared in accordance with generally accepted accounting principles, consistently applied, and audited by an independent, certified public accountant, which financial statement shall be prepared on a consolidated basis, provided, however, that the Lender shall, to the extent permitted by law, maintain the confidentiality of the information provided to the Lender under this paragraph; and

- (ii) In the event that Emergent no longer prepares financial statements which include the financial results of the Borrower, the Borrower shall deliver to the Lender the Borrower's financial statements on the same terms as specified in (i) above.
  - (iii) Any additional information reasonably requested by the Lender.
- (d) Good Standing. The Borrower shall maintain its existence as a Maryland corporation and its good standing and qualification to do business in the State.
- (e) <u>State Drug Policy</u>. The Borrower will comply with the State's policy concerning drug and alcohol free workplaces, as set forth in COMAR 01.01.1989.18 and 21.11.08, for the term of this Agreement. Specifically, the Borrower shall (to the extent within the Borrower's or any other member of the Corporate Group's control):
  - (i) Make a good faith effort to eliminate illegal drug use and alcohol and drug abuse from its workplaces during the term of this Agreement;
  - (ii) Prohibit the unlawful manufacture, distribution, dispensation, possession, or use of drugs in its workplaces;
  - (iii) Prohibit its employees from working under the influence of alcohol or drugs;
- (iv) Not hire or assign to work on an activity funded in whole or part with State funds, anyone whom it knows, or in the exercise of due diligence it should know, currently abuses alcohol or drugs and is not actively engaged in a bona fide rehabilitation program;
- (v) Promptly inform the appropriate law enforcement agency of every drug related crime that to its knowledge occurs in any of its workplaces if any of its employees has observed the violation or otherwise has reliable information that a violation has occurred; and
- (vi) Notify employees that drug and alcohol abuse are banned in the workplaces, impose sanctions on employees who abuse drugs and alcohol in the workplaces, and institute steps to maintain drug and alcohol free workplaces.
  - (f) Completion. The Borrower shall:
    - (i) Cause the Project to be completed by the Completion Date, free and clear of any Liens or claims for Liens;
    - (ii) Cause the Project to be completed in accordance with the Application, the Act, the Regulations, and the terms of this Agreement; and
    - (iii) Satisfy all applicable Laws for the operation of Building 1 by the Completion Date.

- (g) Payment of Contractors. The Borrower will promptly pay, or cause to be paid, all contractors and materialmen the amounts due them, subject, however, to the right of the Borrower to contest the same in good faith.
- (h) Maintenance of the Project. The Borrower shall, at its sole cost and expense: (i) Keep, or cause to be kept, the Complex in good condition, working order, and repair; (ii) Make, or cause to be made, all replacements to the Complex so that the Complex will always be in good condition; (iii) Operate, or cause to be operated, the Complex in the manner in which similar property is operated by persons operating a first-class business of a similar nature.

#### (i) Insurance.

- (i) During the term of this Agreement the Borrower shall obtain and maintain, except as provided below, the following insurance coverages:
- (1) During any period of construction on any part of the Complex, builder's all-risk insurance of the type customarily carried in the case of similar construction for the full replacement cost of work in place and materials stored in connection with such construction;
- (2) Comprehensive general public liability and property damage insurance in amounts usually carried by similar operations against claims for bodily injury, death, or damage to property occurring on the Complex;
  - (3) "All risk" coverage for the Complex in amounts necessary to prevent the application of any co-insurance provisions up to the full replacement value of the Complex;
  - (4) Workers' compensation insurance for all contractors and subcontractors employed at the Complex and all employees of the Borrower employed in the State; and
- (5) If any part of the Complex is, or is later found to be, in an area that has been identified by the Federal Insurance Administration as having special flood and mudslide hazards, and in which the sale of flood insurance is available under the National Flood Insurance Act of 1968, a flood insurance policy satisfactory to the Lender. If no part of the Complex is in an area having special flood and mudslide hazards, the Borrower shall deliver to the Lender a certificate or letter issued by its insurance company stating that no part of the Complex is in a special flood and mudslide hazard area.
- (ii) All insurance policies shall be with responsible companies acceptable to the Lender and shall each bear an endorsement that it shall not be canceled, terminated, endorsed, or amended without 45 days written notice to the Lender.
- (iii) Upon request, the Borrower shall file with the Lender a detailed list of the insurance then in effect covering the Complex, stating the names of the insurance companies, the amounts and rates of insurance, dates of the expiration thereof and the properties and risks covered thereby.

- (iv) The Borrower shall cause certificates of insurance, evidencing that the Borrower maintains the insurance required under this subsection, to be delivered annually to the Lender.
- (v) The Borrower shall give the Lender prompt notice of any loss covered by the builder's all-risk or the all-risk insurance required under this Agreement.
- (j) Notification of Claims. The Borrower shall promptly notify the Lender of any (i) action or prospective claims or litigation, including tax deficiencies, that may be asserted against the Borrower, and (ii) default or event of default under the terms of any bond, debenture, note, or other evidence of indebtedness of the Borrower; provided, however, that notice shall not be required under this subsection if the amount at issue is less than \$500,000 or the Borrower diligently pursues a bona fide defense to any event specified in (i) or (ii).
- (k) Access. Subject to safety limitations and legal limits of general applicability, any duly authorized representative of the Lender shall, at all reasonable times, have access to all portions of the Complex, and if no Default has occurred and is continuing, subject to reasonable advance notice.
- (I) <u>Books and Records</u>. The Borrower shall keep any books, records, and other documents that may be required under the rules and procedures now or hereafter applicable to MEDAAF loans made by the Lender, and as may be reasonably necessary to disclose fully the amount and disposition of the Loan, the total costs incurred to complete the Project, and the source of all funds expended towards the costs of the Project. All books, records and other documents shall be maintained at the offices of the Borrower for inspection, copying, audit and examination at all reasonable times by any duly authorized representative of the Lender. All books, records and other documents shall be maintained until the first to occur of (i) three years after the Completion Date, or (ii) the completion of an audit of the Project by the State.
- (m) <u>Taxes</u>. The Borrower shall promptly pay all Taxes imposed on the Borrower and its properties prior to the date when any interest or penalty would accrue for non-payment, except for those Taxes being contested in good faith by appropriate proceedings by the Borrower.
  - (n) Press Releases. Without the prior consent of the Lender, the Borrower may not issue any press releases in connection with the Loan, the State, or the Lender.
- (o) <u>Further Assurances</u>. At any time, upon request by the Lender, the Borrower, at its sole expense, will make, execute, and deliver, or cause to be made, executed, and delivered, any additional documents that may, in the reasonable opinion of the Lender, be necessary or desirable to effectuate, complete, perfect, continue, or preserve the Obligations. Upon any failure by the Borrower to do so, the Lender may make and execute any such documents in the name of the Borrower, and at the sole expense of the Borrower, and the Borrower hereby irrevocably appoints the Lender the agent and attorney-in-fact of the Borrower to do so, this appointment being coupled with an interest. The Lender may, at its option, advance the Expenses incurred in making and executing any such documents and the Borrower shall reimburse the Lender for any sums advanced with interest at a rate equal to 12% per annum. Any such Expenses, together with interest, same

shall be part of the Obligations.

- (p) <u>Indemnification</u>. The Borrower releases the State and the Lender from, and agrees to protect, indemnify and save each of them harmless against, any Claims and Expenses incurred by, or asserted against, any of them, arising in connection with the Loan, the Project, or the Complex, except Claims or Expenses arising out of the willful misconduct or gross negligence of the State or the Lender. All money expended by the State on the Lender as a result of such Claims and Expenses, together with interest at a rate equal to 12% per annum from the date of payment, shall constitute an additional indebtedness of the Borrower and shall be immediately due and payable by the Borrower to the State and the Lender. Nothing contained in this Section 3.02(p) or in the Financing Documents shall be construed as a limit on the Obligations. This Section 3.02(p) shall survive termination of this Agreement and repayment of the Loan and Note in full.
- (q) Contractor's Non-Discrimination. The Borrower shall not discriminate on the basis of race, color, sex, religion, or national or ethnic origin in its hiring of contractors to carry out any portion of the Project. Borrower shall prohibit its contractors from engaging in such discrimination in the hiring of subcontractors to carry out any portion of the Project.
- (r) <u>Certificate Of Occupancy</u>. Within 30 business days of the date the Borrower first obtains a certificate of occupancy (other than a core and shell certificate) for all or any portion of Building 1, the Borrower shall provide the Lender with a copy of such certificate of occupancy.
- (s) Expenses. All Expenses incurred by the Lender shall become part of the Obligations and shall be repaid by the Borrower on demand, together with interest on the amount of such Expenses at a rate equal to 12% per annum from the date of incurrence.
  - (t) Compliance With Laws. The Borrower will comply with all Laws.

# (u) Letter of Credit.

- (i) Subject to the provisions of Section 5.16 below, the Borrower shall maintain the Letter of Credit to secure the Obligations at all times during the term of the Loan.
- (ii) The initial Letter of Credit shall automatically renew for successive one year terms unless the Lender receives written notice of non-renewal from the issuer of the current Letter of Credit at least one hundred twenty (120) days before the expiration of the current Letter of Credit. In the event the Lender receives a notice of non-renewal, the Borrower must provide the Lender with a substitute Letter of Credit, substantially in the form of Exhibit D attached hereto at least ninety (90) days prior to the expiration of the Letter of Credit then in effect.
- (iii) The original Letter of Credit or substitute Letter of Credit shall be issued by Mercantile Potomac Bank, a financial institution acceptable to the Lender, or a financial institution the long-term debt of which is rated at least A by Moody's or at least A by S&P, or other comparable ratings if the indicated ratings are no longer in use. Any substitute Letter of Credit shall be subject to the approval of the Lender.

(iv) Upon the repayment or forgiveness of the Loan in full to the satisfaction of the Lender, including the passage of any preference periods under applicable bankruptcy Law, the Lender will release the current Letter of Credit.

# ARTICLE IV DEFAULT AND REMEDIES

# Section 4.01. Defaults.

The following events shall constitute a Default under this Agreement:

- (a) The Borrower fails to pay the principal amount of the Loan and interest thereon according to the terms of the Note or any other payment required by any of the Financing Documents, including the Obligations;
- (b) The Borrower ceases to use Building 1, or an alternate facility located within the jurisdiction of the Local Government and within a Priority Funding Area and acceptable to the Lender, for the research, development, or manufacturing of vaccines, as contemplated in this Agreement, the Application, and the Commitment Letter;
  - (c) Any Loan proceeds are used for any purpose other than Eligible Project Costs;
- (d) The Borrower breaches any covenant, representation, warranty, or other provision of this Agreement, which breach is not cured within 30 calendar days from the date the Borrower receives (as provided in Section 5.01 below) written notice of the breach from the Lender; provided, however that the Borrower shall not receive a 30 calendar day cure period under this subsection for any breach for which there is a specific Default set forth in this Section;
- (e) The Borrower breaches (i) any covenant, representation, warranty, or other provision in any other Financing Document, which breach continues beyond any applicable grace or cure period, or (ii) the provisions of Section 3.02(a), (b), (f), (j), (n), or (u) of this Agreement;
- (f) Any statement made in any certificate, report or opinion (including legal opinions), financial statement, or other document furnished in connection with the Loan was incorrect in any material respect when made:
- (g) Any change in any zoning ordinance or any other public restriction is enacted which limits or defines the uses that may be made on any part of the Facility, so that the use of the Facility would be in violation of the restriction or zoning change and the Facility would not be useable for a purpose consistent with the Act, except during the pendency of any good faith contest thereof;
- (h) Any portion of, or interest in, Building 1 is sold, leased, subleased, transferred, encumbered, or otherwise conveyed, without the prior written consent of the Lender; provided, however, that a transfer or lease between members of the Corporate Group shall be permitted without the prior written consent of the Lender (which transfer or lease must be in compliance with the terms of the Deed of Trust for so long as the Deed of Trust is in effect);

- (i) The Borrower fails to comply with any requirement of any Governmental Authority within 60 days after written notice of the requirement is made or within any other time period set by the Governmental Authority; or if any proceeding is commenced or action taken to enforce any remedy for a violation of any requirement of a Governmental Authority or any restrictive covenant affecting any part of the Complex, except during the period of any good faith contest thereof by Borrower;
  - (j) The Project is not completed, as determined in the sole discretion of the Lender, by the Completion Date;
- (k) One or more defaults are declared under the terms of any bond, debenture, note, or other evidence of indebtedness of the Borrower if the aggregate principal amount of all bonds, debentures, notes, or other evidence of indebtedness declared to be in default exceeds \$500,000, and the Borrower fails to cure such default(s) within any applicable grace or cure period; provided, however, that it shall not be a Default under this subsection if the Borrower is diligently pursuing a bona fide defense to any such declared default, unless such default is under a MIDFA insured loan;
- (l) Final judgment for the payment of money in excess of \$1,000,000 is rendered against the Borrower and is not discharged or a stay of execution thereon or a bond is not procured within 30 days from the date of entry thereof, or if thereafter the judgment remains unsatisfied for a period of 30 days after the termination of any such stay of execution thereon or bond;
- (m) Any court of competent jurisdiction makes a final order (i) adjudicating the Borrower a bankrupt, (ii) appointing a trustee or receiver of a substantial part of the property of the Borrower, (iii) approving a petition for, or affecting an arrangement in, bankruptcy, a reorganization pursuant to federal bankruptcy law, or any other judicial modification or alterations of the rights of the Lender or of other creditors of the Borrower, (iv) assuming custody or sequestering any substantial part of the property of the Borrower, or (v) attaching or garnishing any substantial part of the property of the Borrower; or if the Borrower (A) files such petition, or (B) takes or consents to any other actions seeking any such judicial order, or (C) makes an assignment for the benefit of creditors, or (D) fails to pay debts generally as they become due;
- (n) Without the prior written consent of the Lender, the Borrower (i) sells or transfers all or substantially all of its business assets, (ii) begins any proceeding to dissolve or liquidate, (iii) changes the form of business entity through which it presently conducts its business, or (iv) merges or consolidates; provided, however, that mergers or consolidations are permitted between members of the Corporate Group without the prior written consent of the Lender, so long as the Borrower notifies the Lender of a permitted merger or consolidation within 30 business days after its finalization;
  - (o) Without the prior written consent of the Lender, the Borrower is dissolved by operation of law or in any other manner;

- (p) The Lender makes a good faith determination that a material adverse change has occurred in the financial condition of the Corporate Group from the condition set forth in the most recent financial statement of the Corporate Group furnished to the Lender, or from the financial condition of the Corporate Group as most recently disclosed to the Lender in any other manner, which materially impairs the ability of the Corporate Group to diligently pursue the completion of the Project as required herein;
- (q) The Borrower relocates to an area which is not a Priority Funding Area, as that term is defined in Title 5-7B of the State Finance and Procurement Article of the Annotated Code of Maryland, or Building 1 is not in a Priority Funding Area as of the date of this Agreement.
  - (r) By October 31, 2005, the Local Government fails to disburse the amount of the Local Contribution to the Borrower;
- (s) A default or event of default occurs under the terms of (i) any of the other Financing Documents, (ii) the MITP Documents, (iii) any loan to any member of the Corporate Group or is otherwise related to the Project, which is insured by MIDFA, (iv) any of the Mercantile Senior Loan Documents or Mercantile Subordinate Loan Documents, or (v) any of the documents executed in connection with the Local Contribution beyond any applicable grace or cure period;
- (t) Without the written consent of the Lender, Emergent (or the persons who control Emergent as of the date of this Agreement) owns, either directly or indirectly, less than 51% of the economic and voting interests of the Borrower;
  - (u) As of the Completion Date, the principal amount of the Loan exceeds 70% of the costs of the Project;
- (v) The long-term debt of the current issuer of the Letter of Credit is not rated at least A by Moody's or at least A by S&P, or other comparable ratings if the indicated ratings are no longer in use, or the issuer of the Letter of Credit is not otherwise approved by the Lender as evidenced by its acceptance of a Letter of Credit or replacement Letter of Credit; or
- (w) If at any time after the Borrower occupies the Building 1 through the Forgiveness Date, the Borrower substantially decreases its operations at the Building 1, or an alternate facility located within the jurisdiction of the Local Government and within a Priority Funding Area and acceptable to the Lender; provided, however, that any decrease in operations due to closures of less than 6 weeks in any 52 week period that occur in the ordinary course of business of the operating member of the Corporate Group shall not constitute a Default under this subsection.

# Section 4.02. Remedies

- (a) Upon the occurrence of any Default, the Lender may:
  - (i) Require the immediate repayment of the entire outstanding principal indebtedness, together with all accrued interest, under the Note and any Obligations;

- (ii) At any time proceed to protect and enforce all rights and remedies available to the Lender under this Agreement or by Law, by any other proceedings, whether for specific performance of any agreement contained in this Agreement, damages, or other relief;
  - (iii) Exercise the Lender's rights under the Letter of Credit; or
  - (iv) Exercise the Lender's rights under any of the Guaranties or the Deed of Trust.
- (b) All remedies provided for in this Agreement or by Law are cumulative and are in addition to any other rights and remedies available to the Lender under any Law. The exercise of any right or remedy by the Lender shall not constitute a cure or waiver of any Default by the Borrower, nor invalidate any act done pursuant to any notice of Default, nor prejudice the Lender in the exercise of those rights.
- (c) The failure of the Lender to insist upon performance of any term of this Agreement shall not constitute a waiver of any term of this Agreement. No act of the Lender shall be construed as an election to proceed under any one provision in this Agreement to the exclusion of any other provision.
  - (d) If the Lender suspends or terminates this Agreement, the rights and remedies available to the Lender shall survive the suspension or termination.

# Section 4.03. Setoff.

The Lender may set off against and apply any funds of the Borrower on deposit with, or under the control of, the State to the payment of the Obligations, without notice and without resort to any judicial proceeding.

# ARTICLE V MISCELLANEOUS

# Section 5.01. Notices.

- (a) All communications between the parties made pursuant to this Agreement shall be in writing
- (b) Any communication shall (a) when mailed by certified mail, return receipt requested, be effective three business days after it is deposited in the mails, (b) when mailed for next day delivery by a reputable overnight courier service which requires signed receipts to acknowledge delivery, be effective one business day after mailing, and (c) when sent by fax, be effective when it is faxed and receipt of the communication is confirmed. Communications shall be delivered to the office of the addressee, as follows:

(i) Communications to the Lender shall be mailed to:

Department of Business and Economic Development 217 East Redwood Street, 22nd Floor Baltimore, Maryland 21202

Attention: Financing Programs Accounting and Administration

FAX Number: (410) 333-6931

With a copy to the Counsel to the Lender, on the 11th Floor at the same address, or if by fax, to 410-333-8298.

(ii) Communications to the Borrower shall be mailed to:

Advanced Biosolutions, Inc. Attention: President c/o Antex Biologics, Inc. 300 Professional Drive Gaithersburg, Maryland 20879 FAX Number:

(c) The Borrower and the Lender may change their notice addresses by sending written notice to the other party.

(d) The Lender agrees to send a copy of any notice of default sent by the Lender to the Borrower to Mercantile Potomac Bank at the following address:

702 Russell Avenue, Suite 700 Gaithersburg, MD 20877 Attn: Brett Kaplowitz FAX Number: 301-788-4132

# Section 5.02. Assignment.

No benefit or burden imposed on the Borrower under this Agreement may be assigned without the prior written consent of the Lender.

# Section 5.03. Successors Bound

This Agreement shall inure to the benefit of, and shall be binding upon, each of the parties and their successors and permitted assigns.

# Section 5.04. Severability.

The invalidity of any part of this Agreement shall not affect the validity of the remaining provisions of this Agreement.

# Section 5.05. Entire Agreement.

This Agreement constitutes the entire agreement between the Borrower and the Lender and supersedes all prior oral and written agreements, representations, and negotiations between the parties concerning the Loan and the Obligations. If there is any inconsistency between this Agreement and the Application or the Commitment Letter, the provisions of this Agreement shall prevail.

# Section 5.06. Amendment of Agreement.

This Agreement may be amended only in writing executed by the Lender and the Borrower.

# Section 5.07. Headings.

The headings used in this Agreement are for convenience only and do not constitute a part of this Agreement.

# Section 5.08. Disclaimer of Relationships.

The Borrower acknowledges that the obligation of the Lender is limited to making the Loan on the terms set forth in this Agreement. Nothing in this Agreement, and no act of the Lender or the Borrower, shall be deemed to create any relationship of third-party beneficiary, principal and agent, limited or general partnership, joint venture, or any other relationship between the Borrower and the Lender. In addition, by inspecting any part of the Facility or by accepting or approving any action of the Borrower under any of the Financing Documents, the Lender shall not be considered to warrant the condition, legality, or sufficiency of any part of the Facility or any action taken or not taken by the Borrower.

# Section 5.09. Governing Law.

This Agreement and all of the other Financing Documents shall be governed by the laws of the State.

#### Section 5.10. Term of Agreement

Except as otherwise provided in this Agreement, unless sooner terminated by the mutual consent of the Borrower and the Lender, this Agreement shall remain in full force and effect until the earlier to occur of the date the Loan and the Obligations, together with interest and all other sums due and owing in connection with this Agreement, the Obligations or the Loan, have been paid in full to the satisfaction of the Lender or the Loan and the Obligations are forgiven by the Lender under the provisions of Section 6.03 of this Agreement.

# Section 5.11. Illegality.

If performance of any obligation under any of the Financing Documents would require the performing party to violate the Law, then the performance shall be reduced to the level permitted by Law, and if (1) any provision of this Agreement, other than provisions requiring the Borrower to pay interest, principal, principal and interest, or any other of the Obligations, operates, or would operate, to invalidate any part of this Agreement, then such provision only shall be void as though not set forth in this Agreement, and the remainder of this Agreement shall remain in full force and effect, (2) any provision of this Agreement requires the Borrower to pay interest, principal, principal and interest, or any other of the Obligations, then at the option of the Lender, the entire unpaid sum under the Loan, with all unpaid interest accrued thereon, and all other unpaid Obligations shall become due and payable.

# Section 5.12. WAIVER OF JURY TRIAL.

THE BORROWER HEREBY VOLUNTARILY AND INTENTIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY ACTION, PROCEEDING OR LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER AND IN CONNECTION WITH THE LOAN OR ANY OF THE FINANCING DOCUMENTS.

#### Section 5.13. CONFESSION OF JUDGMENT.

UPON A DEFAULT, THE BORROWER AUTHORIZES THE CLERK OR ANY ATTORNEY OF ANY COURT OF RECORD TO APPEAR FOR IT AND ENTER JUDGMENT BY CONFESSION WITHOUT PRIOR NOTICE OR OPPORTUNITY FOR PRIOR HEARING FOR THE OBLIGATIONS THEN OUTSTANDING, TOGETHER WITH INTEREST, COURT COSTS AND ATTORNEYS' FEES EQUAL TO 15% OF THE SUM OF THE OBLIGATIONS THEN OUTSTANDING. THE BORROWER WAIVES AND RELEASES, TO THE EXTENT PERMITTED BY LAW, ALL ERRORS AND ALL RIGHTS OF EXEMPTION, APPEAL, STAY OF EXECUTION, INQUISITION, AND EXTENSION UPON ANY LEVY ON REAL ESTATE OR PERSONAL PROPERTY TO WHICH THE BORROWER MAY OTHERWISE BE ENTITLED UNDER ANY LAW. THE AUTHORITY TO APPEAR FOR AND ENTER JUDGMENT AGAINST THE BORROWER MAY BE EXERCISED ON ONE OR MORE OCCASIONS, AND SHALL NOT BE EXTINGUISHED BY ANY JUDGMENT ENTERED PURSUANT THERETO. THIS AUTHORITY MAY BE EXERCISED IN THE SAME OR DIFFERENT JURISDICTIONS, AS OFTEN AS THE LENDER DETERMINES TO BE NECESSARY OR DESIRABLE.

# Section 5.14. Expenses

The Borrower shall pay all Expenses in connection with the execution and delivery of any of the Financing Documents.

# Section 5.15. Counterparts.

This Agreement may be executed in one or more counterparts, each of which shall be an original, but all of which, when taken together, shall constitute one document.

# Section 5.16. Release of Collateral.

- (a) The Lender will release the Letter of Credit and the Deed of Trust at any time that the Borrower demonstrates to the satisfaction of the Lender that the Corporate Group has access to the amount of the Borrower's Contribution. Access shall include prior expenditures of amounts included in the term "Borrower's Contribution", as well as access to amounts included in the items listed in such term.
  - (b) The Lender will release the Deed of Trust if at any time the Letter of Credit is increased to \$2,500,000.

# ARTICLE VI FORGIVENESS AND EMPLOYMENT REPORTING

# Section 6.01. Full Repayment.

The Borrower shall repay the outstanding amount of the Loan, together with accrued interest thereon, as provided in the Note, if:

- (a) As of any Calculation Date, the Borrower employs less than 225 Permanent, Full-time Employees; or
- (b) By the Completion Date, the Borrower fails to expend the amount of the Borrower's Contribution towards the costs of the Project.

# Section 6.02. Partial Repayment.

- (a) On the first Calculation Date in which the Corporate Group employs less than 280 Permanent, Full-time Employees, but employs at least 225 Permanent, Full-time Employees, the Borrower shall repay to the Lender a portion of the Loan equal to \$8,928 for each Permanent, Full-time Employees less than 280, together with accrued interest thereon, as provided in the Note.
- (b) If on a subsequent Calculation Date the Corporate Group employs less than 280 Permanent, Full-time Employees, but employs at least 225 Permanent, Full-time Employees, the Borrower shall repay to the Lender a portion of the Loan equal to \$8,928 for each Permanent, Full-time Employees less than 280, less an amount equal to the amount of the Loan previously repaid to the Lender under this Section 6.02, plus accrued interest on the amount of the Loan to be repaid, as provided in the Note. If the amount resulting from the calculation in the immediately preceding sentence is zero or negative, the Borrower shall not be required to make any payment to the Lender for that Calculation Date; it being expressly understood that nothing in this Section shall be construed to require the Lender to repay any amounts to the Borrower.

### BioSolutions MEDAAF Loan Agreement

October 15, 2004

- (c) Example of Operation of This Section. The following is an example of the intended operation of the preceding paragraph. If the Corporate Group employed 270, 290, 250, and 260 Permanent, Full-time Employees as of each of the Calculation Dates, then:
  - (1) As of December 31, 2009, the Borrower would be required to repay \$89,280, plus accrued interest to the Lender (\$8,928 x (280 270) = \$89,280),
  - (2) As of December 31, 2010, the Borrower would not be required to make any payments to the Lender (as the Borrower employed at least 280 Permanent, Full-time Employees),
- (3) As of December 31, 2011, the Borrower would be required to repay an additional \$178,560, plus accrued interest to the Lender (\$8,928 x (280 250) = \$267,840; \$267,840 \$89,280 = \$178,560, and
- (4) As of December 31, 2012, the Borrower would not be required to make any payments to the Lender (\$8,928 x (280 260) = \$178,560; \$178,560 \$267,840 = (\$89,280); as this number is negative, no payment would be required).

As of the Forgiveness Date, the Lender will forgive the amount of the Loan which is not subject to repayment under this Article VI, if no Default exists, and no event, circumstance, act or omission which, with the giving of notice, the passage of time, or both, would constitute a Default. Determination of amounts to be forgiven shall be made after determining any amounts required to be repaid under this Article VI.

#### Section 6.04. General Conditions

- (a) All information submitted by the Borrower to the Lender as evidence of compliance with any requirement of this Article must be in form and substance acceptable to the Lender.
- (b) The Lender shall not be obligated to forgive all or any portion of the Loan or permit repayment as provided in this Article if a Default exists, or an event, circumstance, act or omission exists which, with the giving of notice, the passage of time, or both, would constitute a Default.
  - (c) All calculations of the Corporate Group's employment shall be based upon the employment reports received by the Lender under Section 6.05 below.

### Section 6.05. Employee Reporting Requirement.

(a) On the dates specified below, the Borrower shall submit an Employee Report to the Lender with information effective as of the dates specified below:

### BioSolutions MEDAAF Loan Agreement October 15, 2004

 Report Date
 Effective Date of Information

 February 15, 2010
 December 31, 2009

 February 15, 2011
 December 31, 2010

 February 15, 2012
 December 31, 2011

 February 15, 2013
 December 31, 2012

(b) Upon the request of the Lender, the Borrower shall provide the Lender with any information and reports that the Lender determines, in its reasonable discretion, are needed to verify information contained in an Employee Report. The Borrower shall permit the Lender to inspect the employee records of the Borrower, or cause an employing member of the Corporate Group to permit the Lender to inspect the employee records of that Corporate Group member, to confirm the information contained in an Employee Report.

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(c) The failure to hire and maintain Permanent, Full-time Employees at the Facility as required under this Article VI shall not constitute a Default under the terms of this Agreement.

IN WITNESS WHEREOF, the Borrower and the Lender have caused this Agreement to be executed and delivered as of the date first above written.

WITNESS:	DEPARTMENT OF BUSINESS AND ECONOMIC DEVELOPMENT
/s/ Gloria M. Shryock	By: /s/ Aris Melissaratos
Name: Gloria M. Shryock	Name: Aris Melissaratos
	Title: Secretary
WITNESS:	ADVANCED BIOSOLUTIONS, INC.
/s/ José Ochoa	By: /s/ Y. F. El-Hibri (SEAL)
Name: José Ochoa	Name: Y. Fuad El-Hibri
	Title: President

BioSolutions MEDAAF Loan Agreement October 15, 2004

### STATE OF MARYLAND, CITY/COUNTY OF Baltimore, TO WIT:

I HEREBY CERTIFY that on this 14th day of October, 2004, before me, a Notary Public in the State of Maryland, personally appeared Aris Melissaratos, who acknowledged himself to be the Secretary of Business and Economic Development, known or satisfactorily proven to me to be the person whose name is subscribed to this document, and acknowledged that he executed it on behalf of Business and Economic Development as its duly authorized Secretary.

AS WITNESS my hand and Notarial Seal.

/s/ Robin G. Whitfield	
Notary Public	

My Commission expires: 3/1/08

### STATE OF MARYLAND, CITY/COUNTY OF Montgomery, TO WIT:

I HEREBY CERTIFY that on this 14th day of October 14th, 2004, before me, a Notary Public in the State of Maryland, personally appeared Fuad El-Hibri, who acknowledged himself/herself to be the President of Advanced BioSolutions, Inc., known or satisfactorily proven to me to be the person whose name is subscribed to this document, and acknowledged that she/he executed it on behalf of Advanced BioSolutions, Inc., as its duly authorized President.

AS WITNESS my hand and Notarial Seal.

/s/ [Illegible]		
Notary Public		

My Commission expires: March 1, 2006

BioSolutions MEDAAF Loan Agreement October 15, 2004

## EXHIBIT A REQUEST FOR DISBURSEMENT

- 1. Project Name: MEDAAF—BioSoIutions
- 2. Applicant: Advanced BioSolutions, Inc.
- 3. Request No.: One (1)
- 4. Amount Requested: \$2,500,000

Cer		

Advanced BioSolutions, Inc. (the "Borrower") hereby certifies that:

- 1. The attached request is for funds to reimburse the Borrower for a portion of the costs incurred in connection with the Project as approved by MEDAAF and as set forth in the Loan Agreement between the Borrower and the Department of Business and Economic Development (the "Lender") dated \_\_\_\_\_\_\_, 2004 (the "Agreement").
  - 2. This request is not for previously requested funds.
  - 3. The conditions to be satisfied prior to the disbursement of MEDAAF funds as set forth in the Agreement have been met.
  - 4. No default exists under the Agreement or the Deed of Trust Note executed in connection with the Agreemen

4. No default exists under the Agreement of the Deed of Trust Note exe	cuted in connection v	with the Agreement.	
5. The representations and warranties made by the Borrower in the Agree	eement are true and c	correct.	
WITNESS:	ADVANCED	BIOSOLUTIONS, INC.	
	Ву:		(SEAL)
Name:	Name:		
	Title:		
	Date:		_
		25	

1. Project Name: MEDAAF—Advanced BioSolutions, Inc.

### EXHIBIT B

Maryland Economic Development Assistance Authority and Fund ("MEDAAF") Final Report and Certification of Completion Costs

2. Borrower: Advanced BioSolutions	s, Inc.			
3. Period Covered:	to			
4. Activity:				
Costs of Project	Costs Paid by MEDAAF	Other Source	Other Source	Other Source
TOTAL:				
*(Please specify in parenthesis the en	ntity which paid each particular cost.)			
<b>CERTIFICATION:</b>				
	by certifies that: (1) the above costs ha Project, and (2) the information provide		ormed or equipment actually acquired and insta	alled in accordance with an
WITNESS:		ADVANCED BIOSOLUTIONS,	INC.	
		Ву:	(SEAL)	
Name:				
		Title:		
		Date:		
		27		

# LOAN AGREEMENT EXHIBIT C

### PRE-CLOSING AND CLOSING CHECKLIST

## \$2,500,000 CONDITIONAL MEDAAF LOAN TO ADVANCED BIOSOLUTIONS, INC.

### PRE-CLOSING AND CLOSING CHECKLIST

Closing Date: \_\_\_

Recipient: Advanced BioSolutions, Inc. Finance Specialist: Mary DiFerdinando Title Company: Chicago Title

Recipient's Attorney: Richard Newman AAG: David Rawle Title Company Attorney: Richard Zeidman/Jon Frank

Item	Received	Reviewed	Accepted	Responsibility
I. PRE-CLOSING				
1.1 Application			X	BioSolutions
1.2 Priority Funding Area Certification			X	DBED
1.3 State Clearing House Review				DBED
1.4 Conditional Commitment Letter			X	DBED
1.5 Secretary's Approval			X	DBED
1.6 County's Resolution Endorsing MEDAAF Financing and Project/ Authorizing Local Match—				
TIF		X		County
1.7 Recipient's Organizational Documents:				
1.7.1 Corporate Certificate		X		BioSolutions
A. Articles of Incorporation			X	BioSolutions
B. Bylaws				BioSolutions
C. Corporate Authority Resolution				BioSolutions
1.7.2 Good Standing Certificate SDAT			X	BioSolutions
1.8 Emergent's Organizational Documents:				
1.8.1 Corporate Certificate		X		BioSolutions
A. Articles of Incorporation			X	BioSolutions
B. Bylaws	X			BioSolutions
C. Corporate Authority Resolution		X		
1.8.2 Good Standing Certificate- State of Organization			X	BioSolutions
1.9 BioPort's Organizational Documents:				
1.9.1 Corporate Certificate		X		BioSolutions
A. Articles of Incorporation			X	BioSolutions
B. Bylaws				BioSolutions
C. Corporate Authority Resolution		X		BioSolutions
1.9.2 Good Standing Certificate—				

Item	Received	Reviewed	Accepted	Responsibility
State of Organization	<u> </u>		X	BioSolutions
1.10 Antex's Organizational Documents:				
1.10.1 Corporate Certificate		X		BioSolutions
A. Articles of Incorporation	<u></u>		X	BioSolutions
B. Bylaws	<u></u>			BioSolutions
C. Corporate Authority Resolution	<u></u> _	X		BioSolutions
1.10.2 Good Standing Certificate—State of Organization	<u></u> _		X	BioSolutions
1.11 Emergent's Financials	<u> </u>		X	BioSolutions
1.12 Insurance:	<del></del>			
1.12.1 General Liability Certificate		X		BioSolutions
1.12.2 Excess Liability Certificate	<u></u>	X		BioSolutions
1.12.3 All Risk Binding Certificate	<u></u>		X	BioSolutions
1.12.4 Workers' Compensation Certificate			X	BioSolutions
1.13 Real Property Documents:				
1.13.1 Contract of Sale			X	BioSolutions
1.13.2 Condominium Documents		X		BioSolutions
1.13.3 Draft Deed		X		BioSolutions
1.13.4 Evidence of Zoning Compliance			X	BioSolutions
1.13.5 Survey (ALTA)			X	BioSolutions
1.13.6 Commitment for Title Insurance		X		Title
1.13.7 Insured Closing Letter			X	BioSolutions
1.13.8 Appraisal				BioSolutions
1.13.9 Environmental Review			X	BioSolutions
1.13.10 Environmental Reliance Letter			X	BioSolutions
1.13.11 Flood Letter/Insurance				BioSolutions
1.14 Lease Agreement (Building 3)		X		BioSolutions
1.15 Project Budget			X	BioSolutions
1.16 Certificate of Occupancy				BioSolutions
1.17 Site Plan	<u></u>		X	BioSolutions
1.18 DLLR Authorization	<u></u>			BioSolutions
				BioSolutions
II. CLOSING				
2.1 Loan Documents:				
2.1.1 Deed of Trust Note		X		DBED
2.1.2 Loan Agreement	· <del></del>	X	<u> </u>	DBED
2.1.3 Deed of Trust	<u> </u>	X		DBED
2.1.4 Guaranty Agreement (Emergent)	<u> </u>	X	<u> </u>	DBED
2.1.5 Guaranty Agreement (BioPort)		X		DBED
2.1.6 Guaranty Agreement (Antex)		X		DBED
2.1.7 Letter of Credit	<u> </u>	X		Bank
	<u> </u>			
2				

### October 5, 2004

Item		Received	Reviewed	Accepted	Responsibility
2.1.8 Opinion Letter of Recipient's/Guarantor's Counsel		X			BioSolutions
2.1.9 Release of Lien				<u></u>	Title
2.2 Copies of Loan Documents for Senior Loan				<u></u>	BioSolutions
2.3 Closing Instruction Letter					DBED
2.4 Settlement Sheet					Title
2.5 Request for Disbursement					BioSolutions
2.6 Copy of Check and Receipt					DBED
III. POST CLOSING					
3.1 Final Title Insurance Commitment					Title
3.2 Final Deed					Title
3.2 T.M. 2004					1100
	3				

# LOAN AGREEMENT EXHIBIT D

### FORM OF LETTER OF CREDIT

### (NAME AND ADDRESS OF BANK ISSUING THE LETTER OF CREDIT)

### UNCONDITIONAL IRREVOCABLE RENEWABLE

LETTER OF CREDIT

Letter of Credit No.:	
Name of Project:	
Date:	

Maryland Department of Business and Economic Development 217 East Redwood Street, 22nd Floor Baltimore, Maryland 21202

Ladies and Gentlemen:

At the request of Advanced BioSolutions, Inc. (the "Borrower") we hereby establish this Unconditional Irrevocable Letter of Credit in favor of the Maryland Department of Business and Economic Development (the "Beneficiary") authorizing you or your transferee to draw on us at sight the amount set forth below.

- 1. Credit Amount. The credit available under this Letter of Credit is U.S. \$1,250,000 (the "Maximum Credit").
- 2. Expiration and Automatic Renewal. This Letter of Credit automatically shall expire at the close of business on the first Business Day on or after [insert the date which is one year after the date of issuance] (the "Expiration Date"); provided, however, this Letter of Credit shall be renewed automatically on the Expiration Date and on such date annually thereafter for a period of nine years thereafter (the "Annual Renewal Date") unless at least 120 days prior to the Expiration Date or any Annual Renewal Date you receive written notice from us of our election not to renew this Letter of Credit. Any such notice or any other communication to you shall be sent to:

Maryland Department of Business and Economic Development 217 East Redwood Street, 22nd Floor Baltimore, Maryland 21202 Attention: \_\_\_\_\_ Form Letter of Credit February 5, 1996

- 3. <u>Documents To Be Presented</u>. Funds under this Letter of Credit are available to you upon presentation, in accordance with paragraph 4 hereof, to us of a certificate signed by you in the form of <u>Exhibit A</u> attached hereto, appropriately completed (a "Demand for Payment").
- 4. <u>Method and Notice of Presentment</u>. A Demand for Payment may be delivered to us in person, by mail, by an express delivery service or by telecopy. A Demand for Payment shall be presented during our business hours on any Business Day prior to the expiration of this Letter of Credit at our office at [insert street address of bank and office or department to which documents should be delivered]. A Demand for Payment shall be deemed to have been presented on the date actually received by us. "Business Day" means any day other than a Saturday, Sunday or legal holiday on which banking institutions in [insert state where bank office is located] are authorized or required by law to close.
- 5. <u>Time and Method for Payment</u>. Notwithstanding any provisions to the contrary in the Uniform Commercial Code or the Uniform Customs and Practices for Documentary Credits, if a Demand for Payment is made by you at or prior to 11:00 A.M. on a Business Day, and provided that such Demand for Payment is accompanied by the certificate specified in paragraph 3 hereof, payment shall be made to you of the amount demanded on or before 3:00 P.M. on the same Business Day; if any demand for payment is made by you after 11:00 A.M., such demand shall be deemed to have been received prior to 11:00 A.M. on the next Business Day.

Payments made in accordance with this paragraph 5 shall be made with the Bank's own funds in immediately available funds by federal reserve wire transfer unless the Beneficiary agrees to accept payment by cashier's check.

- 6. <u>Transferability</u>. This Letter of Credit is transferable in its entirety, but not in part, without charge and may be successively transferred. Transfer of this Letter of Credit to a transferee shall be effected by the presentation to us of a copy of this Letter of Credit accompanied by a certificate substantially in the form of <u>Exhibit B</u> attached hereto.
  - 7. Irrevocability. This Letter of Credit is irrevocable.
  - 8. Governing Law. To the extent consistent with the express provisions hereof, this Letter of Credit shall be governed by the Uniform Commercial Code and the laws of the State of Maryland.
- 9. Complete Agreement. This Letter of Credit sets forth in full the terms of our undertaking, and this undertaking shall not in any way be modified, amended, amplified or limited by reference to any document, instrument or agreement referred to herein or in which this Letter of Credit is referred to or to which this Letter of Credit relates, except for the exhibits attached hereto and made a part hereof, and any such reference shall not be deemed to incorporate herein by reference any document, instrument or agreement except for such exhibits or any amendment to which you consent.

Form Letter of Credit February 5, 1996

We hereby confirm to you that a demand for payment presented in compliance with the terms and conditions of this Letter of Credit will be honored on sight in accordance with the provisions of this Letter of Credit.

Very truly yours,
[NAME OF BANK ISSUING LETTER OF CREDIT]
By: Title:

#### DEED OF TRUST NOTE

\$2,500,000	
(Financed Amount)	, Marylar

FOR VALUE RECEIVED, ADVANCED BIOSOLUTIONS, INC., a Maryland corporation (the "Borrower"), promises to pay to the order of the DEPARTMENT OF BUSINESS AND ECONOMIC DEVELOPMENT, a principal department of the State of Maryland (the "Lender"), the principal sum of TWO MILLION FIVE HUNDRED THOUSAND DOLLARS (\$2,500,000) (the "Loan"), or so much as has been disbursed to the Borrower under the terms of a Loan Agreement of even date herewith between the Borrower and the Lender (the "Loan Agreement"), together with interest thereon at the rate or rates hereafter specified and all other sums that may be payable to the Lender by the Borrower pursuant to this Deed of Trust Note (the "Note"). All capitalized terms used in this Note, if not defined in this Note, have the meanings given in the Loan Agreement. The following terms shall apply to this Note.

- 1. Interes
  - (a) Interest Rate. Prior to a Default, as defined in Section 8 below, the unpaid principal balance outstanding pursuant to this Note shall bear interest at the rate of 3% per annum.
  - (b) Default Rate. Upon the occurrence of a Default, the unpaid principal balance outstanding pursuant to this Note shall bear interest at the rate of 12% per annum.
- 2. Calculation of Interest. All interest payable under the terms of this Note shall be calculated on the basis of a 360-day year and the actual number of days elapsed.
- 3. Repayment.
- (a) <u>Deferral</u>. Interest shall accrue on the principal balance of the Loan from the date the Loan proceeds are disbursed to the Borrower. Except for amounts of this Loan that are required to be repaid under the succeeding provisions of this Note, the Borrower's payment of principal and accrued interest shall be deferred.
  - (b) <u>December 31, 2009</u>. If as of December 31, 2009, the Borrower is required to repay:
- (i) The full amount of the Loan under Section 6.01 of the Loan Agreement, the Borrower shall repay the entire principal amount of the Loan, together with accrued interest from the date of disbursement of the Loan proceeds through the date of repayment, within 90 days after the Borrower receives written demand for payment from the Lender.

### MEDAFF BioSolutions Note October 14, 2004

- (ii) Any part of the Loan as provided in Section 6.02 of the Loan Agreement, the Borrower shall make the required repayment of principal, together with accrued interest from the date of disbursement of the Loan proceeds through the date of repayment, within 90 days after the Borrower receives written demand for payment from the Lender.
  - (c) December 31, 2010. If as of December 31, 2010, the Borrower is required to repay:
- (i) The full amount of the Loan under Section 6.01 of the Loan Agreement, the Borrower shall repay the entire principal amount of the Loan, together with accrued interest from the date of disbursement of the Loan proceeds through the date of repayment, within 90 days after the Borrower receives written demand for payment from the Lender.
- (ii) Any part of the Loan as provided in Section 6.02 of the Loan Agreement, the Borrower shall make the required repayment of principal, together with accrued interest from the date of disbursement of the Loan proceeds through the date of repayment, within 90 days after the Borrower receives written demand for payment from the Lender.
  - (d) December 31, 2011. If as of December 31, 2011, the Borrower is required to repay:
- (i) The full amount of the Loan under Section 6.01 of the Loan Agreement, the Borrower shall repay the entire principal amount of the Loan, together with accrued interest from the date of disbursement of the Loan proceeds through the date of repayment, within 90 days after the Borrower receives written demand for payment from the Lender.
- (ii) Any part of the Loan as provided in Section 6.02 of the Loan Agreement, the Borrower shall make the required repayment of principal, together with accrued interest from the date of disbursement of the Loan proceeds through the date of repayment, within 90 days after the Borrower receives written demand for payment from the Lender.
  - (e) December 31, 2012. If as of December 31, 2012:
- (i) The Borrower is required to repay the full amount of the Loan under Section 6.01 of the Loan Agreement, the Borrower shall repay the entire principal amount of the Loan, together with accrued interest from the date of disbursement of the Loan proceeds through the date of repayment, within 90 days after the Borrower receives written demand for payment from the Lender.

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- (ii) The Borrower is required to repay any part of the Loan as provided in Section 6.02 of the Loan Agreement, the Borrower shall make the required repayment of principal, together with accrued interest from the date of disbursement of the Loan proceeds through the date of repayment, within 90 days after the Borrower receives written demand for payment from the Lender.
- (iii) There remains any outstanding principal balance of the Loan, after determining whether any repayment is required under subsections (e)(i) or (ii) above, the Lender will forgive the outstanding principal balance of the Loan which is not subject to repayment as provided in Section 6.03 of the Agreement.
- (f) This Note may be subject to multiple maturity dates. The date on which any payment of principal under this Note is due under the terms above shall be a "Maturity Date". On a Maturity Date, the Borrower shall pay the portion of the then remaining principal balance that is subject to repayment, related accrued and unpaid interest and any other amounts outstanding under the Financing Documents (as defined in the Agreement) that are related to the portion of principal which is due.
- (g) The Lender shall have no obligation to defer any amounts due under this Note or to forgive any amounts if the Borrower is in Default under the terms of this Note or Section 4.01 of the Agreement.
- 4. <u>Late Payment Charge</u>. If any payment due hereunder is not received by the Lender within 15 calendar days after its due date, the Department may require the Borrower to pay a late payment charge equal to five percent of the amount then due.

#### 5. Application of Payments.

- (a) <u>Scheduled Payments</u>. All scheduled payments made pursuant to this Note shall be applied first to accrued interest, then to principal, and then to late payments, charges or other sums owed to the Lender, or in any other manner that the Lender, in its sole discretion, may determine.
- (b) <u>Prepayments</u>. The Lender may apply any prepayment, whether voluntary or involuntary, first to late charges and fees, then to accrued interest and default interest, and then to principal in the inverse order of scheduled maturities, or in any other manner that the Lender, in its sole discretion, may determine.
  - 6. Prepayment. The Borrower may prepay all or part of this Note at any time without premium or penalty.
- 7. <u>Place of Payment</u>. All payments due under this Note, and all prepayments, shall be delivered to: Department of Business and Economic Development, P.O. Box 41429, Baltimore, MD 21203-6429, or to any other place that the Lender may designate in writing, and shall be made in immediately available funds in a manner acceptable to the Lender.

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- 8. Default. The occurrence of any of the following events shall constitute a default (a "Default") under the terms of this Note:
  - (a) The failure of the Borrower to pay the Lender when due any amounts payable by the Borrower to the Lender under the terms of this Note; or
- (b) The occurrence of a default under the terms of the Loan Agreement or any of the other Financing Documents (as defined in the Loan Agreement), which default remains uncured beyond any applicable grace or cure period.
- 9. Acceleration. Upon a Default, the Lender, in its sole discretion and without further notice or demand, may declare the entire unpaid principal balance of this Note plus accrued interest and all other sums due under this Note to be immediately due and payable and may exercise any rights and remedies available under any of the Financing Documents.
- 10. Confession of Judgment. Upon a Default, the Borrower authorizes the clerk or any attorney of any court of record' to appear for it and enter judgment by confession, without prior notice or opportunity for prior hearing for the principal balance then outstanding under this Note, together with interest, court costs, and the attorneys' fees equal to the amount specified in Section 14 below. The Borrower waives and releases, to the extent permitted by law, all errors and all rights of exemption, appeal, stay of execution, inquisition, and extension upon any levy on real estate or personal property to which the Borrower may otherwise be entitled under any current or future law of the United States of America or of any state or possession of the United States of America. The authority to appear for and enter judgment against the Borrower may be exercised on one or more occasions, and shall not be extinguished by any judgment entered pursuant thereto. This authority may be exercised in the same or different jurisdictions, as often as the Lender determines to be necessary or desirable.
- 11. Consent to Jurisdiction. The Borrower irrevocably submits to the jurisdiction of any state or federal court sitting in the State of Maryland over any proceeding arising out of, or relating to, this Note. The Borrower irrevocably waives, to the fullest extent permitted by law, any objection that the Borrower may now or hereafter have to the setting of venue of any proceeding brought in any such court and any claim that any proceeding brought in any such court was brought in an inconvenient forum.
- 12. Service of Process. The Borrower hereby consents to process being served in any proceeding instituted in connection with this Note by (i) the mailing of a copy thereof by certified mail, postage prepaid, return receipt requested, to the Borrower at the address listed in Section 5.01 of the Loan Agreement and (ii) serving a copy thereof upon CSC-Lawyers Incorporated Service Company, the agent designated by the Borrower as its agent for service of process. The Borrower irrevocably agrees that the service specified herein shall be deemed to be service of process upon the Borrower in any proceeding. Nothing in this Note shall affect the Lender's right to serve process in any other manner permitted by law.

#### MEDAFF BioSolutions Note October 14, 2004

- 13. Notices. Any notice or other communication to the Borrower or the Lender shall be deemed properly given when delivered in accordance with Section 5.01 of the Loan Agreement.
- 14. Expenses of Collection. If this Note is referred to an attorney for collection after a Default, the Borrower shall pay all costs of collection, including attorneys' fees equal to 15% of the sum of the principal balance then outstanding and interest then due hereunder.
- 15. <u>Subsequent Holder</u>. The Lender may pledge, transfer, or assign this Note and its rights under the Financing Documents. Any pledge, transfer, or assignment of rights shall also apply to any renewals, extensions or modifications. A transferee, pledgee, or assignee shall have the same rights as the Lender hereunder with respect to this Note.
  - 16. Waiver of Protest. The Borrower, and all parties to this Note, whether maker, endorser, or guarantor waives presentment, notice of dishonor and protest.
  - 17. Choice of Law; Modifications; Cumulative Rights; Extensions of Maturity.
- (a) The Borrower acknowledges that the Lender is a principal department of the State of Maryland, that final credit decisions with respect to the making of the Loan are made in Maryland and, that those credit decisions assume that the substantive laws of Maryland apply. Therefore, the Borrower agrees that this Note shall be governed by the laws of the State of Maryland.
- (b) No modification or amendment of this Note shall be effective unless in writing signed by the Lender and the Borrower, and any modification or amendment shall apply only with respect to the specific instance involved.
  - (c) No waiver of any provision of this Note shall be effective unless in writing signed by the Lender. Any waiver shall apply only with respect to the specific instance involved.
- (d) By accepting partial payment of any amount due and payable under this Note, the Lender does not waive the right either to require prompt payment when due of all other amounts due and payable under this Note or to exercise any rights and remedies available to it in order to collect all other amounts due and payable under this Note.
- (e) Each right, power, and remedy of the Lender under this Note or under law shall be cumulative and concurrent, and the exercise of any one of them shall not preclude the simultaneous or later exercise by the Lender of any other.
- (f) No failure or delay by the Lender to insist upon the strict performance of any provision of this Note or to exercise any right, power, or remedy consequent upon a breach thereof shall constitute a waiver thereof, or preclude the Lender from exercising any such right, power, or remedy.

### MEDAFF BioSolutions Note

October 14, 2004

- 18. <u>Illegality</u>. If any provision of this Note is found to be invalid, illegal, or unenforceable in any respect, the invalidity, illegality, or unenforceability shall not affect any other provision of this Note, but this Note shall be construed as if the invalid, illegal, or unenforceable provision had never been part of this Note, but only to the extent it is invalid, illegal, or unenforceable.
  - 19. Security. The repayment of the Loan evidenced by this Note is secured as set forth in the Loan Agreement.
  - 20. Conflicts. In the event of a conflict between the terms of this Note and the terms of the Loan Agreement, the terms of the Loan Agreement shall prevail.

IN WITNESS WHEREOF, and intending to be legally bound hereby, the undersigned executes this Note under seal as Borrower as of the date written at the beginning of this Note.

ATTEST: BORROWER:

### ADVANCED BIOSOLUTIONS, INC.

/s/ Jose Ochoa By: /s/ Y. Fuad El-Hibri (SEAL)
Name: Jose Ochoa Name: Y. Fuad El-Hibri

Title: President

### STATE OF MARYLAND, CITY/COUNTY OF MONTGOMERY, TO WIT:

I HEREBY CERTIFY that on this 15th day of October, 2004, before me, a Notary Public in the State of Maryland, personally appeared Y. Fuad El-Hibri, who acknowledged himself/herself to be the President of Advanced BioSolutions, Inc., known or satisfactorily proven to me to be the person whose name is subscribed to this document, and acknowledged that she/he executed it on behalf of Advanced BioSolutions, Inc., as its duly authorized President.

AS WITNESS my hand and Notarial Seal.

/s/ Catherine C. Lynch Notary Public

My Commission expires: October 30, 2004

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

016 - FTWM

### Fifth Third Bank

Term Note

OFFICER No. 04244 \$2,400,000,00 NOTE No. **0904879830- August 10, 2004**(Effective Date)

1. PROMISE TO PAY. On or before September 1, 2007 (the "Maturity Date"), the undersigned, Bioport Corporation, a Michigan corporation located at 3500 North Martin Luther King Jr. Boulevard, Lansing, Ingham County, Michigan 48906 ("Borrower") for value received, hereby promises to pay to the order of Fifth Third Bank (Western Michigan), a Michigan banking corporation located at 111 Lyon Street, NW, Grand Rapids, Kent County, Michigan 49503 for itself and as agent for any affiliate of Fifth Third Bancorp (together with its successors and assigns, the "Lender") the sum of Two Million Four Hundred Thousand and 00/100 Dollars (\$2,400,000.00) (the "Borrowing"), plus interest as provided herein, less such amounts as shall have been repaid in accordance with this Note. The outstanding balance of this Note shall appear on a supplemental bank record and is not necessarily the face amount of this Note, which record shall evidence the balance due pursuant to this Note at any time. As used herein, "Local Time" means the time at the office of Lender specified in this Note.

Principal and interest payments shall be initiated by Lender in accordance with the terms of this Note from Borrower's account through Billpayer 2000®. Borrower hereby authorizes Lender to initiate such payments from Borrower's account located at <u>Fifth Third Bank</u>, routing number [\*\*] account number [\*\*]. Borrower acknowledges and agrees that use of BillPayer 2000® shall be governed by the BillPayer 2000® Terms and Conditions, a copy of which Borrower acknowledges receipt. Borrower further acknowledges and agrees to maintain payments hereunder through BillPayer 2000® throughout the term of this Note. Each payment hereunder shall be applied first to advanced costs, charges and fees, then to accrued interest, and then to principal.

Principal shall be due and payable in 36 monthly installments, twelve installments each in the amount of \$40,000.00 on the 1st day of each calendar month beginning on October 1, 2004; twelve installments each in the amount of \$53,334.00 on the 1st day of each calendar month beginning on October 1, 2005; twelve installments each in the amount of \$106,666.00 on the 1st day of each calendar month beginning on October 1, 2006; provided that the entire principal balance, together with all accrued and unpaid interest and any other charges, advances and fees, if any, outstanding hereunder shall be due and payable in full on the earlier of the Maturity Date or upon acceleration of the Note.

The principal sum outstanding shall bear interest at a floating rate per annum equal to 0.375% less than the rate of interest per annum established from time to time by Fifth Third Bank at its principal office as its "Prime Rate", whether or not Fifth Third Bank shall at times lend to Borrowers at lower rates of interest or, if there is no such prime rate, then such other rate as may be published by Fifth Third Bank for a substitute for the prime rate (the "Interest Rate") upon at least ten (10) days prior written notice to Borrower. In the event of a change in said Prime Rate, the Interest Rate shall be changed immediately to the percentage stated above less than such new Prime Rate. Interest shall be calculated based on a 360-day year and charged for the actual number of days elapsed, and shall be payable on the 1st day of each month beginning on October 1, 2004.

Notwithstanding any provision to the contrary in this Note, in no event shall the interest rate charged on the Borrowing exceed the maximum rate of interest permitted under applicable state and/or federal usury law. Any payment of interest that would be deemed unlawful under applicable law for any reason shall be deemed received on account of, and will automatically be applied to reduce, the principal sum outstanding and any other sums (other than interest) due and payable to Lender under this Note, and the provisions hereof shall be deemed amended to provide for the highest rate of interest permitted under applicable law.

2. <u>SECURITY AGREEMENT.</u> To secure repayment of this Note and all other Obligations (as defined below) together with all modifications, extensions and renewals thereof, Borrower hereby grants Lender a continuing security interest in all right, title and interest of Borrower in and to the following property, whether now owned or hereafter acquired (collectively, the "Collateral"): The Enterprise Resource Planning System described on <u>Schedule A</u> hereto, together with all replacements thereof, insurance or condemnation proceeds thereof, documents related to the installation and operation thereof, all tort or other claims against third parties arising out of damage thereto or destruction thereof, all property received

wholly or partly in trade or exchange therefore, all fixtures related to the installation and operation thereof, all leases thereof, and all rents, revenues, issues, profits and proceeds arising from the sale, lease, license, encumbrance, collection or any other temporary or permanent disposition thereof, or any other interest therein.

Borrower also grants Lender a security interest in all of the Collateral as agent for all affiliates of Fifth Third Bancorp for all Obligations of Borrower to such affiliates. Said security interest shall not be enforced to the extent prohibited by the Truth in Lending Act as implemented by Federal Reserve Regulation Z.

- 3. <u>USE OF PROCEEDS.</u> Borrower certifies that the proceeds of this loan are to be used for business purposes.
- 4. NOTE PROCESSING FEE. Lender may charge, and Borrower agrees to pay on the above Effective Date, a note processing fee in the amount of \$3,000.00.
- 5. REPRESENTATIONS AND WARRANTIES. Borrower hereby warrants and represents to Lender the following:
  - (a) <u>Organization and Qualification</u>. Borrower is duly organized, validly existing and in good standing under the laws of the State of its incorporation, has the power and authority to carry on its business and to enter into and perform all documents relating to this loan transaction, and is qualified and licensed to do business in each jurisdiction in which such qualification or licensing is required, except where the failure to be so qualified would not have a material adverse effect on Borrower's business. All information provided to Lender with respect to Borrower and its operations is true and correct.
  - (b) <u>Due Authorization</u>. Borrower has full power and authority to sign, deliver and perform the Loan Documents. The signing, delivery and performance of the Loan Documents: (1) have been duly authorized by appropriate corporate action of Borrower, (2) will not violate the provisions of Borrower's articles of incorporation or bylaws or of any law, rule, judgment, order, agreement or instrument to which Borrower is a party or by which it is bound and (3) do not require any approval or consent of any public authority or other third party, except for (i) consents and approvals that have been obtained prior to the date hereof; or (ii) approvals or consents, the failure of which to obtain, individually or in the aggregate, do not have a material adverse effect on Borrower and do not materially impair the ability of the Borrower to perform its obligations under the Loan Documents. The Borrower has properly signed and delivered the Loan Documents, and the Loan Documents are the valid and binding obligations of the Borrower and are enforceable against the Borrower in accordance with their terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors and the rules of law governing specific performance, injunctive relief and other equitable remedies.
  - (c) <u>Litigation</u>, Except as disclosed in <u>Schedule B</u>, there are no suits or proceedings pending or threatened against or affecting Borrower, and no proceedings before any governmental body are pending or threatened against Borrower that if determined adversely to Borrower would reasonably be expected to have a material adverse effect on the Borrower's business.
  - (d) <u>Business</u>. Borrower has all requisite corporate power and authority and all necessary licenses and permits to own and operate its properties and to carry on its business as it now conducts it and as it contemplates that it will conduct it in the future. Borrower is in compliance with all laws, rules and regulations that apply to Borrower, its operations or its properties, except where any noncompliance would not have a material adverse effect on Borrower's business.

#### (e) Licenses, etc.

- (i) Borrower owns, jointly owns, or has been licensed the right to use pursuant to licenses that remain in full force and effect Intellectual Property sufficient to operate its business substantially as it is presently being conducted.
- (ii) Except as disclosed in <u>Schedule B</u>, there is no action, suit or proceeding pending against or, to the knowledge of the Borrower, threatened against the Borrower (1) challenging the rights of the Borrower in any Intellectual Property owned or used by Borrower or (2) alleging that products manufactured, used, imported or sold by Borrower conflict with, misappropriate, infringe or violate the Intellectual Property of any third party, except in each case for actions, suits or proceedings the outcome of which individually or in the aggregate would not have a material adverse effect on Borrower's business.

- (f) <u>Laws and Taxes</u>. Borrower is in material compliance with all laws, regulations, rulings, orders, injunctions, decrees, conditions or other requirements applicable to or imposed upon Borrower by any law or by any governmental authority, court or agency, except where any non-compliance would not have a material adverse effect on Borrower's business. Borrower has filed all required tax returns and reports that are now required to be filed by it in connection with any federal, state and local tax, duty or charge levied, assessed or imposed upon Borrower or its assets, including unemployment, social security, and real estate taxes. Borrower has paid all taxes which are now due and payable. No taxing authority has asserted or assessed any additional tax liabilities against Borrower which are outstanding on this date, and Borrower has not filed for any extension of time for the payment of any tax or the filing of any tax return or report.
- (g) <u>Title</u>. Borrower has good and marketable title to the assets reflected on the most recent balance sheet submitted to Lender, free and clear from all liens and encumbrances of any kind, except for (collectively, the "Permitted Liens") (1) a security interest, mortgage or other lien in favor of Lender (2) an existing security interest or lien described on Schedule C attached to this Agreement, (3) the proposed mortgage, security interest or lien on real property described on Scheduled C attached to this Agreement (4) a lien for taxes that are not delinquent or, in a jurisdiction where payment of taxes is abated during the period of any contest, being contested in good faith by appropriate proceedings, if adequate reserves for it have been set aside under GAAP on Borrower's books and (5) an inchoate material men's, mechanics', workmen's, repairmen's or other like lien arising in the ordinary course of business, if the obligation secured is not delinquent or is being contested in good faith by appropriate proceedings, if adequate reserves for it have been set aside under GAAP on Borrower's books.
  - (h) Subsidiaries and Partnerships. Except as set forth on Schedule D. Borrower has no subsidiaries and is not a party to any partnership agreement or joint venture agreement.
- 6. <u>AFFIRMATIVE COVENANTS.</u> Borrower covenants with, and represents and warrants to, Lender that, from and after the execution date of the Loan Documents until the Obligations are paid and satisfied in full:
  - (a) Financial Statements. Borrower shall maintain a standard and modern system for accounting and shall furnish to Lender:
    - (i) Within 20 days after the end of each month, a copy of Borrower's internally prepared unaudited consolidated financial statements for that month and for the year to date in a form as is customarily prepared by Borrower, prepared and certified as complete and correct, subject to changes resulting from year-end adjustments, by the principal financial officer of Borrower.
    - (ii) Within 20 days after the end of each calendar quarter, a copy of Borrower's accounts receivable aging report for that quarter and for the year to date in a form, as is customarily prepared by Borrower, prepared and certified as complete and correct, subject to changes resulting from year-end adjustments, by the principal financial officer of Borrower;
    - (iii) Within 120 days after the end of each fiscal year, a copy of Borrower's financial statements audited by a firm of independent certified public accountants acceptable to Lender (which acceptance shall not be unreasonably withheld) and accompanied by an audit opinion of such accountants without qualification;
    - (iv) With the statements submitted above, a certificate signed by the principal financial officer of Borrower, (i) stating he is familiar with all documents relating to Lender and that no Event of Default specified herein, nor any event which upon notice or lapse of time, or both would constitute such an Event of Default, has occurred, or if any such condition or event existed or exists, specifying it and describing what action Borrower has taken or proposes to take with respect thereto, and (ii) setting forth, in summary form, figures showing the financial status of Borrower in respect of the financial restrictions contained herein;
    - (v) Immediately upon any executive officer of Borrower obtaining knowledge of any condition or event which constitutes or, after notice or lapse of time or both, would constitute an Event of Default, a certificate of such person specifying the nature and period of the existence thereof, and what action Borrower has taken or is taking or proposes to take in respect thereof;

All of the statements referred to in (i), (ii) and (iii) above shall be in conformance with generally accepted accounting principles and give representatives of Lender access thereto at all reasonable times, including permission to examine, copy and make abstracts from any such books and records solely for the purpose of evaluating the status of the loan and such other information which might be helpful to Lender in evaluating the status of the loans as it may reasonably request from time to time.

With all financial statements delivered to Lender as provided in (i), (ii) and (iii) above, Borrower shall deliver to Lender a Financial Statement Compliance Certificate in addition to the other information set forth therein, which certifies the Borrower's compliance with the financial covenants set forth herein and that no Event of Default has occurred.

If at any time Borrower has any additional subsidiaries which have financial statements that are required to be consolidated with those of Borrower under generally accepted accounting principles, the financial statements required by subsections (i), (ii) and (iii) above shall be the financial statements of Borrower and all such subsidiaries prepared on a consolidated and consolidating basis.

- (b) <u>Condition and Repair.</u> Borrower shall maintain its equipment and all Collateral used in the operation of its business in good repair and working order and shall make all appropriate repairs, and replacements thereof.
- (c) Insurance. At its own cost, Borrower shall obtain and maintain insurance against (a) loss, destruction or damage to its properties and business of the kinds and in the amounts customarily insured against by corporations with established reputations engaged in the same or similar business as Borrower and, in any event, sufficient to fully protect Lender 's interest in the Collateral, and (b) insurance against public liability and third party property damage of the kinds and in the amounts customarily insured against by corporations with established reputations engaged in the same or similar business as Borrower. All such policies shall (i) be issued by financially sound and reputable insurers, (ii) name Lender as an additional insured and, where applicable, as loss payee under a Lender loss payable endorsement satisfactory to Lender , and (iii) shall provide for thirty (30) days written notice to Lender before such policy is altered or canceled. All of the insurance policies required hereby shall be evidenced by one or more Certificates of Insurance delivered to Lender by Borrower on the Closing Date and at such other times as Lender may request from time to time.
- (d) <u>Taxes</u>. Borrower shall pay when due all taxes, assessments and other governmental charges imposed upon it or its assets, franchises, business, income or profits before any penalty or interest accrues thereon, and all claims (including, without limitation, claims for labor, services, materials and supplies) for sums which by law might be a lien or charge upon any of its assets, provided that (unless any material item or property would be lost, forfeited or materially damaged as a result thereof) no such charge or claim need be paid if it is being diligently contested in good faith, if Lender is notified in advance of such contest and if Borrower establishes an adequate reserve or other appropriate provision required by generally accepted accounting principles.
- (e) Compliance with Laws. Borrower shall comply with all federal, state and local laws, regulations and orders applicable to Borrower or its assets including but not limited to all Environmental Laws, in all respects material to Borrower's business or assets and shall immediately notify Lender of any violation of any rule, regulation, statute, ordinance, order or law relating to the public health or the environment and of any complaint or notifications received by Borrower regarding to any environmental or safety and health rule, regulation, statute, ordinance or law. Borrower shall obtain and maintain any and all licenses, permits, franchises, governmental authorizations and as may be required from time to time by applicable law for the conduct of its business except where failure would not have a material adverse effect on Borrower's business.
- (f) <u>Depository/Banking Services</u>. Lender shall be a principal depository in which Borrower's funds are deposited, and a principal bank of account of Borrower, as long as any Obligations are outstanding.
- (g) Other Amounts Deemed Loans. If Borrower fails to pay any tax, assessment, governmental charge or levy or to maintain insurance within the time permitted or required by this Note, or to discharge any Lien prohibited hereby, or to comply with any other Obligation, Lender may, but shall not be obligated to, pay, satisfy, discharge or bond the same for the account of Borrower. To the extent permitted by law and at the option of Lender, all monies so paid by Lender on behalf of Borrower shall be deemed Obligations and Borrower's payments under this Note may be increased to provide for payment of such Obligations plus interest thereon.
- (h) <u>Further Assurances</u>. Borrower shall execute, acknowledge and deliver, or cause to be executed, acknowledged or delivered, any and all such further assurances and other agreements or instruments, and take or cause to be taken all such other action, as shall be reasonably necessary from time to time to give full effect to the Loan Documents and the transactions contemplated thereby.
- 7. <u>DEFINITIONS.</u> Certain capitalized terms have the meanings set forth on any exhibit hereto, in the Security Agreement, if applicable, or any other Loan Document. All financial terms used herein but not defined on the exhibits, in the Security Agreement, if applicable or any other Loan Document have the meanings given to them by generally accepted

accounting principles. All other undefined terms have the meanings given to them in the Uniform Commercial Code as adopted in the state whose law governs this instrument. The following definitions are used herein:

- (a) "Affiliate" means, as to Borrower, (a) any person or entity which, directly or indirectly, is in control of, is controlled by or is under common control with, Borrower, or (b) any person who is a director, officer or employee (i) of Borrower or (ii) of any person described in the preceding clause (a).
- (b) "Lien" means any security interest, mortgage, pledge, assignment, lien or other encumbrance of any kind, including interests of vendors or lessors under conditional sale contracts or capital leases, but shall exclude (a) a lien for taxes that are not delinquent or, in a jurisdiction where payment of taxes is abated during the period of any contest, being contested in good faith by appropriate proceedings, if adequate reserves for it have been set aside under GAAP on Borrower's books and (b) an inchoate material men's, mechanics', workmen's, repairmen's or other like lien arising in the ordinary course of business, if the obligation secured is not delinquent or is being contested in good faith by appropriate proceedings, if adequate reserves for it have been set aside under GAAP on Borrower's books.
- (c) "Loan Documents" means any and all Rate Management Agreements and each and every document or agreement executed by any party evidencing, guarantying or securing any of the Obligations; and "Loan Document" means anyone of the Loan Documents.
- (d) "Obligation(s)" means all loans, advances, indebtedness and each and every other obligation or liability of Borrower owed to each of Lender and/or any affiliate of Fifth Third Bancorp, created pursuant to this Note, of every kind and description whether now existing or hereafter arising and whether direct or indirect, primary or as guarantor or surety, absolute or contingent, liquidated or unliquidated, matured or unmatured, whether or not secured by additional collateral, and including, without limitation, all loans, advances, indebtedness and each and every obligation or liability arising under this Note, any and all Rate Management Obligations (as defined in the Loan Documents), all obligations to perform or forbear from performing acts, and agreements, instruments and documents evidencing, guarantying, securing or otherwise executed in connection with any of the foregoing, together with any amendments, modifications and restatements thereof.
- (e) "Rate Management Agreement" means any agreement, device or arrangement providing for payments which are related to fluctuations of interest rates, exchange rates, forward rates, or equity prices, including, but not limited to, dollar-denominated or cross- currency interest rate exchange agreements, forward currency exchange agreements, interest rate cap or collar protection agreements, forward rate currency or interest rate options, puts and warrants, and any agreement pertaining to equity derivative transactions (e.g., equity or equity index swaps, options, caps, floors, collars and forwards), including without limitation any ISDA Master Agreement between Borrower and Lender or any affiliate of Fifth Third Bancorp, and any schedules, confirmations and documents and other confirming evidence between the parties confirming transactions thereunder, all whether now existing or hereafter arising, and in each case as amended, modified or supplemented from time to time.
- (f) "Rate Management Obligations" means any and all obligations of Borrower to Lender or any affiliate of Fifth Third Bancorp, whether absolute, contingent or otherwise and howsoever and whensoever (whether now or hereafter) created, arising, evidenced or acquired (including all renewals, extensions and modifications thereof and substitutions therefore), under or in connection with (i) any and all Rate Management Agreements, and (ii) any and all cancellations, buy backs, reversals, terminations or assignments of any Rate Management Agreement.
- 8. EVENTS OF DEFAULT. Upon the occurrence of any of the following events (each, an "Event of Default") not cured within 30 days (unless some other cure period is provided below) from written, notice of default, Lender may at its option declare this Note and all Obligations to be fully due and payable in their aggregate amount, together with accrued interest and all prepayment premiums, fees, and charges applicable thereto:
  - (a) Any failure to make any payment when due of principal or accrued interest on this Note or any other Obligation and such nonpayment remains uncured for a period of 10 days following written notice thereof.
  - (b) Any representation or warranty of Borrower set forth in this Note or in any agreement, instrument, document, certificate or financial statement evidencing, guarantying, securing or otherwise related to, this Note or any other Obligation shall be materially inaccurate or misleading when made.
  - (c) Borrower shall fail to observe or perform any other term or condition of this Note or any other term or condition set forth in any agreement, instrument, document, certificate or financial statement evidencing, guarantying or otherwise related to this Note or any other Obligation, or Borrower shall otherwise default in the observance or performance of any covenant or agreement set forth in any of the foregoing for a period of 30 days.

- (d) Any failure to submit to Lender current financial information upon request where such failure is not cured within thirty (30) days following written notice.
- (e) The creation of any Lien (except for Permitted Liens) on, the institution of any garnishment proceedings by attachment, levy or otherwise against, the entry of a final order of judgment (following all appeals) against, or the seizure of, any of the property of Borrower in an amount in excess of five million dollars (\$5,000,000) which judgment seizure or proceeding is not resolved in favor of Borrower within ninety (90) days thereafter.
- (f) In the judgment of Lender, any material adverse change occurs in the existing or prospective financial condition of Borrower that may affect the ability of Borrower to repay the Obligations, or the Lender deems itself insecure.
- (g) A commencement by the Borrower or any endorser or guarantor of the Obligations of a voluntary case under any applicable bankruptcy, insolvency or other similar law now or hereafter in effect; or the entry of a decree or order for relief in respect of the Borrower or any endorser or guarantor of the Obligations in a case under any such law or appointing a receiver, liquidator, assignee, custodian, trustee, sequestrator (or other similar official) of the Borrower or any endorser or guarantor of the Obligations, or for substantially all of the property of Borrower or any endorser or guarantor of the Obligations, or ordering the wind-up or liquidation of the affairs of Borrower or any endorser or guarantor of the Obligations; or the filing and pendency for 30 days without dismissal of a petition initiating an involuntary case under any such bankruptcy, insolvency or similar law; or the making by Borrower or any endorser or guarantor of the Obligations of any general assignment for the benefit of creditors; or the failure of the Borrower or any endorser or guarantor of the Obligations generally to pay its debts as such debts become due; or the taking of action by the Borrower or any endorser or guarantor of the Obligations in furtherance of any of the foregoing.
- (h) Nonpayment by the Borrower of any Rate Management Obligation when due or the breach by the Borrower of any term, provision or condition contained in any Rate Management Agreement in each case not cured within ten (10) days following written notice thereof.
  - (i) Any sale, conveyance or transfer of any rights in the Collateral securing the Obligations, or any destruction, loss or damage of or to a material portion of the Collateral.
- 9. <u>REMEDIES.</u> In addition to any other remedy permitted by law, Lender may at any time, without notice, apply the Collateral to this Note or such other Obligations, whether due or not, and Lender may, at its option, proceed to enforce and protect its rights by an action at law or in equity or by any other appropriate proceedings; provided that this Note and the Obligations shall be accelerated automatically and immediately if the Event of Default is a filing under the Bankruptcy Code. Notwithstanding any other legal or equitable rights of Lender, Lender, in the Event of Default, is (a) hereby irrevocably appointed and constituted attorney-in-fact, coupled with an interest, with full power of substitution, to exercise all rights of ownership with respect to the Collateral including, but not limited to, the right to collect all income or other distributions arising therefrom; and (b) is hereby given full power to collect, sell, assign, transfer and deliver all of said Collateral or any part thereof, or any substitutes therefore, or any additions thereto, through any private or public sale without either demand or notice to Borrower, or any advertisement, the same being hereby expressly waived, to the extent permitted by law, at which sale Lender is authorized to purchase said property or any part thereof, free from any right of redemption on the part of Borrower, which is hereby expressly waived and released. In case of sale for any cause, after deducting all costs and expenses of every kind, Lender may apply, as it shall deem proper, the residue of the proceeds of such sale toward the payment of anyone or more or all of the Obligations of Borrower, whether due or not due, to Lender; after such application and the return of any surplus, Borrower agrees to be and remains liable to Lender for any and every deficiency after application as aforesaid upon this and any other Obligation. Borrower shall pay all costs of collection incurred by Lender, including its reasonable attorney's fees, if this Note is referred to

If this Note is placed in the hands of attorneys for collection or is collected through any legal proceedings, Borrower promises and agrees to pay, in addition to the principal, interest and other sums due and payable hereon, all costs of collecting or attempting to collect this Note, including all reasonable attorneys' fees and disbursements.

Lender's rights and remedies hereunder are cumulative, and may be exercised together, separately, and in any order. No delay on the part of Lender in the exercise of any such right or remedy shall operate as a waiver. No single or partial exercise by Lender of any right or remedy shall preclude any other further exercise of it or the exercise of any other right or remedy. No waiver or indulgence by Lender of any Event of Default shall be effective unless in writing and signed by Lender, nor shall a waiver on one occasion be construed as a waiver of any other occurrence in the future.

- 10. <u>LATE PAYMENTS: DEFAULT RATE: FEES.</u> If any payment is not paid when due (whether by acceleration or otherwise) or within 10 days thereafter, undersigned agrees to pay to Lender a late payment fee as provided for in any loan agreement or 5% of the payment amount, whichever is greater with a minimum fee of \$20.00. After an Event of Default, Borrower agrees to pay to Lender a fixed charge of \$25.00, or Borrower agrees that Lender may, without notice, increase the Interest Rate by 6% (the "Default Rate"), whichever is greater. Lender may impose a non-sufficient funds fee for any check that is presented for payment that is returned for any reason. In addition, Lender may charge loan documentation fees as may be reasonably determined by the Lender.
- 11. <u>PREPAYMENT.</u> Borrower may prepay all or part of this Note without penalty or additional fees or charges, which prepaid amounts shall be applied to the amounts due in reverse order of their due dates. Partial prepayments shall not excuse any subsequent payment due.
  - 12. ENTIRE AGREEMENT. Borrower agrees that there are no conditions or understandings which are not expressed in this Note and the documents referred to herein.
  - 13. SEVERABILITY. The declaration of invalidity of any provision of this Note shall not affect any part of the remainder of the provisions.
- 14. <u>ASSIGNMENT.</u> Borrower agrees not to assign any of Borrower's rights, remedies or obligations described in this Note without the prior written consent of Lender, which consent may be withheld in Lender's sole discretion. Borrower agrees that Lender may assign some or all of its rights and remedies described in this Note without notice to, or prior consent from, the Borrower.
- 15. MODIFICATION' WAIVER OF LENDER. The modification or waiver of any of Borrower's obligations or Lender's rights under this Note must be contained in a writing signed by Lender. Lender may perform Borrower's obligations, or delay or fail to exercise any of its rights or remedies, without causing a waiver of those obligations or rights. A waiver on one occasion shall not constitute a waiver on another occasion. Borrower's obligations under this Note shall not be affected if Lender amends, compromises, exchanges, fails to exercise, impairs or releases the Collateral or any other property securing the Obligations.
- 16. <u>WAIVER OF BORROWER</u>. Demand, presentment, protest and notice of dishonor, notice of protest and notice of default are hereby waived by Borrower, and any endorser or guarantor hereof. Borrower, hereby waives all suretyship defenses including but not limited to all defenses based upon impairment of Collateral and all suretyship defenses described in Section 3-605 of the Uniform Commercial Code (the "UCC"). Such waiver is entered to the full extent permitted by Section 3-605 (i) of the UCC.
- 17. GOVERNING LAW CONSENT TO JURISDICTION. This Note is delivered in, is intended to be performed in, will be construed and enforceable in accordance with and governed by the internal laws of, the State of Michigan, without regard to principles of conflicts of law. Borrower agrees that the state and federal courts in the County where the Lender is located shall have exclusive jurisdiction over all matters arising out of this Note, and that service of process in any such proceeding shall be effective if mailed to Borrower at the address set forth herein.
- 18. <u>JURY WAIVER.</u> BORROWER, AND ANY ENDORSER OR GUARANTOR HEREOF, WAIVE THE RIGHT TO A TRIAL BY JURY OF ANY MATTERS ARISING OUT OF THIS NOTE OR THE TRANSACTIONS CONTEMPLATED HEREBY.

IS NOTE ON THE TRANSACTIONS CONTENT LATED HEREDT.	
	BORROWER:
	Bioport Corporation, a Michigan corporation
	/s/ Michael A. Zamiara
	(Authorized Signer)
	Michael A. Zamiara, Chief Financial Officer
	(Print Name and Title)
	By: /s/ Scott Heibeck
	(Authorized Signer)
	Scott Heibeck, Associate Director of Finance
	(Print Name and Title)

## Schedule A Description of Enterprise Resource Planning System

The Enterprise Resource Planning (ERP) System is system that integrates departments and functions across the Organization and automates tasks involved in performing business processes. The ERP system was licensed from SAP, the world's largest enterprise software manufacturer, is supported with specific hardware primarily purchased from Dell, and was implemented using Clarkston Consulting Company.

### Schedule B Pending Litigation

- 1) Bates, et al., v. Rumsfeld, et al., Case No. 01CV00941, United States District Court for the District of Columbia (filed May 2, 2001; dismissed May 30, 2002).
- 2) Doe #1, et al. v. Rumsfeld, et al., Case No. 1:03-CV-00707-EGS, United States District Court for the District of Columbia (filed March 18, 2003; BioPort is not a party in this case).
- 3) Ammend, et. al. v. BioPort, Inc., et. al., Case No. 5:03-CV-031, United States District Court for the Western District of Michigan (filed March 21, 2003); Rugo et. al. v. BioPort, Corporation, et al., Case No. 1:01CV02190, United States District Court for the District of Columbia (filed October 19, 2001, and subsequently dismissed without prejudice and refiled in the Western District of Michigan as Ammend); Bonasse, et al. v. BioPort, et al., Case No. 02-CV-00880, United States District Court for the District of Columbia (filed May 7, 2002, and subsequently dismissed without prejudice and refiled in the Western District of Michigan as Ammend; Lahiff, et al. v. BioPort, et. al., Case No. 02-CV-01945 United States District Court for the District of Columbia (filed October 2, 2002, and subsequently dismissed without prejudice and refiled in the Western District of Michigan under Ammend).
- 4) Allaire, et al. v. BioPort Corporation, et al., Case No. 02-CV-00248 United States District Court for the District of Columbia, (filed February 7, 2002, and subsequently transferred to the United States District Court for the Western District of Michigan, Case No. 1:03CV254).
- 5) Fleming et. al v. BioPort, et. al., Case No. 3:03CV0581, United States District Court for the Western District of Louisiana (filed March 27, 2003 and transferred to the Western District of Michigan and consolidated with Ammend).
- 6) Suk v. BioPort Corporation, et al., Civil Action No. 03CV2610, United States District Court for the District of New Jersey (filed May 30, 2003, and transferred to the Western District of Michigan and consolidated with Ammend).
- 7) United States ex. rel. Dingle and Rempfer v. BioPort et al., Case No. 5:00-CV-124, United States District Court for the Western District of Michigan (filed October 10, 2000; case dismissed June 18, 2003, on appeal to the United States Court of Appeal for the Sixth Circuit).
- 8) Counter, et al. v. Abbott Laboratories, et al., Case No. 15285 BHO1, Brazoria County, Texas (filed May 7, 2001, dismissed on August 2, 2001); Reyna v American Home Products, Case No. C-557-02-F, Hidalgo County, Texas (removed to the United States District Court for the Southern District of Texas, Case No. M-02-366, on August 19, 2002); and Rosello v American Home Products, Case No. C-1590-03-F, Hidalgo County, Texas (filed August 27, 2003 and removed to the United States District Court for the Southern District of Texas, Case No. M-03-CV-259, on September 19, 2003) (the plaintiffs in these cases all voluntarily dismissed BioPort).
- 9) Collins v. American Home Products, et al., Case No. 3:01CV979LN, United States District Court for the Southern District of Mississippi (filed December 17, 2001; dismissed August 2, 2002; on appeal to the United States Court of Appeals for the Fifth Circuit).
- 10) Stewart v. American Home Products, et. al., Case No. 3:02CV427LN, United States District Court for the Southern District of Mississippi (filed May 1, 2002; dismissed August 2, 2002; on appeal to the United States Court of Appeals for the Fifth Circuit).
- 11) Ray v. American Home Products, et. al., Case No. 2002-0276 CICI, Sunflower County, Mississippi (filed December 31, 2002, and removed to United States District Court for the Northern District of Mississippi, Case No. 4:03CV265PB on May 5, 2003, stay issued on October 10, 2003; and Case No. 4:03CV263PB on May 19, 2003, stay issued on December 1, 2003).

- 12) Alexander, as next friend, et al. v. American Home Products Corporation, et al., No. 2002-0761, Sunflower County, Mississippi (filed December 31, 2002, and removed to United States District Court for the Northern District of Mississippi, Case No. 4:03CV261EMB on May 19, 2003, stay issued on December 1, 2003).
- 13) Alexander, et al. v. American Home Products Corporation, et al., No. 2002-0763, Sunflower County, Mississippi (filed December 31, 2002, and removed to United States District Court for the Northern District of Mississippi, Case No. 4:03CV262PB on May 19, 2003, stay issued on October 10, 2003).
- 14) Guyton, et al., v. American Home Products, et. al., Case No. 2002-0394, Madison County, Mississippi (filed December 31, 2002, and removed to United States District Court for the Northern District of Mississippi, Case No. 3:03CV704LN on May 19, 2003, stay issued on October 10, 2003).
- 15) Keys, et al., v. American Home Products, et. al., Case No. 2:03CV300PG, United States District Court for the Southern District of Mississippi (filed May 19, 2003; stay issued on July 9, 2004).
- 16) Townsend, et al., v. American Home Products, et. al., Case No. 2:03-CV-302-PG,
- United States District Court for the Southern District of Mississippi (filed May 19, 2003).
- 17) Del Rio, et al., v. American Home Products, et. al., Case No. 2:03-CV-301-PG, United States District Court for the Southern District of Mississippi (filed May 19, 2003; stay issued on July 9, 2004).
- 18) Hutchenson, et al. v. American Home Products Corporation, et al., No. 2002-0765, Sunflower County, Mississippi (filed December 31, 2002; removed to United States District Court for the Northern District of Mississippi, Case No. 4:03CV264PB on May 20, 2003, stay issued on December 1, 2003).
- 19) King, as next friend, et al., v. American Home Products Corporation, et al., Case No. 2002-188, Bolivar County, Mississippi (filed December 31, 2002, removed to United States District Court for the Northern District of Mississippi, Case No. 2:03CV188PB on May 19, 2003, stay issued on November 28, 2003).
- 20) King, et al., v. American Home Products Corporation, et al., No. 2002-187, Bolivar County, Mississippi (filed December 31, 2002; removed to United States District Court for the Northern District of Mississippi, Case No. 2:03CV187PB on May 19, 2003, stay issued on November 28, 2003)
- 21) Schmuck v. Abbott Laboratories, et al., Case No. BC 2552268, Los Angeles, California (filed August 1, 2001, and consolidated with Allen v. Abbott Laboratories, Case No. 02CC00108 Orange County, California (filed April 26, 2002) and Werley v. Abbott Laboratories, Case No. 787422, San Diego County, California (filed April 25, 2002)).
- Cases filed in Madison County, Illinois:
  - a) Goodman v. Abbott Laboratories, et al., Case No 02-L-641 (filed May 7, 2002);
  - b) Livi v. Abbott Labs, et al., Case No. 02-L-643 (filed April 30, 2002);
  - c) Hornstein v. Abbott Laboratories, et al., Case No. 02-L-642 (filed May 7, 2002);
  - d) Delghingaro v. Abbott Laboratories, Case No. 02-L-1344 (filed September 30, 2002);
  - Gabor v. Abbott Laboratories, Case No. 02-L-1345 (filed September 30, 2002); e)
  - Robinson v. Abbott Laboratories. Case No. 02-L-1346 (filed September 30, 2002): f)
  - Howard v. Abbott Laboratories, Case No. 02-L-1487 (filed November 4, 2002); g)
  - h) Trocke v. Abbott Laboratories, Case No. 02-L-1486 (filed November 4, 2002);
  - Curia (Christopher) v. Abbott Laboratories, Case No. 02-L-1593 (filed December 2, 2002); i)
  - j) Mahnke v. Abbott Laboratories, Case No. 02-L-1594 (filed December 12, 2002);
  - Barkwell v. Abbott Laboratories, Case No. 02-L-845 (filed June 13, 2002); k
  - l) Choate v. Abbott Laboratories, Case No. 02-L-844 (filed June 13, 2002);
  - Conrick v. Abbott Laboratories, Case No. 02-L-843 (filed June 13, 2002); m)
  - Curia v. Abbott Laboratories, Case No. 02-L-842 (filed June 13, 2002); n)
  - Guinn v. Abbott Labs, Case No. 02-L-841 (filed June 13, 2002); o)
  - p) Owczarzak v. Abbott Laboratories, Case No-L-840 (filed June 13, 2002);
  - Thomason v. Abbott Labs, Case No. 02-L-896 (filed June 26, 2002); q)

- r) Strohbeck v. Abott Laboratories, Case No. 03-L-93 (filed January 27, 2003);
- s) Kramer v. Abbott Labs, Case No. 03-L-670 (filed May 22, 2002);
- t) Zezulak v. Abbott Labs, Case No. 03-L-1175 (filed August 25, 2003);
- u) Spaetzel v. Abbott Labs, Case No. 03-L-1972 (filed December 5, 2003);
- v) Sexton v. Abbott Labs, Case No. 03-L-1971 (filed December 5, 2003);
- w) Weider v. Abbott Labs, Case No. 03-L-1559 (filed November 19, 2003);
- x) Weider (II) v. Abbott Labs, No. 04-L-181 (filed February 23, 2004);
- y) Fredericks v. Abbott Labs, Case No. 03-L-1037 (filed July 23, 2003);
- z) Vaselopulos v. Abbott Labs, No. 03-L-1176 (filed August 25, 2003);
- aa) Villareal v. Abbott Labs, Case No. 04-L-180 (filed February 23, 2004);
- bb) Peterman v. Abbott Labs, Case No. 04-L-0443 (filed April 1, 2004);
- cc) Sumner v. Abbott Labs, Case No. 04-L-442 (filed May 25, 2004);
- dd) Miller (Alan & Kimberly) v. Abbott Labs, et, al., Case No 04-L-443 (filed May 25, 2004);
- ee) Miller (II) v. Abbott Labs, Case No. 04-L-650 (filed June 18, 2004); and

Case filed in Cook County, Illinois:

- ff) Reilly v. Abbott Labs, Case No. 02-L-14697 (filed November 20, 2002).
- 22) Golbitz v. BioPort Corporation, et al., Case No. 02-07799, Court of Common Pleas of Montgomery County, Pennsylvania (filed March 24, 2002; withdrawn May 10, 2002).
- 23) Johnson-Leva v. BioPort Corporation, Case No. 03-2183-NZ, Ingham County, Michigan, (filed December 16, 2003).
- 24) Stevens v. Battelle Memorial Inst., et al., Case No. 010344XXCCAB, Palm Beach County, Florida (removed to United States District Court for the Southern District of Florida, Case No. 04-CV-80253 on March 17, 2004).
- 25) BioPort Corporation v. Elan Pharmaceuticals, Inc. and Athena Neurosciences, Inc. (cross-complainants Elan Pharmaceuticals, Inc. and Athena Neurosciences, Inc. v. BioPort Corporation and The State of Michigan), Case No. CV 423886, County of San Mateo, California (filed June 27, 2002).
- 26) 1997 Notice of Intent to Revoke issued by the U.S. Food and Drug Administration relating to a 1996 team biologics team inspection.

### Schedule C Permitted Liens

Creditor	Description	Unpaid Principal and Interest as of June 30, 2004	Collateral
State of Michigan	Royalty Obligation	3,629,599	none
State of Michigan	Product Donation Obligation	2,236,880	none
	Environmental Remediation		
State of Michigan	Liability	317,051	none
US Dept. of Defense	FAV026 Obligation	970,205	none
US Dept. of Defense	Spare Parts Obligation	429,812	none
Pitney Bowes	Copiers & Fax Machines	103,900	copiers & equipment
	Schedule Numbers:		
	5395546-314		
	5395546-315		
	5395546-316		
	5395546-317		
Ingersol	Bobcat Operating Lease	14,215	Bobcat
GMAC	2002 Chevrolet Minivan	19,708	2002 Chevy Minivan
			2001 Chevy
GMAC	2001 Chevrolet Silverado	558	Silverado
Volkswagon USA	2001 Volksagon Passat	13,816	2001 Passat
GE Capital	Copier Operating Leases	14,210	2 Copiers
	ESOP Stock Repurchase		
BioPort Employees	Obligation	900,061	none
	Antex Building Operating		
Alexandria Real Estate	Lease through 12/1/08	4,320,000	none
	EWR Building Operating		
East West Resources	Sublease through 7/31/05	143,000	none

Any and all covenants, restrictions and easements of record in the land records relating to the Real Property.

### Real Property

#### Clinton County:

A parcel of land in the SE ½ of Section 32, T5N, R2W, Clinton County, Michigan and more particularly described as beginning at the S½ corner of said section 32; thence N00° 12'30"W 2152.16 feet on the N-S ¼ line of said section 32; thence S89° 57'16" E 683.94 feet to the westerly Right-of-Way of Dewitt Road at a point 500.00 feet southerly of the E-W ¼ line of said section 32; thence on the westerly Right-of-Way of DeWitt Road for the next five calls; thence S04 03'50"E 112.68 feet; thence 299.44 feet on the arc of a curve to the left with a central angle of 23 26'19", a radius of 731.99 feet and long chord bearing and distance of S15°47'00"E 297.36 feet; thence S27 30'10"E 927.69 feet; thence 356.62 feet on the arc of a curve to the right with a central angle of 27 41'37", a radius of 737.82 feet and a long chord bearing and distance of S13 39'21"E 353.16 feet; thence S00 11'27" W 30.40 feet; thence S80 7'13"W 171.96 feet; thence S17 13'15"W 128.78 feet; thence S02 36'04"W 161.34 feet; thence N89 59'39"W 420.93 feet; thence S00 07°E 267.69 feet to the south line of said section 32; thence N89 59'49"W 642.45 feet on the south line of said section 32 to the N1/4 corner of section 5, T4N, R2W; thence S89 27'29"W 6.45 feet on the south line of said section 32 to the point of beginning, containing 46.94 acres, more or less.

#### Ingham County:

A parcel of land in the NE 1/4 of section 5, T4N, R2W, Ingham County, Michigan and more particularly described as commencing at the northeast corner of said section 5; thence N89°59'49"W 124.94 feet, on the north line of said section 5; thence S00°00'11"W 33.00 feet, to the point of the beginning of this description; thence S33°12'59"W 315.33 feet; thence N53°08'14"W 101.37 feet; thence S89°11'38"W 47.55 feet; thence S00°42'03"W 63.21 feet; thence S89°45'02"W 73.97 feet; thence S00°59'58"W 106.92 feet; thence 132.16 feet, on the arc of a curve to the right with a central angle of 33°53'13", a radius of 223.46 feet, and a long chord bearing and distance of S22°22'16"W 130.25 feet; thence S59°26'51"W 14.65 feet; thence S77°08'54"W 92.93 feet; thence S88°34'58"W 131.49 feet; thence S01°57'43"E 41.46 feet; thence S88°02'17"W 153.47 feet; thence S01°57'43"E 132.00 feet; thence S88°02'17"W 351.61 feet; to the easterly right of way line of Logan Street; thence N00°28'13"E 716.63 feet, to the southerly right of way line of Sheridan Road; thence S89°59'49"E 1155.21 feet, on said right of way to the point of beginning, containing 12.56 acres. more or less.

#### Frederick County:

Building 1 and associated proposed land condominium unit within that certain parcel of land known as Lot 3 situate and lying in the Dudrow Business Park, Frederick, Maryland, containing approximately 23.68 acres of land, more or less, and further shown and described as Lot 3 on that certain subdivision plat entitled "LOTS 1 & 3, PARKLAND OUTLOT, AND REMAINDER, DUDROW BUSINESS PARK" recorded among the Plat Records of Frederick County, Maryland at Plat Book 57, Page 10

### Schedule D Subsidiaries, Partnerships and Joint Ventures

BioPort Corporation presently holds 100% of the issued and outstanding capital stock of Antex Biologics Inc., Antex Pharma Inc. and Advanced BioSolutions, Inc.

### EXHIBIT A

### Collateral Locations

3500 North Martin Luther King Jr. Boulevard, Lansing, MI 48906

#### LOAN AGREEMENT

THIS LOAN AGREEMENT (this "Agreement") is dated as of April 25th 2006, by and among **EMERGENT FREDERICK LLC**, a Maryland limited liability company, which maintains its chief executive office at 300 Professional Drive, Suite 100, Gaithersburg, Maryland 20879 (the "Borrower"), and **EMERGENT BIOSOLUTIONS INC.**, a Delaware corporation (the "Guarantor") and **HSBC REALTY CREDIT CORPORATION (USA)**, a Delaware corporation (the "Bank").

WHEREAS, the Borrower has applied to the Bank for a Loan of EIGHT MILLION FIVE HUNDRED THOUSAND and No/100 Dollars (\$8,500,000.00) (the "Loan"); and

WHEREAS, the Loan will be of benefit to the Guarantor and the Guarantor desires to induce the Bank to make the Loan by guaranteeing the payment of the Loan; and

WHEREAS, the Bank is willing to make the Loan to the Borrower upon the terms and subject to the conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the foregoing and of the agreements, covenants and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows;

### SECTION 1. DEFINITIONS

As used herein, the following terms, when initial capital letters are used, shall have the respective meanings set forth below. In addition, all terms defined in the Maryland Uniform Commercial Code shall have the meanings given therein unless otherwise defined herein.

1.01 Defined Terms. As used in this Agreement, the following terms shall have the following meanings, unless the context otherwise requires:

"Affiliate" shall mean (a) any entity in which the Borrower legally or beneficially owns or holds, directly or indirectly, any capital stock, membership interest or other equity interest; (b) any person or entity that is a partner in or member of the Borrower or a partnership or limited liability company in which the Borrower is a partner, (c) any person that is a director, officer, member, stockholder (legally or beneficially) or other affiliate of any of the foregoing or of the Borrower; and (d) any person or entity that directly or indirectly controls, is under the control of, or is under common control with, the Borrower, including, without limitation, any person or entity that directly or indirectly has the right or power to direct the management or policies of the Borrower and any person or entity whose management or policies the Borrower directly or indirectly has the right or power to direct.

"Collateral" shall mean the Property and assets of Borrower expressly described in the Deed of Trust.

"Deed of Trust" shall mean the Purchase Money Deed of Trust Assignment of Rents and Leases and Security Agreement, of even date herewith, made and executed by the Borrower for

the benefit of the Bank, as amended, supplemented, restated or modified from time to time, to secure the Note, which Deed of Trust, when recorded, shall create a first lien on the Property.

"Environmental Laws" shall mean all federal, State and local laws, whether now or hereafter enacted, and as amended from time to time, relating to pollution or protection of the environment and the handling of Hazardous Materials; including, without limitation, laws relating to emissions, discharges, releases or threatened releases of Hazardous Materials into the environment (including, without limitation, ambient air, surface water, ground water or land), or otherwise relating to the manufacture, generation, production, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, and any and all regulations, codes, plans, orders, decrees, judgments, injunctions, notices or demand letters issued, entered, promulgated or approved thereunder

"ERISA" shall mean the Employee Retirement Income Security Act of 1974, as amended from time to time, and any successor legislation, and all regulations, codes, orders, decrees, judgments, injunctions, notices or demand letters issued, entered, promulgated or approved thereunder.

"Event of Default" shall mean any of the events specified in Section 6 hereof, provided that any requirement for the giving of notice, the lapse of time, or both have been satisfied.

"GAAP" shall mean generally accepted accounting principles

"Guaranty" shall mean the Guaranty, of even date herewith, made and executed by the Guarantor for the benefit of the Bank, as amended, supplemented, restated or modified from time to time.

"Hazardous Materials" shall mean any (i) hazardous, regulated and/or toxic chemicals, materials, substances or wastes occurring in the air, water, soil or ground water or noise in, on, over or under the Property or the improvements thereon, as defined by the Comprehensive Environmental Response, Compensation, and Liability Act (Superfund or CERCLA), and the Superfund Amendments and the Reauthorization Act of 1986 (SARA), 42 U.S.C. § 9601 et seq., the Emergency Planning and Community Right-to-Know Act, 42 U.S.C. § 11001 et seq., the Resource Conservation and Recovery Act (the Solid Waste Disposal Act or RCRA), 42 U.S.C. § 6901 et seq., the Federal Water Pollution Control Act, (CWA), 33 U.S.C. § 1251 et seq., the Clean Air Act (CAA), 42 U.S.C. § 7401 et seq., the Hazardous Materials Transportation Act, 49 U.S.C. § 1801 et seq., the Federal Water Pollution Control Act, 33 U.S.C. § 1251 et seq., the Safe Drinking Water Act, 42 U.S.C. § 300 ft. seq. and the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C.A. § 136 et seq., the Uranium Mill Tailings Radiation Control Act, 42 U.S.C. § 7901 et seq., the Occupational Safety and Health Act, 29 U.S.C. § 655 et seq., the National Environmental Policy Act, 42 U.S.C. § 4321 et seq., and the Noise Control Act, 42 U.S.C. § 4901 et seq., or comparable state statutes, as each such statute may be amended from time to time, and/or as defined in regulations promulgated thereunder; (ii) oil, petroleum products, and their by-products; (iii) any substance, the presence of which is prohibited or controlled by any other applicable federal or state or local laws, regulations, statutes or ordinances now in force or hereafter enacted relating to waste disposal or environmental protection with respect to hazardous, toxic or other substances generated, produced, leaked, released, spilled or disposed of at or from the Property;

(iv) any other substance which by law requires special handling in its collection, storage, treatment or disposal including, but not limited to, asbestos or asbestos-containing material in any form that could be friable, polychlorinated biphenyls (PCBs), was formaldehyde foam insulation and lead-based paints, but mot including small quantities of such materials present on the Property in retail containers, (v) Microbial Matter or infectious substances; (vi) underground or above-ground storage tanks, whether empty or containing any substance, the presence of which on the Property is prohibited by any federal, state or local authority; (vii) any substance that requires special handling; and (viii) any other material or substance now or in the future defined as a "hazardous substance," "hazardous material," hazardous waste," "toxic substance," "toxic pollutant," "contaminant," or "pollutant" within the meaning of any Environmental Laws. "Microbial Matter" shall mean the presence of fungi or bacterial matter (which is not normally found in the environment) which reproduces through the release of spores or the splitting of cells, including, but not limited to, mold, mildew and viruses, whether or not such Microbial Matter is living.

"Lien" shall mean any mortgage, pledge, deed of trust, assignment, security interest, encumbrance, hypothecation, lien, encroachment, reservation, right of way, easement, covenant, condition, restriction or charge of any kind (including any conditional sale or other title retention agreement, any financing lease having substantially the same economic effect as any of the foregoing, and the filing of, or agreement to give, any financing statement under the Uniform Commercial Code or comparable law of any jurisdiction).

"Loan Documents" shall mean the Note, this Agreement, the Guaranty, the Deed of Trust, and any other agreement or document referred to herein or now or hereafter delivered and executed by the Borrower and/or the Guarantor and/or the Bank in connection with the Loan contemplated hereby, together with any and all revisions, amendments, restatements and modifications to, replacements of and substitutions for, any of the foregoing.

"Note" shall mean the promissory note of even date herewith executed by the Borrower and consented to by the Guarantor to evidence the Loan, as amended, supplemented, restated, replaced or modified from time to time.

"Permitted Liens" shall mean: (a) Liens, if any, for taxes, front foot benefit charges, assessments and other charges enumerated in Section 1.03(a) of the Deed of Trust, not yet due or payable; (b) applicable building and zoning laws and regulations; (c) any mechanic's, artisan's, materialman's, landlord's, carrier's or other like Lien arising in the ordinary course of business with respect to obligations which are not due; (d) any and all municipal and public utility easements of record; (e) any Lien arising out of a judgment, order or award with respect to which the Borrower shall in good faith be prosecuting diligently an appeal or proceeding for review, and with respect to which there shall be in effect a subsisting stay of execution pending such appeal or proceeding for review, provided appropriate reserves therefor are established by the Borrower in accordance with GAAP and provided such Lien is subordinate to any security interest of the Bank in the property encumbered by such Lien; (f) any deposit of funds made in the ordinary course of business to secure obligations of the Borrower under worker's compensation laws, unemployment insurance laws or similar legislation, to secure public or statutory obligations of the Borrower, to secure surety, appeal or customs bonds in proceedings to which the Borrower is a party, or to secure the Borrower's performance in connection with bids, tenders, contracts (other than contracts for the payment of money), leases or subleases made by the Borrower in the

ordinary course of business; (g) any Lien set forth in the Commitment for Title Insurance No. CTIC-05185 issued by Chicago Title Insurance Company, as updated to the date of this Agreement; (h) any lease, sublease or agreement for occupancy or use for any part of the Property, so long as those leases, subleases or agreements are subordinate to the Deed of Trust and have been approved by the Bank; (i) a Lien in favor of the Bank; and (j) such other matters affecting title to the Property as are approved by the Bank in writing;

"Property" shall mean that certain real property and improvements thereof owned by the Borrower and located at 7118 Geoffrey Way, Frederick, Maryland, as more particularly described in the Deed of Trust.

"Subsidiary" shall mean any corporation at least a majority of the outstanding voting stock of which, now or in the future, is owned or controlled by the Borrower, directly or indirectly, or through one or more intermediaries.

- 1.02 Accounting Terms. As used in this Agreement and any of the other Loan Documents, as well as in any certificate, report or other document made or delivered pursuant to or in connection with this Agreement, accounting terms not defined herein and accounting terms only partly defined herein shall have the respective meanings given to them under GAAP.
- 1.03 <u>Use of Defined Terns.</u> All terms defined in this Agreement shall have the defined meanings when used in any of the other Loan Documents or in any certificate, report or other document made or delivered pursuant to or in connection with this Agreement, unless the context shall require otherwise.

### SECTION 2. LOAN AND REPAYMENT

- 2.01 Loan. Subject to the terms and conditions set forth herein, the Bank agrees to lend to the Borrower, in a single advance to be made on or about the date hereof, the sum of Eight Million Five Hundred Thousand and No/100 Dollars (\$8,500,000.00).
  - 2.02 Note. The Borrower's indebtedness to the Bank for the Loan together with interest accrued thereon, shall be evidenced by the Note.
  - 2.03 Repayment of Loan. The Borrower shall repay the Loan, together with interest accrued thereon, in accordance with the terms of the Note.
  - 2.04 Fees. As of the date hereof; the Borrower has paid to the Bank the commitment fee of Eighty Five Thousand and No/100 Dollars (\$85,000.00) for the Loan.

## SECTION 3. CONDITIONS PRECEDENT.

The Bank shall have no obligation to make any advance under the Loan Documents unless and until:

3.01 Delivery of Documents. The Borrower shall have delivered to the Bank the following:

- (i) a certificate of good standing for the Borrower certified by the Secretary of State, or other appropriate governmental authority, of the state of incorporation of the Borrower;
- (ii) a certificate of the Borrower, certifying as to attached copies of its certificate of organization and operating agreement and the consent of its members authorizing the execution, delivery and performance of the Loan Documents to which the Borrower is a party, the borrowings by the Borrower hereunder, and the granting of the Liens contemplated by the Loan Documents, and certifying as to the incumbency, authority and signatures of the manager(s) of the Borrower authorized to sign the Loan Documents on behalf of the Borrower;
- (iii) a certificate of good standing for the Guarantor certified by the Secretary of State, or other appropriate governmental authority, of the state of incorporation of the Guarantor and of the Guarantor's principal place of business;
- (iv) a certificate of the Guarantor, certifying as to attached copies of its certificate of incorporation and bylaws and the resolutions of its Board of Directors authorizing the execution, delivery and performance of the Loan Documents to which the Guarantor is a party, and certifying as to the incumbency, authority and signatures of the officers of the Guarantor authorized to sign the Loan Documents on behalf of the Guarantor;
  - (v) the original Agreement executed by the Borrower and the Guarantor;
  - (vi) the original Note executed by the Borrower and consented to by the Guarantor;
  - (vii) the original Guaranty executed by the Guarantor;
  - (viii) the original Deed of Trust executed by the Borrower;
- (ix) a written opinion of counsel to the Borrower and the Guarantor dated as of the date of this Agreement and addressed to the Bank, which opinion must be, in form and content, satisfactory to the Bank:
- (x) such financing statements or other documents which the Bank may reasonably request in connection with the Collateral; evidence satisfactory to the Bank that all filings under the Uniform Commercial Code or with any federal or state agency or department that the Bank or its counsel deems necessary or desirable in connection with the creation and perfection of the security interest granted hereunder have been effected; and such other evidence as the Bank may require that confirms that, as a result of such filings, the Bank's security interest in the Collateral is consistent with the representation contained in this Agreement relating thereto;
  - (xi) the insurance policies evidencing the insurance coverages required by the Deed of Trust and this Agreement, together with proof of payment of the premiums for such insurance;

- (xii) all fees payable to the Bank, including reasonable legal fees, commitment fees, administration fees, etc.;
- (xiii) such executed agreements, notices or other documents in form and substance satisfactory to the Bank in connection with the Bank's control of any rights in any deposit accounts, electronic chattel paper, investment property or letter of credit.
- (xiv) such other loan documents, agreements, consents, approvals, certificates, resolutions, instruments, opinions and other documents and materials as listed on any closing checklist or as the Bank may reasonably request.
- 3.02 <u>Compliance</u>. The Borrower and the Guarantor shall have complied and shall then be in compliance in all material respects with all material terms, covenants and conditions of this Agreement.
  - 3.03 No Default. There shall exist no Event of Default (as hereinafter defined) and no event which, upon notice or lapse of time or both, would constitute an Event of Default.
  - 3.04 Representations True. The representations and warranties contained in this Agreement shall be true and correct in all material respects.
- 3.05 No Material Adverse Change. There shall be no materially adverse change in the total financial condition of the Borrower or the Guarantor, taken as a whole, from the financial condition of the Borrower or the Guarantor, as the case may be, as set forth in the financial statements furnished to the Bank pursuant to this Agreement or from the financial condition of the Borrower or any Guarantor previously disclosed to the Bank in any other manner.
- 3.06 <u>Appraisal</u>. The Bank shall have received, at the Borrower's expense, an appraisal for the Property showing that the amount of the Loan is no more than 75% of the fair market value of the Property, and being otherwise satisfactory in form and substance to the Bank.
  - 3.07 Environmental. The Bank shall have received, at the Borrower's expense, environmental reports with respect to the Property which are satisfactory in form and substance to the Bank.

### SECTION 4. REPRESENTATIONS AND WARRANTIES

To induce the Bank to enter into this Agreement, the Borrower, as to itself, and the Guarantor, as to itself, represent, warrant and agree as of the date hereof and continuing so long as any obligation of the Borrower and/or the Guarantor exists to the Bank under the Loan Documents as follows:

4.01 <u>Corporate Status: Subsidiaries</u>. The Borrower is a limited liability company, duly organized and validly existing in the jurisdiction in which it is organized, has the power and authority to own its properties and to carry on its business as currently conducted, and is duly qualified to do business and is in good standing in each jurisdiction in which the transaction of its business makes such qualification necessary. The Borrower has no subsidiaries other than those previously disclosed to the Bank in writing.

- 4.02 Mergers and Consolidations. Except as previously disclosed to the Bank in writing, no entity has merged into the Borrower or been consolidated with the Borrower, and the business of the Borrower has not ever been conducted as a partnership or proprietorship in the past.
- 4.03 <u>Purchase of Assets</u>. Except as previously disclosed to the Bank in writing, no entity has sold substantially all of its assets to the Borrower or sold assets to the Borrower outside the ordinary course of such seller's business or in a transaction subject to the bulk transfer laws at any time in the past.
- 4.04 Borrower's and Guarantor's Authority and Capacity. The Borrower and the Guarantor have the full legal right, authority and capacity to execute, deliver and perform the Loan Documents to which they are a party and to incur the obligations provided for therein. The execution, delivery and performance of the Loan Documents and the obligations provided for therein have been duly and validly authorized by all necessary corporate actions on the part of the Borrower (all of which actions are in full force and effect), and do not and will not require any consent or approval of the stockholders of the Borrower which has not been obtained.
- 4.05 <u>Binding Agreement of Borrower and the Guarantor</u>. The Loan Documents are the valid and legally binding obligations and agreements of the Borrower and of the Guarantor, enforceable in accordance with their respective terms.
- 4.06 No Conflicting Law and Agreements. The execution, delivery and performance by the Borrower of the Loan Documents will not violate any provision of law, any order of any court or government instrumentality or agency, any indenture, any loan or credit agreement or any other material agreement, commitment, lease, contract, deed of trust, mortgage, note or other instrument binding on the Borrower or affecting the Property, or be in conflict with, result in a breach of, in any material respect, or constitute (with due notice, lapse of time, or both) a default (as defined therein) under any such indenture, agreement, commitment, lease, contract, deed of trust, mortgage, note or other instrument, or result in the creation or imposition of any Lien of any nature whatsoever upon any of the Collateral, or result in or require the acceleration of any indebtedness of the Borrower.
- 4.07 <u>Compliance with Laws</u>. The Borrower is in compliance in all material respects with any federal, State and local laws, rules and regulations including, but not limited to Environmental Laws and the Fair Labor Standards Act. The Borrower and the Guarantor maintain all of the necessary permits, licenses and certifications necessary for the operation of their businesses. All of the foregoing are in full force and effect and not in known conflict with the rights of others. The Borrower is not in breach of or default (as defined therein) under the provisions of any of the foregoing, nor is there any event, fact, condition or circumstance which, with notice or passage of time or both, would constitute or result in a conflict, breach, default or event of default (as defined therein) under, any of the foregoing which, if not remedied within any applicable grace or cure period could reasonably be expected to have a material adverse effect on the Borrower.
  - 4.08 Taxes. The Borrower has filed or caused to be filed all Federal, state and local income, excise, property and other tax returns which are required to be filed. All such returns are

true and correct in all material respects and the Borrower has paid or caused to be paid all taxes, assessments, interest and penalties as shown on such returns or on any assessment received by them, to the extent that such taxes have become due, including, but not limited to, all F.I.C.A. payments and withholding taxes. The amounts reserved as a liability for income and other taxes payable in the most recent financial statements of the Borrower provided to the Bank pursuant to this Agreement are sufficient for the payment of all unpaid Federal, state, county and local income, excise, property and other taxes, whether or not disputed, of the Borrower and the Guarantor accrued for or applicable to the period and on the dates of such financial statements and all years and periods prior thereto and for which the Borrower, any existing Subsidiary or the Guarantor may be liable in its or their own right or as a transferee of the assets of, or as successor to, any other person or entity.

- 4.09 <u>Financial Condition</u>. The financial statements of the Borrower and the Guarantor and other related information previously submitted to the Bank are true, complete and correct in all material respects, fairly represent the financial condition of the Borrower and the Guarantor and the result of their respective operations and transactions as of the dates and for the periods of such statements and have been prepared in accordance with GAAP applied on a consistent basis throughout the period involved. There are no liabilities, direct or indirect, fixed or contingent, matured or unmatured, known to the Borrower or the Guarantor which are not reflected therein. There has been no material adverse change in the business, operations, prospects, assets, properties or condition (financial or otherwise) of the Borrower or the Guarantor, taken as a whole since the date of said financial statements.
- 4.10 <u>Title To Properties</u>. The Borrower has good, valid, insurable (in the case of real property) and marketable title to all of their properties and assets including the Collateral (whether real or personal, tangible or intangible) reflected on the financial statements referred to in this Agreement, except for such properties and assets as have been disposed of since the date of such financial statements as no longer used or useful in the conduct of their business or as have been disposed of in the ordinary course of business, and all such properties and assets are free and clear of all Liens except for Permitted Liens. None of the real property included in such properties of the Borrower is subject to any covenant or other restriction preventing or limiting the right of the record owner to convey or use it, all such real property has adequate rights of ingress and egress, and all such real property has direct and unobstructed access to electric, gas, water, sewer and telephone lines, all of which are adequate for the uses to which such property is currently devoted.
- 4.11 <u>Litigation</u>. Except as previously disclosed to the Bank in writing, there are no actions, claims, suits or proceedings pending, or, to the knowledge of the Borrower, threatened or reasonably anticipated against or affecting the Borrower at law or in equity including, without limitation, under ERISA or any Environmental Laws or before or by any governmental instrumentality or agency (domestic or foreign), commission, board, bureau, arbitrator or arbitration panel, and there is no probable judgment, liability or award which may reasonably be expected to result in any material adverse change in the business, operations, prospects, properties or assets or condition, financial or otherwise, of the Borrower or the Guarantor. The Borrower is not in default with respect to any judgment, order, writ, injunction, decree, rule, award or regulation of any court, governmental instrumentality or agency, commission, board, bureau, or arbitrator or arbitration panel.

4.12 No Other Defaults. Except as previously disclosed to the Bank in writing, the Borrower is not in default under any contract, agreement, commitment or other instrument which default would have a material adverse effect on the business, properties or condition, financial or otherwise, of the Borrower, or in the performance of any covenants or conditions respecting any of their indebtedness. No holder of any indebtedness of the Borrower has given notice of any asserted default thereunder. No liquidation or dissolution of the Borrower or the Guarantor and no receivership, insolvency, bankruptcy, reorganization or other similar proceeding relative to the Borrower or the Guarantor or their properties is pending or, to the knowledge of the Borrower or the Guarantor, is threatened against them or any of them.

4.13 ERISA. (a) The pension, profit sharing, savings, stock bonus and other deferred compensation plans established and maintained by the Borrower, the Guarantor and any Commonly Controlled Entity (as defined below) which are subject to the requirements of ERISA, if any, were stated in their inception or have, since ERISA became effective with respect to such plans, been amended and restated in a manner designed to qualify under the applicable requirements of ERISA and the Internal Revenue Service Code of 1986, as amended (the "Code"); and subsequent to such statement, or restatement, those plans and their related trusts have received favorable determinations from the Internal Revenue Service holding that such plans and trusts so qualify; (b) to the knowledge of the Borrower and the Guarantor, there is no current matter which would materially adversely affect the qualified tax-exempt status of any pension, profit-sharing, savings; stock bonus or other deferred compensation plan and their related trusts of either of the Borrower or any Commonly Controlled Entity under the Code; (c) neither the Borrower, the Guarantor, nor any Commonly Controlled Entity has incurred in connection with any such plan any "accumulated funding deficiency" (as defined in Section 302 of ERISA or Section 412(a) of the Code) whether or not waived; (d) there has been no "prohibited transaction" (within the meaning of Section 4975 of the Code or Section 406 of ERISA) involving any such plan of the Borrower, the Guarantor, or any Commonly Controlled Entity; (e) no "reportable event," as defined by Title IV of ERISA, has occurred with respect to any plan subject to the minimum funding requirements of Section 412 of the Code maintained for employees of the Borrower or any Commonly Controlled Entity; (f) no "multi-employer plan" (as defined in ERISA) to which either of the Borrower, the Guarantor or any Commonly Controlled Entity has an obligation to contribute, has "terminated," as that term is defined in ERISA; (g) neither the Borrower, the Guarantor, nor any Commonly Controlled Entity has withdrawn, in a "complete withdrawal" (as defined in ERISA), from any "multi-employer plan" to which either the Borrower or such Commonly Controlled Entity had an obligation to contribute; (h) neither the Borrower, the Guarantor nor any Commonly Controlled Entity has withdrawn, in a "partial withdrawal" (as defined in ERISA), from any "multi-employer plan" to which either the Borrower, the Guarantor or such Commonly Controlled Entity had an obligation to contribute; and (i) no "multi-employer plan" to which either the Borrower, the Guarantor or any Commonly Controlled Entity had an obligation to contribute is in "reorganization" (as defined in ERISA and the Code) nor has notice been received from the administrator of any "multi-employer plan" to which either the Borrower, the Guarantor, or any Commonly Controlled Entity bas an obligation to contribute that any such plan will be placed in "reorganization." For purposes of this Section, the term "Commonly Controlled Entity' means any corporation which is a member of a controlled group of corporations (as defined for purposes of Section 414(6) of the Code) of which the Borrower is a member and any trade or business (whether or not incorporated) which is under "common control" (as defined for purposes of Section 414(c) of the Code) with the Borrower.

- 4.14 Other Security Interests. The Borrower is the owner of the Collateral, free from any Lien except a Permitted Lien.
- 4.15 <u>Franchises, Patents, Etc.</u> Except as previously disclosed to the Bank in writing, no franchises, licenses, trademarks, trade names, copyrights or patents are owned or licensed by, or registered in the name of, or have been applied for by, the Borrower, and no such rights or agreements we necessary to the conduct of the present business of the Borrower. The Borrower has no knowledge of and has not received any notice to the effect that any product it manufactures or sells, or any service it renders, or any process, method, know-how, trade secret, part or material it employs in the manufacture of any product it makes or sells or any service it renders, or the marketing or use by it or another of any such product or service, may infringe any trademark, trade name, copyright, patent, trade secret or legally protectable right of any other person or entity.
- 4.16 <u>Approvals</u>. No approval, consent or other action by any governmental instrumentality or agency or any other person or entity, which approval, consent, or other action has not been obtained or taken or which does not remain in effect as of the date hereof, is or will be necessary to permit the valid execution, delivery and performance by the Borrower and the Guarantor of the Loan Documents.
- 4.17 <u>Tradenames, Name Changes</u>. Except as stated above or previously disclosed to the Bank in writing, the Borrower utilizes no tradenames in the conduct of its business and has not changed its name.
- 4.18 <u>Labor Relations</u>. There are no strikes, work stoppages, material grievance proceedings or other material controversies pending or, to the best of Borrower's knowledge, threatened between the Borrower and any employees engaged in the business of the Borrower or any union or other collective bargaining unit representing such employees. The Borrower has complied and is in compliance with all laws relating to the employment of labor, including, without limitation, provisions relating to wages, hours, collective bargaining, occupational safety and health, equal employment opportunities and the withholding of income taxes and social security contributions, the non-compliance with which might materially adversely affect its business, operations, prospects, assets, properties or condition (financial or otherwise).

### SECTION 5. AFFIRMATIVE COVENANTS

The Borrower, as to itself, and the Guarantor, as to itself, covenant and agree that, so long as any of the Loan Documents shall remain in effect, or unless the Bank shall otherwise consent in writing, they will:

- 5.01 Payment of Loan. Comply with the terms and conditions for repayment of the Loan in accordance with the terms of the Note and Guaranty.
- 5.02 Financial Statements. Furnish to the Bank:
- (a) as soon as available but in no event more than one hundred twenty (120) days after the last day of each fiscal year of the Borrower and the Guarantor, consolidated financial statements of the Borrower and the Guarantor containing a balance sheet, a statement of

income and expenses and a statement of changes in financial condition as of the close of such period, prepared in accordance with GAAP applied on a basis consistent with prior periods, showing the financial condition of the Borrower and the Guarantor at the close of such year in form reasonably satisfactory to the Bank and prepared and audited by Ernst & Young, or another independent certified public accountant reasonably satisfactory to the Bank;

- (b) as soon as available but in no event more than forty five (45) days after the last day of each quarter of each fiscal year of the Borrower and the Guarantor, consolidated financial statements of the Borrower and the Guarantor containing a balance sheet, a statement of income and expenses and a statement of changes in financial condition as of the close of such period, prepared in accordance with GAAP applied on a basis consistent with prior periods, showing the financial condition of the Borrower and the Guarantor at the close of such period, in form reasonably satisfactory to the Bank:
- (c) in the event that a portion of the Property has been leased to third party, unaffiliated tenants, as soon as available but in no event more than forty five (45) days after the last day of each quarter of each fiscal year, a detailed budget and report of operating expenses for the Property;
- (d) in the event that a portion of the Property has been leased to third party, unaffiliated tenants, as soon as available but in no event more than forty five (45) days after the last day of each fiscal year, projections for the Property for the following fiscal year;
- (e) promptly, and from time to time, such other information regarding the operation, business, affairs and financial condition of the Borrower and the Guarantor as the Bank may reasonably request, including, but not limited to interim financial statements including an income statement, balance sheet, aging of accounts receivable and/or accounts payable;
- (f) within thirty (30) days after the last day of each of the quarters of each fiscal year of the Borrower, a certificate of the chief financial officer of the Borrower (i) certifying that to the best of his knowledge no Event of Default has occurred and is continuing or, if an Event of Default has occurred and is continuing, a statement as to the nature thereof and the action which is proposed to be taken with respect thereto and (ii) with computation demonstrating compliance with the covenants contained in Sections 5.18 and 5.19; and
- (g) Borrower and Guarantor will use commercially reasonable efforts to cause its independent certified public accountant who audited its financial statements to provide simultaneously with the delivery of the annual financial statements a certificate acceptable to the Bank in its reasonable discretion to the effect that, in making the examination necessary for the audit of such statements, they have obtained no knowledge of any condition or event which constitutes a failure to comply with the covenants contained in Sections 5.18 and 5.19 of this Agreement, or if such accountants shall have obtained knowledge of any such condition or event, specify in such certificate each such condition or event of which they have knowledge and the nature and status thereof.

The financial statements of the Borrower and the Guarantor delivered to the Bank pursuant to this Section shall each be certified by the president or chief financial officer of the

Borrower or the Guarantor, as the case may be, as to the authenticity, accuracy of integrity of the representation contained therein and as having been prepared in accordance with GAAP applied on a basis consistent with prior periods. Any such financial information provided to the Bank shall be maintained by the Bank as confidential proprietary records. The Bank hereby acknowledges that the Borrower may not have its own separate financial statements and shall be permitted to supply financial statements consolidated with Guarantor's financial statements.

- 5.03 <u>Maintaining Records: Access to Properties and Inspections.</u> Maintain financial records in accordance with GAAP consistently applied and permit any authorized representative designated by the Bank to visit and inspect any of the properties of the Borrower or the Guarantor (including, without limitation, their books of account, records, correspondence and other papers and to make extracts therefrom) and to discuss their affairs, finances and accounts with their respective officers and their respective independent certified public accountants or other parties preparing statements for or on behalf of the Borrower or the Guarantor, subject to advance notice and subject to safety limitations and legal limits of general applicability.
- 5.04 <u>Place of Business</u>, <u>Location of Records</u>; <u>Notices</u>. Maintain their executive offices and their records at their current locations. The Bank shall be entitled to rely upon the foregoing unless it receives fourteen (14) days advance written notice of a change in such executive offices or in such office where such records are kept.
- 5.05 <u>Maintenance of Business</u>. (a) Maintain the corporate existence of the Borrower and the Guarantor in good standing and in existence in the State of its original formation; and (b) maintain and keep in full force and effect all licenses and permits necessary to the proper conduct of the Borrower's and the Guarantor's business.
- 5.06 Insurance. The Borrower shall maintain and pay for insurance covering such risks and in such amounts and with such insurance companies as shall be satisfactory to the Bank, and deliver the policies or certificates of all such insurance to the Bank with satisfactory lender's loss payable endorsements naming the Bank as loss payee; and maintain, with financially sound and reputable insurers, insurance with respect to their properties and business against such casualties and contingencies of such types (including personal injury and property damage liability insurance, automobile liability insurance, product liability insurance, biomedical insurance, worker's compensation insurance, business interruption insurance, employee dishonesty insurance, and directors' and officers' liability insurance) and in such amounts as is customary in the case of persons or entities in the same or similar business. Each policy or insurance required hereunder shall require the insurer to give not less than thirty (30) days prior written notice to the Bank in the event of cancellation of such policy for any reason whatsoever, and shall provide that the interest of the Bank thereunder shall not be impaired or invalidated by any act or neglect of the Borrower or the owner of any of the insurance property or by the occupation of the premises wherein such property is located for purposes more hazardous than are permitted by such policy. If the Borrower fails to provide and pay for such insurance, the Bank may, at the Borrower's expense, procure the same, but shall not be required to do so. The Borrower agrees to deliver to the Bank, promptly as rendered, true copies of any reports made to any insurance company.
  - 5.07 Execution of Documents. At the reasonable request of the Bank, execute and deliver such financing statements, documents and instruments including, but not limited to,

written acknowledgments from any third party holding all or any portion of the Collateral that it does so for the Bank's benefit and any control agreements with respect to any investment property, letter of-credit rights, deposit accounts or electronic chattel paper, and perform all other acts as the Bank deems necessary or desirable, and pay, upon demand, all reasonable costs and expenses (including reasonable attorneys' fees and disbursements) incurred by the Bank in connection therewith.

- 5.08 Obligations and Taxes. Pay all indebtedness and obligations promptly and in accordance with their terms, and pay and discharge promptly all taxes, assessments and governmental charges or levies imposed upon them or in respect of their property and the Collateral, including, but not limited to, all F.I.C.A. payments and withholding taxes, before the same shall become in default, as well as all claims for labor, materials, and supplies or otherwise which, if unpaid, might become a Lien upon such properties or any part thereof, provided, however, that the Borrower and the Guarantor are not required hereby to pay and discharge or to cause to be paid and discharged any such indebtedness, obligation, tax, assessment, charge, levy or claim so long as the validity thereof shall be contested in good faith by appropriate proceedings and the Borrower and the Guarantor shall set aside on their books reserves which are in conformity with generally accepted accounting principles and which the Bank deems adequate with respect to any such tax, assessment, charge, levy or claim so contested.
- 5.09 <u>Litigation Notice</u>. Give the Bank prompt notice of any action, suit or proceeding at law or in equity or by or before any governmental instrumentality or agency (domestic or foreign), commission, board, bureau, arbitrator or arbitration panel which, if adversely determined, could materially impair or affect the right of the Borrower to carry on its business substantially as now conducted or could materially affect its respective business, operations, prospects, properties, assets (including the Collateral) or condition, financial or otherwise, in each case if in excess of \$1,000,000,000.
- 5.10 Notification Relating to Hazardous Materials. Immediately advise the Bank in writing of (a) any and all enforcement, cleanup, remediation or removal, pursuant to any governmental or regulatory actions instituted, completed or threatened pursuant to any applicable federal, state, or local laws, ordinances or regulations relating to any Hazardous Materials affecting the Property or the business operations of the Borrower, and (b) all claims made or threatened by any third party against the Borrower relating to damages, contribution, cost recovery compensation, loss or injury resulting from any Hazardous Materials. The Borrower shall immediately notify the Bank of any remedial action taken by the Borrower with respect to the Property or the business operations of the Borrower.
- 5.11 Access Onto Property. Allow the appropriate agents and contractors of the Bank to enter upon the Property for the purposes of conducting environmental investigations and audits (including taking physical samples) and such other action deemed necessary by the Bank to insure compliance by the Borrower with all Environmental Laws, subject to advance notice and subject to safety limitations and legal limits of general applicability. The Borrower acknowledges that no adequate remedy at law exists for a violation of this covenant and agrees that the Bank is entitled to specific performance of its rights under this covenant, subject to advance notice and subject to safety limitations and legal limits of general applicability. The right of access granted herein shall continue until this Agreement is terminated

- 5.12 Notice of Default; Material Adverse Change. Promptly notify the Bank of any condition or event that constitutes, or with the running of time, the giving of notice, or both, would constitute, an Event of Default, and promptly inform the Bank of any material adverse change in the financial condition of the Borrower or of the Guarantor, as set forth in Section 6.11 below.
- 5.13 Borrower's Claims. Promptly notify the Bank in writing of any action or omission of the Bank which the Borrower claims caused or may cause injury, loss or damage to the Borrower. Failure of the Borrower to so notify the Bank of such claim to which it has knowledge within one hundred eighty (180) days after the Borrower determines that it has such claim shall constitute a waiver of such claim.
- 5.14 <u>Defense of Collateral</u>. Defend the Collateral, and the Bank's first and prior security interest therein, against all claims and demands of all persons at anytime claiming the same or any interest therein and pay, upon demand, all reasonable costs and expenses (including reasonable attorneys' fees and disbursements) incurred by the Bank in connection therewith.
- 5.15 <u>Use of Proceeds</u>. Use the proceeds of the Loan solely for the purchase of the Property or for any commercial purpose not violative of or inconsistent with any provision of this Agreement or the Loan Documents.
- 5.16 Compliance with Laws. Comply, in all material respects, with all federal, state and local laws, rules and regulations including, but not limited to Environmental Laws and the Fair Labor Standards Act applicable to its business, whether now in effect or hereafter enacted, and upon request of the Bank, the Borrower will provide the Bank with such evidence of compliance as the Bank may reasonably request.
- 5.17 <u>Hazardous Materials</u>. With respect to all property owned, subleased, operated or occupied by the Borrower, maintain and cause all operators, tenants, subtenants, licensees and occupants of all such property to maintain such property free of all Hazardous Materials, other than those Hazardous Materials used in compliance with all Environmental Laws and prevent all such property from being used for the manufacture, generation, production, processing, distribution, use, treatment, storage, disposal, transport or handling of any Hazardous Materials other than those Hazardous Materials used in compliance with all Environmental Laws; and deliver to the Bank copies of all reports prepared by any governmental authority, any environmental auditor or engineer, or any other person, relating to or in connection with the Borrower's compliance with any Environmental Laws, unless the Borrower cannot obtain such reports or copies thereof.

### SECTION 6. EVENTS OF DEFAULT

The occurrence of any one or more of the following events shall constitute an Event of Default hereunder (subject to any applicable notice and cure periods contained in the Loan Documents):

6.01 Payments. Default shall be made in the payment of the principal of, or any installment of principal of, or interest on, the Note, whether at the due date thereof, at a date fixed for prepayment thereof, upon acceleration thereof or otherwise.

- 6.02 <u>Representations</u>. Any representation or warranty made in or in connection with any of the Loan Documents shall prove to have been false or misleading in any material respect when made or deemed to have been made.
- 6.03 Covenants. Default shall be made in the due observance or performance of any covenant, condition or agreement on the part of the Borrower or the Guarantor pursuant to the terms of any of the Loan Documents, and not already subject to a grace or cure period, and such default shall continue unremedied for thirty (30) business days after notice to the Borrower and the Guarantor thereof
- 6.04 (a) <u>Voluntary Bankruptcy. Etc.</u> The Borrower: (i) voluntarily is adjudicated as bankrupt or insolvent, (ii) seeks or consents to the appointment of a receiver or trustee for itself or for all or any part of its property, (iii) files a petition seeking relief under the bankruptcy or similar laws of the United States or any state or any other competent jurisdiction, (iv) makes a general assignment for the benefit of creditors, or (v) admits in writing its inability to pay its debts as they mature.
- (b) Involuntary Bankruptcy. Etc. A court of competent jurisdiction enters an order, judgment or decree appointing, without the consent of the Borrower, a receiver or trustee for Borrower, for all or any part of its property, or a petition is filed against the Borrower seeking relief under the bankruptcy or other similar laws of the United States or any state or other competent jurisdiction, and such petition, order, judgment or decree shall remain in force undischarged or unstayed for a period of 60 calendar days.
  - 6.05 Attachment. The issuance of any attachment or garnishment against the Borrower or the Guarantor.
- 6.06 Cross Default. The occurrence of (a) an uncured event of default (as defined therein) under any of the Loan Documents, (b) any uncured event of default under (i) any promissory note payable to the Bank under which the Borrower or the Guarantor is an obligor, or (ii) any other agreement between the Borrower or the Guarantor and the Bank, or (c) an uncured event of default (as defined therein) under any other indebtedness or liability for borrowed money of the Borrower in an amount in excess of \$1,000,000.00, if the effect of such default is to accelerate the maturity of such evidence of indebtedness or liability or to permit the holder thereof to cause any indebtedness to become due prior to its stated maturity and the Bank determines, in its discretion, that such default impairs or prevents the Borrower from performing its obligations under the Loan Documents.
- 6.07 <u>Judgment</u>. Unless in the opinion of the Bank, adequately covered by insurance, the entry of one or more final judgments, decrees or orders for the payment of money involving more than \$1,000,000.00 in the aggregate against the Borrower and all applicable periods for appeal have terminated and such judgment or decree is not satisfied within sixty (60) days thereafter.
- 6.08 Loss, Damage to Collateral. Loss, theft, damage, or destruction of any material portion of the Collateral for which there is either no insurance coverage or for which, in the opinion of the Bank, there is insufficient insurance coverage.

- 6.09 <u>Validity of Loan Documents</u>. Any Loan Document shall, at any time after its execution and delivery and for any reason, cease to be in full force and effect or shall be declared null and void, or the validity or enforceability thereof shall be contested by the Borrower or the Guarantor, or the Borrower or the Guarantor shall deny it has any further liability or obligation thereunder.
- 6.10 Payments to Subordinated Creditors. The Borrower makes any payment on account of indebtedness that has been subordinated to the Loan, other than payments specifically permitted by the terms of such subordination or in the ordinary course of business.
  - 6.11 Material Adverse Change. There shall be no materially adverse change in the total financial condition of the Borrower or the Guarantor, taken as a whole.

## SECTION 7. RIGHTS AND REMEDIES

- 7.01 Remedies. If any one or more Events of Default shall occur, then in each and every such case, the Bank may at any time thereafter exercise and/or enforce any of the following rights and remedies:
- (a) <u>Acceleration.</u> Declare the Note to be immediately due and payable, together with accrued interest thereon, without presentment, demand, protest or notice of dishonor, all of which the Borrower and the Guarantor hereby waive.
- (b) Possession and Collection (i) Take possession or control of, sell or otherwise dispose of all of any part of the Collateral; (ii) endorse as the agent of the Borrower any chattel paper, documents, or instruments forming all or any part of the Collateral; (iii) pay, purchase, contest, or compromise any encumbrance, charge, or lien that, in the opinion of the Bank, appears to be prior or superior to its Lien and pay all reasonable expenses incurred in connection therewith; (iv) take any other action which the Bank deems necessary or desirable to protect and realize upon its security interest in the Collateral; and (v) in addition to the foregoing, and not in substitution therefor, exercise any one or more of the rights and remedies exercisable by the Bank under other provisions of this Agreement, under the Note, under any of the other Loan Documents, or provided by applicable law (including, without limitation, the Uniform Commercial Code as in effect in Maryland) and may specifically disclaim any warranties of title or the like. In taking possession of the Collateral the Bank may proceed without legal process, if this can be done without breach of the peace. The Borrower waives any right it may have to require the Bank to pursue any third person for payment of the Loan.
- (c) <u>Receiver</u>. Obtain appointment of a receiver for all or any of the Collateral, the Borrower and the Guarantor hereby consenting to the appointment of such a receiver and each agreeing not to oppose any such appointment. Any receiver so appointed shall have such powers as may be conferred by the appointing authority including any or all of the powers, rights and remedies which the Bank is authorized to exercise by the Loan Documents, and shall have the right to incur such obligations and to issue such certificates therefor as the appointing authority shall authorize.

- (d) <u>Performance by Bank</u>. Make such payment or perform any of the conditions, covenants, terms, stipulations or agreements contained in this Agreement or any of the other Loan Documents for the account and at the expense of the Borrower.
- 7.02 Sales on Credit. If the Bank sells any of the Collateral upon credit, the Borrower will be credited only with payments actually made by the purchaser, received by the Bank and applied to the indebtedness of the purchaser. In the event the purchaser fails to pay for the Collateral, the Bank may resell the Collateral and the Borrower shall be credited with the proceeds of the sale.
- 7.03 <u>Proceeds</u>. Any proceeds of the collection of the Loan or of the sale or other disposition of the Collateral will be applied by the Bank to the payment of fees and costs, and any balance of such proceeds (if any) will be applied by the Bank to the payment of the remaining Loan (whether then due or not), at such time or times and in such order and manner of application as the Bank may from time to time in its sole discretion determine. If the sale or other disposition of the Collateral fails to pay the Loan in full, the Borrower and the Guarantor shall remain jointly and severally liable to the Bank for any deficiency.
- 7.04 Notices. Any notices required under the Maryland Uniform Commercial Code with respect to the sale or other disposition of the Collateral shall be deemed reasonable if mailed by the Bank to the persons entitled thereto at their last known address at least ten (10) days prior to disposition of the Collateral.
- 7.05 Waiver of Jury Trial. THE BORROWER, THE GUARANTOR AND THE BANK HEREBY VOLUNTARILY AND KNOWINGLY WAIVE ANY RIGHT THEY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION, PROCEEDING, OR COUNTERCLAIM BROUGHT BY ANY PARTY AGAINST THE OTHER ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREIN. THE BORROWER AND THE GUARANTOR ACKNOWLEDGE THAT THEY HAVE BEEN INFORMED BY THE BANK THAT THE PROVISIONS OF THIS PARAGRAPH CONSTITUTE A MATERIAL INDUCEMENT UPON WHICH THE BANK HAS RELIED, IS RELYING AND WILL RELY IN MAKING THE LOAN. THE BORROWER AND THE GUARANTOR HEREBY CERTIFY THAT NO REPRESENTATIVE OR AGENT OF THE BANK (INCLUDING ITS COUNSEL) HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT THE BANK WOULD NOT, IN THE EVENT OF LITIGATION, ENFORCE THIS WAIVER OF RIGHT TO JURY TRIAL. THE BORROWER AND THE GUARANTOR ACKNOWLEDGE THAT THEY HAVE CONSULTED WITH AN ATTORNEY AND FULLY UNDERSTAND THE LEGAL EFFECT OF THE PROVISIONS OF THIS PARAGRAPH.
- 7.06 <u>Cumulative Remedies</u>. Each right, power and remedy of the Bank as provided for in the Loan Documents, or now or hereafter existing at law or in equity or by statute or otherwise shall be cumulative and concurrent and shall be in addition to every other such right, power or remedy, and the exercise or beginning of the exercise by the Bank of any one or more of such rights; powers or remedies shall not preclude the simultaneous or later exercise by the Bank of any or all other such rights, powers or remedies. The Bank may comply with any applicable state

or federal law requirements in connection with a disposition of the Collateral and compliance will not be considered to adversely affect the commercial reasonableness of any sale of the Collateral.

7.07 No Waiver. No failure or delay by the Bank in insisting upon the strict performance of any term, condition, or covenant of the Loan Documents or in exercising any right, power or remedy consequent upon an Event of Default shall constitute a waiver of any such term, condition or covenant or of any such breach, or preclude the Bank from exercising any such right, power or remedy at any later time or times. By accepting payment after the due date of any amount payable under the Loan Documents, the Bank shall not be deemed to waive the right either to require prompt payment when due of all other amounts payable under the Loan Documents, or to declare a default for failure to effect such prompt payment of any such other amount.

## SECTION 8. MISCELLANEOUS

8.01 <u>Survival</u>. All covenants, agreements, representations and warranties made in this Agreement and the Loan Documents shall survive the execution and delivery of the Note and shall continue in full force and effect so long as the Note, or any of the other obligations under the Loan Documents, or any renewal or extensions of the Note, is outstanding and unpaid.

8.02 Notices. All notices, demands, instructions and other communications required or permitted to be given to or made upon any party hereto shall be in writing, personally delivered or sent by postage prepaid first class certified mail, return receipt requested, overnight courier or by facsimile machine, and shall be deemed to be given on the day that such writing is delivered or sent by facsimile machine or one (1) business day after such notice is sent by overnight courier or three (3) business days after said notice is sent by certified mail. Unless otherwise specified in a notice sent or delivered in accordance with the foregoing provisions of this paragraph, notices, demands, instructions and other communications in writing shall be given to or made upon the respective parties hereto at their respective addresses indicated for such party below:

Bank: HSBC Realty Credit Corporation (USA)

1130 Connecticut Avenue, N. W., 12th Floor

Washington, D. C. 20036

Attention: Jeffrey M. Henry, Vice President Facsimile Number: (202) 496-8758

With Copy to: McGuireWoods LLP

1750 Tysons Boulevard, Suite 1800 McLean, Virginia 22102-3915 Attn: E. Kristen Moye, Attorney-at-Law

Telecopier: 703-712-5238

Borrower and

**Guarantor:** Emergent Frederick LLC

Emergent Biosolutions Inc. 300 Professional Drive, Suite 100 Gaithersburg, MD 20879 Attn: Don Elsey, Vice President and

Attn: Legal Department

Facsimile Number: (301) 590-1252

With Copy to: Linowes and Blocher LLP

7200 Wisconsin Avenue, Suite 800 Bethesda, Maryland 20814 Attn: Richard Zeidman, Esquire Facsimile Number: (301) 654-2801

or at such other address as the parties may have furnished to each other in writing, and shall be deemed to be given on delivery or upon mailing.

8.03 Costs and Expenses. The Borrower and the Guarantor shall bear any and all reasonable fees, costs and expenses, of whatever kind and nature, including any taxes of any kind and reasonable attorneys' fees and disbursements, which the Bank may incur: (a) in connection with the closing of the Loan, including, without limitation, the filing of public notices, the preparation of the Loan Documents, the recording of the UCC financing statements, and the making of title examinations, and in connection with any amendment of the Loan Documents; (b) in maintaining, preserving, enforcing or foreclosing any pledge, lien, encumbrance or security interest granted hereunder or in connection herewith, whether through judicial proceedings or otherwise; (c) in conducting audits of the Borrower's business and with respect to the Collateral; and (d) in successfully defending or prosecuting any actions or proceedings arising out of or relating to transactions with any one or more of the Borrower and the Guarantor. All such fees, costs and expenses until paid shall be included in the Loan or deducted from any amount due the Borrower or the Guarantor. The Borrower and the Guarantor agree that the attorneys retained by the Bank shall represent only the interests of the Bank.

8.04 <u>Indemnification of Bank</u>. The Borrower and the Guarantor shall protect and indemnify the Bank from and against any and all demands, suits, losses, assessments, fines, claims, damages, penalties, causes of action, costs or other expenses (including, without limitation, reasonable attorneys' fees and disbursements), imposed upon or incurred by or asserted against the Bank or the directors, officers, agents or employees of the Bank, except those arising out of the willful misconduct or gross negligence of the Bank, by reason of and including but not limited to liability or damage resulting from: (a) any failure on the part of the Borrower to perform or comply with any of the terms of this Agreement; (b) any action brought against the Bank attacking the validity of this Agreement or any other Loan Document; and/or (c) actual or threatened damage to the environment, agency costs of investigation, personal injury or death, or property damage, due to a release or alleged release or Hazardous Materials, on or under the Property or arising from the Borrower's business operations.

or gaseous emissions from the Property or arising from the Borrower's business operations resulting from the use or existence of Hazardous Materials, whether such claim proves to be true or false. The term "property damage" as used in this Section includes, but is not limited to, damage of any real or personal property of the Borrower, the Bank, and of any third parties. Any amounts payable to the Bank under this Section which are not paid within thirty (30) days after written demand therefor by the Bank shall bear interest at the rate of interest in effect under the Note from the date of such demand. In the event any action, suit or proceeding is brought against the Bank or the directors, officers, agents or employees of the Bank by reason of any such occurrence, the Borrower, upon the request of the Bank and at the Borrower's expense, shall resist and defend such action, suit or proceeding or cause the same to be resisted and defended by counsel designated by the Borrower and approved by the Bank. Such obligations under this Section as shall have accrued at the time of any termination of this Agreement shall survive any such termination.

- 8.05 Reinstatement of Liens. If, at any time after payment in full by the Borrower of the Loan and termination of the Bank's Liens, any payments on the Loan previously made by the Borrower or any other person must be disgorged by the Bank for any reason whatsoever (including, without limitation, the insolvency, bankruptcy, or reorganization of the Borrower or such other person), this Agreement and the Bank's Liens granted hereunder shall be reinstated as to all disgorged payments as though such payments had not been made, and the Borrower shall sign and deliver to the Bank all documents and things necessary to reperfect all terminated Liens.
- 8.06 <u>Bank Disclosures</u>. Upon the prior written consent of the Borrower (such consent not to be unreasonable withheld or delayed), the Bank may issue press releases concerning, and otherwise publicly announce or publicize, financings provided by the Bank to the Borrower. The Borrower hereby authorizes the Bank to disclose to any subsidiary or affiliate of the Bank, to any fiduciary institution (as "fiduciary institution" is defined in Subtitle 3 of Title 1 of the Financial Institutions Article of the Annotated Code of Maryland, or any successor legislation) or to any banking institution, credit union or savings and loan association organized under the laws of any State, and hereby authorizes all subsidiaries and affiliates of the Bank, to disclose to the Bank, the financial record of the Borrower (as "financial record" is defined in Subtitle 3 of Title 1 of the Financial Institutions Article of the Annotated Code of Maryland, or any successor legislation).
- 8.07 Participation. The Bank shall have the right to grant participations in the Loan held by it to others at any time and from time to time, and the Bank may divulge to any such participant or potential participant all information, reports, financial statements and documents obtained in connection with this Agreement, the Note and any of the other Loan Documents or otherwise.
- 8.08 Change, etc. Neither this Agreement nor any term, condition, representation, warranty, covenant or agreement contained herein may be changed, waived, discharged or terminated orally, but only by an instrument in writing signed by the party against whom such change, waiver, discharge or termination is sought.
- 8.09 Governing Law. This Agreement, the Note and the other Loan Documents shall be governed and construed in accordance with the laws of the State of Maryland (but not including the choice of law rules thereof).

- 8.10 Terms Binding. All of the terms, conditions, stipulations, warranties, representations and covenants of this Agreement shall apply to and be binding upon and shall inure to the benefit of the Borrower, the Guarantor and the Bank and each of their respective heirs, executors, personal representatives, successors and assigns and all persons or entities who become bound as a debtor under this Agreement, but neither the Borrower nor the Guarantor shall have the right to assign this Agreement to any person or entity without the prior written consent of the Bank.
- 8.11 <u>Invalidity of Certain Provisions</u>. If any term or provision of this Agreement or the application thereof to any person or circumstances shall, to any extent, be invalid or unenforceable, the remainder of such term or provision or the application thereof to persons or circumstances other than those as to which it is held invalid or unenforceable shall not be affected thereby and shall be valid and enforceable to the fullest extent permitted by law.
- 8.12 Merger Integration and Interpretation. The Loan Documents contain the entire agreement of the parties with respect to the matters covered and the transactions contemplated hereby and thereby, and no other agreement, statement or promise made by any such party, or by any employee, officer, agent or attorney of any such party, which is not contained herein or therein, shall be valid or binding. Neither this Agreement nor any uncertainty or ambiguity herein shall be construed or resolved against the Bank or the Borrower, whether under any role of construction or otherwise. On the contrary, this Agreement has been reviewed by each of the parties and its counsel and shall be construed and interpreted according to the ordinary meaning of the words used so as to accomplish the purposes and intentions of all parties hereto fairly.
- 8.13 No Partnership; Control; Third Parties. This Agreement contemplates the extension of credit by the Bank, in its capacity as a lender, to the Borrower, in its capacity as a borrower, and for the payment of interest and repayment of principal by the Borrower to the Bank. The relationship between the Bank and the Borrower is limited to that of creditor/secured party, and debtor. The provisions herein for compliance with financial covenants, delivery of financial statements, and other covenants are intended solely for the benefit of the Bank to protect its interests as lender in assuring payments of interest and repayment of principal, and nothing contained in this Agreement shall be construed as permitting or obligating the Bank to act as financial or business advisor or consultant to the Borrower, as permitting or obligating the Bank to control the Borrower, or to conduct the Borrower's operations, as creating any fiduciary obligation on the part of the Bank to the Borrower, as creating any joint venture, agency, or other relationship between the parties other than as explicitly and specifically stated in this Agreement. The Borrower acknowledges that it has had the opportunity to obtain the advice of experienced counsel of its own choosing in connection with the negotiation and execution of this Agreement and to obtain the advice of such counsel with respect to all matters contained herein, including, without limitation, the provision herein relative to the waiver of trial by jury. The Borrower further acknowledges that it is experienced with respect to financial and credit matters and has made its own independent decision to apply to the Bank for credit and to execute and deliver this Agreement. The terms and provisions of the Note and the Loan Documents are for the benefit of the Borrower and the Bank, their respective successors, assigns, endorsees and transferees and all persons claiming under or through them and no other person shall have any right or cause of action or account thereof.

- 8.14 <u>Electronic Transmission of Data</u>. The Bank, the Borrower and the Guarantor agree that certain data related to the Loan (including confidential information, documents, applications and reports) may be transmitted electronically, including transmission over the Internet. This data may be transmitted to, received from or circulated among agents and representatives of the Borrower, the Guarantor and/or the Bank and their affiliates and other persons involved with the subject matter of this Agreement. The Borrower and the Guarantor acknowledge and agree that (a) there are risks associated with the use of electronic transmission and that the Bank does not control the method of transmittal or service providers, (b) the Bank has no obligation or responsibility whatsoever and assumes no duty or obligation for the security, receipt or third party interception of any such transmission, and (c) the Borrower and the Guarantor will release, hold harmless and indemnify the Bank from any claim, damage or loss, including that arising in whole or part from the Bank's strict liability or sole, comparative or contributory negligence, which is related to the electronic transmission of data.
  - 8.15 Gender etc. Whenever used herein, the singular shall include the plural, the plural shall include the singular, and the use of the masculine, feminine or neuter gender shall include all genders.
- 8.16 <u>Authority to File Financing Statements and Amendments</u>. The Borrower hereby authorizes the Bank to file Uniform Commercial Code Financing Statements describing the Collateral without the Borrower's signature thereon. After notice to the Borrower, the Bank is authorized to file amendments without the Borrower's signature thereon to any financing statements naming the Bank as a secured party in order to add collateral or a debtor. The Borrower is not authorized to file correction statements to financing statements.
  - 8.17 Heading. The section and subsection headings of this Agreement are for convenience only, and shall not limit or otherwise affect any of the terms hereof.
- 8.18 <u>Counterparts</u>. To facilitate execution, this Agreement may be executed in any number of counterparts as may be required; and it shall not be necessary that the signatures of, or on behalf of, each party, or that the signatures of all persons required to bind any party, appear on each counterpart; but it shall be sufficient that the signature of, or on behalf of, each party, or that the signatures of the persons required to bind any party, appear on one or more counterparts. All counterparts shall collectively constitute a single agreement. It shall not be necessary in making proof of this Agreement to produce or account for more than a number of counterparts containing the respective signatures of, or on behalf of, all of the parties hereto.

(Signature Page Follows)

IN WITNESS WHEREOF, each of the parties hereto have caused this Agreement to be executed, sealed and attested the day and year first above mentioned.

BORROWER:

ATTEST: EMERGENT FREDERICK LLC,

a Maryland limited liability company

By: /s/ Edward J. Arcuri
Name: Edward J. Arcuri /s/ [Illegible] (SEAL)

Title: Executive Manager

GUARANTOR:

ATTEST: EMERGENT BIOSOLUTIONS INC.

a Delaware corporation

By: /s/ Edward J. Arcuri (SEAL)
Name: Edward J. Arcuri /s/ [Illegible]

EVP & COO Title:

BANK:

HSBC REALTY CREDIT CORPORATION (USA),

a Delaware corporation

/s/ Jeffrey M. Henry By: (SEAL)

Name: Jeffery M. Henry Title: Vice President

# COUNTY COMMISSIONERS OF FREDERICK COUNTY,

## EMERGENT BIOLOGICS INC.

a n d

# MERCANTILE POTOMAC BANK

BOND PURCHASE AGREEMENT

Dated as of March 31, 2005

Frederick County, Maryland Tax Increment Financing Bonds (Dudrow Industrial Park Lot Three Development District) Series 2005

## **BOND PURCHASE AGREEMENT**

March 31, 2005

County Commissioners of Frederick County Winchester Hall, 12 East Church Street Frederick, Maryland 21701

Emergent Biologics Inc. 300 Professional Drive Gaithersburg, Maryland 20879

#### Dear Sirs:

The undersigned (herein called the "Purchaser") hereby offers to enter into this Bond Purchase Agreement with you for the purchase and sale of the Tax Increment Financing Bonds (Dudrow Industrial Park Lot Three Development District) Series 2005 (the "Bonds") described below. This offer is made subject to acceptance by County Commissioners of Frederick County (the "Issuer") and Emergent Biologics Inc. (formerly Advanced BioSolutions, Inc.) (the "Company"). Upon such acceptance, this Bond Purchase Agreement shall become effective in accordance with its terms and shall become binding between you and the undersigned Purchaser.

Section 1. <u>Definitions</u>. For purposes of this Agreement any word not conventionally capitalized and not defined herein shall have the meaning indicated in the Bond Authorization Legislation (hereinafter defined) or in the Proposal Letter dated February 11, 2005 which is attached hereto as <u>Exhibit A</u> and is by this reference incorporated herein (the "Summary") and, in addition, the following terms have the meanings specified below:

"Agreement" means this Bond Purchase Agreement.

"Bond Authorization Legislation" means the Ordinance No.05-02-363 enacted by the Board of County Commissioners of Frederick County on March 1, 2005, and the Written Order of the President of the Board of County Commissioners of Frederick County dated as of the Closing Date.

"Closing" means the closing held on the Closing Date.

"Closing Date" means March 31, 2005, or such later date as the Purchaser, the Company, and the Issuer shall agree upon.

"Commission" means the Securities and Exchange Commission.

- "Development Agreement" means the development agreement dated as of the Closing Date between the Issuer and the Company.
- "Fiscal Year" means the consecutive 12-month period beginning on January 1st of each year and ending on the December 31st of such year.
- "Governmental Body" means any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign.
- "Resolution" means Resolution No. 04-38 adopted on October 5, 2004, by the Board of County Commissioners of Frederick County which created the Dudrow Industrial Park Lot Three Development District and the Dudrow Industrial Park Lot Three Development District Special Fund.
  - "Servicing Agreement" means the Servicing Agreement dated as of the Closing Date between the Issuer, the Purchaser and the Company.

### Section 2. Sale and Purchase of Bonds.

A. <u>Sale of Bonds</u>. Subject to the terms and conditions contained in this Agreement (including the Summary), the Issuer hereby agrees to sell to the Purchaser, and the Purchaser hereby agrees to purchase from the Issuer, for the account of the Purchaser an aggregate of \$300,000 principal amount of the Bonds at a purchase price of \$300,000. The Bonds shall be in substantially the same form as the specimen bond attached to this Agreement as <u>Exhibit B</u> and shall be delivered as one fully registered certificated bond in the denomination or denominations authorized under the Bond Authorization Legislation registered in the name of the Purchaser or such other name as the Purchaser shall have designated in writing at or prior to the Closing.

B. <u>Closing</u>. The sale of the Bonds shall take place on the Closing Date at the offices of Venable LLP, Towson, Maryland. The Purchaser shall make payment of the purchase price for the Bonds on the Closing Date by certified or official bank check or by credit advice of transfer to such account as the Issuer may have designated to the Purchaser in writing no later than the third day prior to such Closing Date. At the Closing, against delivery by Purchaser of the aggregate purchase price for the Bonds, the Issuer will deliver to Purchaser certificates representing the Bonds, registered as specified in paragraph, and bearing the following legend:

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. NO REGISTRATION OF TRANSFER OF SUCH SECURITIES WILL BE MADE ON THE BOND REGISTER UNLESS SUCH TRANSFER IS MADE IN CONNECTION WITH AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT OR PURSUANT TO AN

EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF SUCH ACT OR SUCH ACT DOES NOT APPLY.

NEITHER THE ISSUER OF THIS BOND NOR THE BOND REGISTRAR OR TRANSFER AGENT FOR THIS BOND MAY REGISTER THE TRANSFER OF, OR EXCHANGE THIS BOND FOR, A BOND OF THE ISSUE OF BONDS IN A DENOMINATION WHICH IS LESS THAN THE DENOMINATION OF THIS BOND; PROVIDED THAT EXCHANGE OF THIS BOND FOR ONE OR MORE BONDS IN DENOMINATIONS OF \$100,000 OR MORE SHALL BE PERMITTED IF SUCH EXCHANGE DOES NOT VIOLATE ANY APPLICABLE SECURITIES LAWS INCLUDING SECURITIES AND EXCHANGE COMMISSION RULE 15c2-12.

NEITHER THE ISSUER OF THIS BOND NOR THE TRANSFER AGENT FOR THIS BOND MAY REGISTER THE TRANSFER OF THIS BOND TO A TRANSFEREE UNLESS THE TRANSFEREE IS EITHER A FINANCIAL INSTITUTION OR A SOPHISTICATED INVESTOR WHO IS EXPERIENCED IN BUSINESS AND FINANCIAL MATTERS AND WHO IS ALSO ABLE TO EVALUATE THE RISKS AND MERITS OF INVESTING IN SECURITIES SIMILAR TO THIS BOND.

C. <u>Right to Rescind</u>. The Purchaser shall have the right to rescind or terminate this Agreement at any time on or prior to the Closing Date or if the sale and purchase of the Bonds as provided herein shall in the Purchaser's reasonable judgment become impossible or impractical because, since the date hereof: (1) any outbreak of major hostilities or any other national or international calamity or crisis shall have occurred; (2) a general banking moratorium shall have been declared by Federal or New York State authorities; or (3) trading on the New York Stock Exchange shall have been suspended or minimum or maximum for prices shall have been required on the New York Stock Exchange by such Exchange or by the Commission or any other Governmental Body.

Section 3. Representations and Warranties of the Issuer. The Issuer represents and warrants to the Purchaser that:

- A. <u>Organization and Power</u>. The Issuer is a body politic and corporate and political subdivision of the State of Maryland. The Issuer is authorized and empowered by the provisions of the Act to enter into the transactions contemplated by this Agreement.
- B. <u>Authorization of Agreements. etc.</u> The execution, delivery and performance of this Agreement and the Bonds have been duly authorized by all necessary proceedings of the Issuer, and such execution, delivery and performance do not and will not contravene,

or constitute a default under, any provision of law, ordinance or regulation applicable to the Issuer or any judgment, order, decree, agreement or instrument binding on it or result in the creation of any lien or other encumbrance on any asset of the Issuer other than the restrictions on the Dudrow Industrial Park Lot Three Development District Special Fund under the provisions of the Act and the Resolution. This Agreement constitutes the valid and binding agreement of the Issuer, and the Bonds, when duly executed and delivered by the Issuer in accordance with this Agreement and the Bond Authorization Legislation, will constitute valid and binding obligations of the Issuer.

- C. <u>Governmental Consents</u>. All authorizations, consents and approvals of Governmental Bodies required in connection with the execution and delivery by the Issuer of, or in connection with the performance by the Issuer of its obligations under, this Agreement and the Bonds have been obtained and are in full force and effect.
- D. No Litigation. There is no action, suit or proceeding pending, or to the Issuer's knowledge threatened, against or affecting the Issuer in any court or before any arbitrator or before or by any Governmental Body calling into question the creation, organization or existence of the Issuer, the title of any of its officers to their respective offices, the pledge or lien securing the Bonds, the collection of any amounts pledged to the payment of the Bonds, or the power of the Issuer to enter into the transactions contemplated hereby or wherein an unfavorable decision, ruling or finding would adversely affect the transactions contemplated hereby or would affect the enforceability of the Bonds or any other agreement or instrument to which the Issuer is a party and that is to be used in connection with, or is contemplated by, this Agreement, nor to the knowledge of the Issuer is there any basis therefor.
- E. <u>Collection</u>. In the event that the Company or any other owner fails to pay real estate taxes on the Dudrow Industrial Park Lot Three Development District in a timely manner, the County covenants to pursue such delinquency in accordance with its ordinary and customary collection and tax sale procedures generally applicable to delinquent taxpayers.
- F. <u>Grant of Security Interest</u>. In order to secure the payment of the Bonds from the Dudrow Industrial Park Lot Three Development District Special Fund (the "Special Fund"), the Issuer hereby assigns, pledges and grants to the Purchaser a first lien security interest under the Maryland Uniform Commercial Code in the Special Fund and all monies deposited therein, including investment earnings thereon and all proceeds thereof. The Issuer authorizes the Purchaser to file Financing Statements and to enter into Control Agreements, if the Purchaser deems necessary, in order to perfect the Purchaser's lien and security interest in the Special Fund and all monies therein, including investment earnings thereon and all proceeds of the Special Fund.

Section 4. Representations and Warranties of the Company. The Company represents and warrants to the Issuer and the Purchaser that:

- A. <u>Organization and Power</u>. The Company is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Maryland, and has all corporate powers and all material governmental licenses, authorizations, consents and approvals required to carry on its business as now conducted and to enter into and perform this Agreement.
- B. <u>Authorization of Agreements, etc.</u> This Agreement has been duly authorized by all necessary corporate action on the part of the Company (no action by the stockholders of the Company being required). This Agreement has been duly executed and delivered by the Company and constitutes the valid and binding agreement of the Company except to the extent that enforceability may be effected by any bankruptcy or insolvency proceeding filed by or against the Company and subject to the exercise of judicial discretion in accordance with general principals of equity.

#### C. INTENTIONALLY OMITTED.

- D. No Material Adverse Change. Since June 30, 2004, there has been no material adverse change in the business, financial position, results of operations or prospects of the Company, considered as a whole.
- E. <u>Noncontravention</u>. The execution, delivery and performance by the Company of this Agreement does not and will not contravene, or constitute a default under, any provision of applicable law or regulation or of the certificate of incorporation or by-laws of the Company or of any agreement, judgment, injunction, order, decree or other instrument binding upon the Company or result in the creation of any lien or other encumbrance on any asset of the Company.
- F. <u>Governmental Consents</u>. No consent or approval is required to be obtained from, and no action need be taken by, or document filed with, any Governmental Body in connection with the execution, delivery and performance of this Agreement by the Company, or, if any such action is required, the same has been duly taken, is in full force and effect and constitutes valid and sufficient consent or approval therefor.
- G. <u>Brokers</u>. No person, corporation or other entity has, or as a result of any action of or by the Company in connection with the transactions contemplated hereby and by the Resolution and the Bond Authorization Legislation will have, any right, interest or valid claim against the Purchaser for any commission, fee or other compensation as a broker or finder, or in any similar capacity.
- H. No Litigation. As of the date hereof, there is no action, suit or proceeding pending, or to the best of the Company's knowledge threatened, against or affecting the Company in any court or before any arbitrator or before or by any Governmental Body which in any manner raises any question affecting the validity or enforceability of this Agreement, the Resolution, the Bond Authorization Legislation, or any other agreement or instrument to which the Company is a party and that is to be used in connection with,

or is contemplated by, this Agreement, or which is likely to result in a materially adverse change in the business, financial position or results of operations of the Company nor to the best of the knowledge of the Company is there any basis therefor.

Section 5. Representations and Warranties of the Purchaser. The Purchaser represents and warrants to the Issuer that:

- A. Receipt of Information. The Purchaser has received the information with respect to the Company, it affairs, and the Project which the Purchaser has requested and which the Purchaser as an informed and experienced investor has deemed necessary in order to make an adequate and thorough evaluation of the risks and rewards of an investment in the Bonds.
- B. <u>Limited Obligation</u>. The Purchaser acknowledges that the Bonds are limited obligations of the Issuer and are payable solely from moneys deposited in the Dudrow Industrial Park Lot Three Development District Special Fund created by the Issuer pursuant to Section 14-207 of the Act and the Resolution and that the Special Fund is subject solely to the limitations and restrictions of Section 14-208 of the Act and the Resolution as to the use of moneys in that fund. The Purchaser further acknowledges that the Bonds will be repaid solely by the Issuer's pledge to allocate and divide a portion of the property taxes actually received with respect to the real property located within the Dudrow Industrial Park Lot Three Development District pursuant to Section 14-206(3) of the Act and the Resolution and to pay that portion into the Special Fund. The Bonds are not general obligations of the Issuer and the full faith and credit of the Issuer are not pledged to the payment of the principal of and the interest and any redemption premium on the Bonds. The Purchaser has no right to compel the levy of any taxes by the Issuer and the insufficiency of monies in the Special Fund to pay the Bonds shall not constitute a default under the Bonds.
- C. Review of Documents. The Purchaser has reviewed and approved the form of the Bonds attached to this Agreement as Exhibit B, the Resolution, the Bond Authorization Legislation, and such documents contain the terms which have been agreed to by the Purchaser.
- D. <u>Financial Experience</u>. The Purchaser is experienced in financial and business matters, including the purchase and ownership of taxable and tax-exempt municipal obligations payable solely from incremental real property tax revenues derived from limited owner development districts and is able to evaluate the risks and merits of the investment in purchase of the Bonds.
- E. Access to Information. The Purchaser either has been supplied or has had access to such information with regard to the Company, including financial statements and related financial data, as it deems appropriate and to which a reasonable investor would attach significance in making an investment decision to purchase securities such as the Bonds. The Company has made itself available to the Purchaser at its request to

enable Purchaser to determine those facts about the nature of Company's business, the risks attendant thereto, and the value of the security so as to enable Purchaser to make a knowledgeable decision to purchase the Bonds. The Purchaser has not obtained any interest in real property as security for the Bonds.

- F. No Reliance on the Issuer. Purchaser (1) has not relied upon the Issuer's decision to create the Dudrow Industrial Park Lot Three Development District Special Fund and to issue the Bonds as any confirmation of the creditworthiness of the Company or the security for the Bonds, (2) has not relied upon the Issuer to supply any information whatsoever about the Company, its business, its prospects, or its financial affairs, and (3) has made the decision to purchase the Bonds solely on the basis of its own independent judgment.
- G. Investment Purpose. The Purchaser is purchasing the Bonds for its own account, with the purpose of investment and not with a view to the distribution or resale of the Bonds other than to the Participants. The Purchaser has not offered, offered to sell, offered for sale, or sold the Bonds by means of any form of general advertising and the Purchaser is not an "underwriter" within the meaning of Section 2(11) of the Securities Act of 1933, as amended, and will not sell the Bonds without registration under the Securities Act of 1933, as amended, or an exemption from such registration.
  - H. Authority to Execute. The Purchaser has full power and authority to execute this Agreement and to purchaser or acquire the Bonds.
  - I. Lawful Investment. The Purchaser has satisfied itself that the Bonds are a lawful investment for the Purchaser under all applicable laws.
  - J. No Credit Rating. The Purchaser acknowledges that no credit rating has been sought or obtained with respect to the Bonds
- K. No Continuing Disclosure. The Purchaser acknowledges that because (1) the authorized denomination of the Bonds is \$100,000 and (2) the sale of the Bonds is limited to no more than 35 sophisticated persons none of whom is purchasing for more than one account with a view toward distributing the Bonds, the Issuer shall have no ongoing continuing obligation in connection with the Bonds under Securities and Exchange Commission Rule 15c2-12.

Section 6. <u>Conditions of Closing</u>. The Purchaser's obligation to purchase the Bonds under this Agreement shall be subject to the satisfaction prior to the Closing Date or concurrently with the Closing on such date, of the following conditions:

A. <u>Opinion of Counsel to the Company</u>. The Purchaser shall have received favorable opinions dated the Closing Date from Arent Fox PLLC, special counsel to the Company, satisfactory to the Purchaser and the Purchaser's counsel, to the effect that:

- (1) the Company is a corporation duly incorporated, validly existing, in good standing under the laws of Maryland, and duly authorized to transact business in Maryland, and qualified to do business in Maryland, and has all corporate powers and all material governmental licenses, authorizations, consents and approvals to carry on its business as now conducted and to enter into and perform this Agreement and the Development Agreement;
- (2) this Agreement and the Development Agreement have been duly authorized by all necessary corporate action on the part of the Company. This Agreement and the Development Agreement have been duly executed and delivered by the Company and constitute valid and binding agreements of the Company, subject to the customary qualifications for bankruptcy and the application of equitable principles in actions to enforce contracts;
- (3) to the knowledge of such counsel upon reasonable inquiry, there are no actions, suits or proceedings, pending or threatened against or affecting the Company or any Subsidiary of the Company in any court or before any arbitrator or before or by any Governmental Body in which there is a reasonable possibility of an adverse decision which would materially adversely affect the business, financial position or results of operations of the Company and its Subsidiaries, or which in any manner raises any question affecting the validity of this Agreement or the Development Agreement;
- (4) the execution, by the Company of this Agreement and the Development Agreement do not contravene, or constitute a default under, any provision of applicable law or regulation or of the certificate of incorporation or by-laws of the Company or any agreement, judgment, injunction, order, decree or other instrument binding upon the Company and known to such counsel after reasonable inquiry, or result in the creation of any lien or other encumbrance on any asset of the Company; and
- (5) no consent or approval is required to be by, or document filed with, any Governmental Body in connection with the execution, delivery and performance of this Agreement or the Development Agreement by the Company, or, if such action is required, the same has been duly taken, is in full force and effect and constitutes valid and sufficient authorization therefor.
- B. Opinion of Counsel to Issuer. The Purchaser shall have received a favorable opinion dated the Closing Date from Venable LLP, Baltimore, Maryland, in the form attached to this Agreement as Exhibit C.
- C. <u>Representations and Warranties</u>. The representations and warranties of the Issuer and the Company contained herein shall be true on and as of the Closing Date with the same effect as though such representations and warranties had been made on and as of the Closing Date.

- D. <u>Performance</u>; No <u>Default</u>. The Company shall have performed and complied with all agreements and conditions herein required to be performed or complied with by it prior to or on the Closing Date, and at the time of the Closing no event of default or default shall have occurred and be continuing with respect to the Development Agreement and the Bonds.
- E. <u>Compliance Certificate</u>. Unless this Agreement is dated the Closing Date, the Company shall have delivered to the Purchaser on the Closing Date a certificate, dated the Closing Date, signed by its President or one of its Vice Presidents, certifying that the conditions relating to it in Section 6.D have been fulfilled.
- F. <u>Bond Authorization Legislation</u>. The Bond Authorization Legislation shall have been duly adopted, enacted, and executed by the duly elected or appointed officials of the Issuer, shall be in full force and effect, and shall not be subject to any referendum.
- G. Other Documents and Proceedings. The Purchaser shall have received all other documents and opinions as the Purchaser may have requested relating to (1) the existence of the Company, (2) the corporate and governmental authority for and validity of this Agreement, Bond Authorization Legislation, the Development Agreement, and the Bonds, and (3) other matters relevant to the issuance and sale of the Bonds hereto. All proceedings to be taken in connection with the transactions contemplated by this Agreement, the Resolution, and the Bond Authorization Legislation, and all documents, opinions and certificates incident to such transactions shall be satisfactory in form and substance to the Purchaser.
  - H. The Bonds. The Purchaser shall have received the duly authenticated Bond in compliance with the provisions of Section 2.A hereof.
- I. No Legal Action. There shall not be pending before any court or before any administrative body any action, proceeding or investigation which is directed toward challenging, restraining, prohibiting or invalidating the transactions contemplated hereby, nor shall the Company have received from any Governmental Body official notification in writing objecting to the sale of the Bonds.
  - J. The Servicing Agreement. The Purchaser shall have received a duly executed copy of the Servicing Agreement.

Section 7. INTENTIONALLY OMITTED.

Section 8. A. Environmental Matters. The Company represents and warrants that it is in compliance with the terms and provisions of the Loan Agreement and Deed of Trust between it and the Purchaser dated October 12, 2004, in respect to Hazardous Materials (as defined in those documents).

B. <u>Compliance</u>. With respect to the Project, the Company will at all times comply in all respects with all applicable laws (whether statutory, common law or otherwise), rules, regulations, orders, permits, licenses, ordinances, judgments, or decrees of any Governmental Body, including, without limitation, all laws regarding public health or welfare, environmental protection, water and air pollution, composition of product, underground storage tanks, toxic substances, hazardous wastes, hazardous substances, hazardous materials, waste or used oil, asbestos, occupational health and safety, nuisances, trespass, and negligence, except to the extent the failure to comply would not materially adversely affect the Borrower's properties (including the Project), operations or financial conditions.

Section 9. <u>Payment of Certain Expenses and Taxes by the Company</u>. Whether or not the transactions contemplated by this Agreement shall be consummated, the Company will:

- (1) pay all reasonable expenses incurred by the Purchaser and the Issuer incident to the transactions contemplated by this Agreement or in connection with any enforcement, modification, amendment, or alteration of this Agreement, the Development Agreement, the Bonds, the Resolution, or the Bond Authorization Legislation (whether or not any such enforcement, modification, amendment or alteration becomes effective), including, but not limited to, any out-of-pocket expenses incurred by the Purchaser or the Issuer and the fees, charges and disbursements of counsel for the Issuer and for the Purchaser; and
- (2) pay and hold the Purchaser and the Issuer harmless against any and all liability with respect to amounts payable as a result of (a) any taxes which may be determined to be payable in connection with the execution and delivery of the Bonds, this Agreement, the Development Agreement, Resolution, or the Bond Authorization Legislation, or any modification, amendment or alteration, of the terms or provisions of any of the Bonds, this Agreement, Development Agreement, the Resolution, or the Bond Authorization Legislation, (b) any interest or penalties resulting from any delays in paying any of such expenses, charges, disbursements, liabilities or taxes, and (c) any advisory, placement, brokers', finders' or other similar fees incurred in connection with the sale of the Bonds hereunder.

The obligations of the Company under this Section shall survive the payment of the Bonds

Section 10. <u>Survival of Covenants; Successors and Assigns.</u> All covenants, agreements, representations and warranties made by the Company or the Purchaser in this Agreement or the Development Agreement, and in certificates or other documents delivered pursuant to them, shall survive the delivery of the Bonds to the Purchaser and shall continue in full force and effect, until all the Bonds are paid in full and thereafter to the extent provided by Section 9. All such covenants, agreements, representations and

warranties shall be binding upon any successors and assigns of the Company or the Purchaser, as the case may be, and shall inure to the benefit of their successors and assigns.

- Section 11. A. No Oral Change; Amendments in Writing. This Agreement may not be changed orally, but only by an agreement in writing and signed by the party against whom enforcement of any waiver, change, modification or discharge is sought.
- B. No Assignment of Agreement. The Company may not assign any of its rights or obligations under this Agreement without the Purchaser's written consent, and the Purchaser shall not be required to purchase the Bonds under this Agreement except from the Issuer.
- C. Conflicts. In the event of a conflict between the Summary and the terms hereof, the terms of this Agreement shall control.
- Section 12. Notices. Except as otherwise provided in this Agreement, whenever notice is required to be given pursuant to the provisions of this Agreement or the Support Agreement, such notice shall be in writing and shall be mailed by first class mail postage prepaid addressed as set forth in the Servicing Agreement at the address set forth adjacent to the signatures of the parties hereto.
  - Section 13. Law Governing. This Agreement shall be construed in accordance with and governed by the laws of the State of Maryland.
  - Section 14. Headings. The headings of the sections and subsections of this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement.
- Section 15. Immunity of Officers, Employees and Members of Issuer. No recourse shall be had for the payment of the principal of or premium or interest on any of the Bonds or for any claim based thereon or upon any obligation, covenant or agreement in this Agreement contained against any past, present or future officer, director, member, employee or agent of the Issuer or of any successor political subdivision, as such, either directly or through the Issuer or any successor political subdivision, under any rule of law or equity, statute or constitution or by the enforcement of any assessment or penalty or otherwise, and all such liability of any such officers, directors, members, employees or agents as such is hereby expressly waived and released as a condition of and consideration for the execution of this Agreement and the issuance of the Bonds.

Section 16. Counterparts. This Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

If you agree with the foregoing, please sign two copies of this Agreement in the space provided below for your acceptance and return one copy so executed to the undersigned Purchaser, whereupon this Agreement shall then become a binding agreement between the Purchaser, the Issuer, and the Company.

[SIGNATURES BEGIN ON THE NEXT PAGE]

The foregoing is hereby accepted as of the date set forth above.

Very truly yours,

# MERCANTILE POTOMAC BANK

By: /s/ Christopher A. Hesen
Name: Christopher A. Hesen
Title: Senior Vice-President

[Page 1 of 3 signature pages of Bond Purchase Agreement]

The foregoing is hereby accepted as of the date set forth above.	
EMERGENT BIOLOGICS INC.	
By: /s/ Fuad El-Hibri Name: Title:	
	[Page 2 of 3 signature pages of Bond Purchase Agreement]

The foregoing is hereby accepted as of the date set forth above.

COUNTY COMMISSIONERS OF FREDERICK COUNTY

By: /s/ John L. Thompson Jr.

John L. Thompson, Jr.

President of the Board of County Commissioners

[Page 3 of 3 signature pages of Bond Purchase Agreement]

## EXHIBIT A

# SUMMARY OF TERMS

February 11, 2005

Board of County Commissioners of Frederick County 12 East Church Street Winchester Hall, MD

#### Dear Lady and Gentlemen:

The Mercantile Potomac Bank is pleased to advise you that we have approved your request associated with the planned Tax Increment Financing ("TIF") for economic development purposes as required by the State of Maryland's Department of Business and Economic Development.

Purchaser: Mercantile Potomac Bank ("Bank")

Issuer: County Commissioners of Frederick County ("County" or "Issuer").

Amount: Not to exceed \$325,000.00

Purpose: To fund certain allowable expenditures, including the acquisition of land and site work for the Dudrow Industrial Park, Lot Three Development District also known as the

Units 1, 2 & 3 Wedgewood IV Land Condo.

Term: Five years.

Repayment: Annual payments of principal and interest beginning on December 1, 2005 and annually thereafter due on December 1st of each year.

Funding: Funding will occur on or before March 31, 2005.

Interest Rate: Fixed rate for the five year term at 6.625% (taxable) or the 4.08% (tax-exempt).

Facility/

Collateral: The facility ("Bond") will be a limited obligation of the County under which ninety percent (90%) of the incremental increase of real estate taxes ("Incremental Taxes")

from the TIF district will be deposited in a a special fund and pledged to pay the Bond. Subject to the county's consent, in the event of a default or insufficient debt service coverage, 100% of the Incremental Taxes then remaining in the special fund created to hold the Incremental Taxes will be pledged for debt service requirements

and collection expenses of the Bond.

## Other Conditions:

- 1. Ninety percent (90%) of the Incremental Taxes will be pledged to the debt service assigned to the Bond so that a minimum ratio of 1.0:1.0 of taxes pledged (as a result of final tax assessed value on the property) to annual debt service will be maintained. See Schedule A example of calculation.
- 2. The Bond will also be subject to a Bond Purchase Agreement entered into by the Purchaser, the County and Emergent Biologics Inc. ("Emergent"), which will include the terms and provisions set forth above as well as other terms and conditions reasonably acceptable to the Issuer and Purchaser including the Issuer's covenant to treat the Property in a manner consistent with that of other delinquent taxpayers and to offer the Property for sale under its tax lien in the ordinary course of its tax collection activities.

#### General Conditions:

- 1. Any material change in the conditions contained in this letter, as determined by the Purchaser in its sole discretion, will allow the Purchaser to terminate this letter agreement by written notice to the County, and thereupon Purchaser shall have no further obligations to the County to purchase the bond or otherwise perform any obligation set forth herein or in other related document or agreement.
- 2. <u>Documentation:</u> All documents evidencing or securing the Bond and any other Liabilities (collectively, the "Bond Documents") or relating to any such documents and such other documents, instruments, opinions, assurance, consents, and approvals as the Purchaser may deem necessary shall be subject to the approval of and shall be in form and content satisfactory to the Purchaser and its counsel in their sole but reasonable discretion. In particular, such documents may include, without limitation, but subject to existing and future Deeds of Trust affecting the property, in the sole discretion of the Purchaser and its counsel, provision for application of condemnation proceeds for restoration of the improvements.
- 3. Expenses: Emergent shall pay all fees, expenses, costs and charges with respect to the issuance of the Bond, or in any way connected therewith, including, but not limited to attorney's fees and expenses (including Purchaser's counsel's fees and expenses). The Issuer's counsel will prepare the Bond Documents. Such expenses may be funded by the proceeds of the Bond
- 4. <u>Interest Computation</u>: Late Charges: Interest on the Bond shall be computed on the basis of thirty (30) day months and a 360-day year. Upon default under the Bond documents, a late charge equal to the lesser of five percent (5%) per month or the interest rate otherwise chargeable for the delinquent tax payments based upon the incremental tax payment due for that current tax

year shall be payable from incremental taxes or other funds then available in the special fund, which charge should accrue if any payment of principal or interest pursuant to the bond shall be more than fifteen (15) days delinquent and such interest shall continue to accrue until the default is cured or the Bond is paid in full.

- 5. <u>Evidence of Compliance</u>, etc. Evidence satisfactory to the Purchaser that:
  - i. The Bond and actual use of the Property complies in all material respects with all laws, ordinances, rules and regulations of all governmental authorities having jurisdiction over the same.
  - ii. All requisite approvals for occupancy of the facility have been validly granted without qualifications; and
  - iii. There are no actions or proceedings pending before any court or administrative agency or governmental body at the time which materially and adversely affect the Issuer's or Emergent ability to honor its obligations under the Bond
- 6. <u>Hazardous Materials</u>: Emergent shall represent and warrant that it is in compliance with the provision of the Deed of Trust and Loan Agreement dated October 12, 2004 between it and the Bank in respect to Hazardous Materials as therein defined.
- 7. <u>Assignment:</u> Except to reimburse Emergent for qualifying expenditures, the proceeds of the Bond shall not be assigned by the Issuer without the prior written consent of the Purchaser, and any such assignment without such consent shall be void and, at the option of the Purchaser, be deemed a default, hereunder. The Bond and any other bond or documentation connected with or contemplated by this transaction may be placed, assigned, serviced, and/or participated out (either in whole or in part) by the Purchaser and/or its successors and assigns.
- 8. <u>Termination</u>: The Purchaser may terminate this commitment if, except as may be otherwise provided herein, the Bond or any other feature of the transaction has been or is misrepresented by the Issuer, or any third party in the bond application or otherwise, or if any adverse change, in the sole but reasonable judgment of the Purchaser, shall have occurred with respect to any part of this transaction.
- 9. <u>Actions by the Purchaser</u>: No statement, agreements, or representations oral or written, which may have been made to the Issuer or any third party or to any employee or agent of the Issuer, either by the Purchaser or by any employee, agent, or broker acting on the Purchaser's behalf, with respect to the Bond, shall be of any force or effect, except to the extend stated in this commitment, and all prior agreements and representations with respect to the Bond are merged herein. This commitment may not be changed except by written agreement signed by the Issuer and the Purchaser.

we are very pleased to be able to make this commitment and we look following with the Country and Emergent on the Issuance of the Bond.		
	With regards,	
	/s/ Christopher A. Hesen	
	Christopher A. Hesen Senior Vice President	
Agreed and accepted thisday of February 2005.		
Witness:	Board of County Commissioners Of Frederick County	
	By:	
-		

# Schedule A TIF Bond Calculations For Emergent BioLogics Inc. Facility

Current Estimate

## **Assessed Market Value:**

			Current Estimate
As of January 1, 2004	Land		\$ 773,600.00
As of July 1, 2005	Building		\$ 18,716,062.00
Assessment Ratio:			100%
Assessable Base:			\$ 18,716,062.00
Less Original Assessable Bas	se:		(773,600.00)
Adjusted Assessable Base:			\$ 17,942,462.00
Tax Calculation:			
Tax Calculation:			
County Tax Rate			\$ 1.00
County Base Tax Revenue			\$ 7,736.00
Tax Increment Revenue			\$ 179,424.00
Pledged Allocation @ 90%			\$ 161,481.00
Bond Repayment Scenari	io:		
Taxable Rate			Tax-Exempt Rate
Rate		6.625%	4.08%
Principal		\$325,000.00	\$325,000.00
Term		60 Months	60 Months
P&I		\$78,669.73	\$ 73,287.33
		2.0,002.70	~ · - ,= - · · - •
Coverage		2.053X	2.203X

## EXHIBIT B SPECIMEN BOND

No. R-1 \$300,000.00

# UNITED STATES OF AMERICA STATE OF MARYLAND FREDERICK COUNTY, MARYLAND TAX INCREMENT FINANCING BOND (DUDROW INDUSTRIAL PARK LOT THREE DEVELOPMENT DISTRICT) SERIES 2005

Annual Interest Rate	Maturity Date	Bond Date
4.08%	December 1, 2009	March, 2005

Registered Owner: Mercantile Potomac Bank
Principal Amount: Three Hundred Thousand Dollars

County Commissioners of Frederick County, a body politic and corporate organized and existing under the Constitution and laws of the State of Maryland (the "County"), hereby acknowledges itself indebted for value received and, promises to pay to the Registered Owner shown above, or his registered assigns, on December 1, 2005 and on each December 1 thereafter up to and including the Maturity Date shown above unless this bond shall have been called for prior redemption and payment of the redemption price made or provided for, the Principal Amounts set forth on Schedule A attached hereto and made a part hereof ("Schedule A") and to pay interest on the outstanding principal amount hereof from the date hereof in the amounts set forth on Schedule A.

Interest on this Bond shall be paid at the Annual Interest Rate shown above, payable December 1, 2005 and annually thereafter on December 1 in each year (the "Interest Payment Dates") until payment of such Principal Amount shall be discharged in the amounts set forth on Schedule A. Such interest shall be paid to the person in whose name this bond is registered on the registration books maintained by the Servicer (as hereafter defined) who shall serve as bond registrar for the Bond (the "Bond Registrar") at the close of business on the 15th calendar day of the month next preceding each Interest Payment Date (the "Record Date").

Interest on this Bond shall be computed on the basis of thirty (30) day months and a 360-day year. If any payment due hereunder is not received within fifteen (15) days after its due date, a late charge equal to the lesser of one percent (1%) per month or the interest rate then chargeable by the County for delinquent tax payments shall accrue on such late payment and shall be payable from any late payment proceeds received by the County on the incremental taxes pledged for repayment of this Bond.

This Bond is a limited obligation of the County, payable as provided in the Ordinance, and the full faith and credit and unlimited taxing power of County Commissioners of Frederick County are not pledged to the payment of the principal of this Bond and of the interest to accrue hereon.

Principal of, premium, if any, and interest on this Bond are payable in such money of the United States of America as is lawful at the time of payment.

This Bond is a single bond, limited in aggregate principal amount to \$300,000.00, dated March \_\_\_, 2005 and known as "Frederick County, Maryland, Tax Increment Financing Bond (Dudrow Industrial Park Lot Three Development District) Series 2005 (the "Bond"). The Bond is issued as a registered bond, without coupons, in the denomination of \$300,000.00. The Bond is numbered No. R-1 and matures on December 1, 2009.

The Bond shall be subject to redemption at the option of the County in whole or in part from funds available to the County for such purpose at any time without penalty or premium.

Notice having been given in the required manner hereunder, the Bond or portion of the Bond called for redemption shall, on the redemption date designated in such notice, become and be due and payable at the redemption price provided for redemption of such Bond or portion of such Bond on such date. On the date so designated for redemption, notice having been given as required hereunder and monies for payment of the redemption price being held in separate accounts by the Servicer or the County in trust for the Owner of the Bond or portions thereof to be redeemed, interest on the Bond or portion of Bond shall cease to be entitled to any lien, benefit or security under the Bond Documents, and the Owner of such Bond or portion of such Bond shall have no right in respect thereof except to receive payment of the redemption price thereof and, upon presentation and surrender of the Bond to the Servicer, to receive a new Bond for any unredeemed portion of the Bond.

The Bonds will be transferable only upon the Bond Register by the Bond Registrar. Any Bond presented for transfer, exchange, registration, or redemption shall be accompanied by a written instrument or instruments of transfer or authorization for exchange, in form and with guaranty of signature satisfactory to the Bond Registrar, duly executed by the Registered Owner thereof or by his duly authorized attorney. Upon any transfer or exchange, the County shall execute and the Bond Registrar shall authenticate and deliver in the name of the Registered Owner or the transferee or transferees, as the case may be, a new registered Bond or Bonds of any of the authorized denominations in an aggregate principal amount equal to the principal amount of the Bond exchanged or transferred and maturing on the same date and bearing interest at the same rate. In each case, the County and the Bond Registrar may require payment by the Registered Owner requesting the exchange or transfer of any tax, fee or other governmental charge, shipping charges and insurance that may be required to be paid with respect thereto, but otherwise no charge shall be made to the Registered Owner for the exchange or transfer.

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED. NO REGISTRATION OF TRANSFER OF SUCH SECURITIES WILL BE MADE ON THE BOND REGISTER UNLESS SUCH TRANSFER IS MADE IN CONNECTION WITH AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT OR PURSUANT TO AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF SUCH ACT OR SUCH ACT DOES NOT APPLY.

NEITHER THE ISSUER OF THIS BOND NOR THE BOND REGISTRAR OR TRANSFER AGENT FOR THIS BOND MAY REGISTER THE TRANSFER OF, OR EXCHANGE THIS BOND FOR, A BOND OF THE ISSUE OF BONDS IN A DENOMINATION WHICH IS LESS THAN THE DENOMINATION OF THIS BOND; PROVIDED THAT EXCHANGE OF THIS BOND FOR ONE OR MORE BONDS IN DENOMINATIONS OF \$100,000 OR MORE SHALL BE PERMITTED IF SUCH EXCHANGE DOES NOT VIOLATE ANY APPLICABLE SECURITES LAWS INCLUDING SECURITIES AND EXCHANGE COMMISSION RULE 15C2-12.

NEITHER THE ISSUER OF THIS BOND NOR THE TRANSFER AGENT FOR THIS BOND MAY REGISTER THE TRANSFER OF THIS BOND TO A TRANSFEREE UNLESS THE TRANSFEREE IS EITHER A FINANCIAL INSTITUTION OR A SOPHISTICATED INVESTOR WHO IS EXPERIENCED IN BUSINESS AND FINANCIAL MATTERS AND WHO IS ALSO ABLE TO EVALUATE THE RISKS AND MERITS OF INVESTING IN SECURITIES SIMILAR TO THIS BOND.

The Bond Registrar shall not be required to transfer or exchange any Bond after the mailing of notice calling such Bond or portion thereof for redemption; provided, however, that this limitation shall not apply to any portion of a Bond which is not being called for redemption.

The Bond is issued pursuant to the authority of Article 41, Section 14-201 of the Annotated Code of Maryland and in accordance with Resolution No. 04-38 of the Board of county commissioners of the County adopted on October 5, 2004 and the Ordinance (as hereafter defined).

It is hereby certified and recited that each and every act, condition and thing required to exist, to be done, to have happened and to be performed precedent to and in the issuance of this Bond, does exist, has been done, has happened and has been performed in full and strict compliance with the Constitution and laws of the State of Maryland and Ordinance No. 05-02-363 of the Board of County Commissioners of Frederick County, enacted on March 1, 2005 authorizing the issuance of the issue of Bonds, of which this bond is the sole Bond (the "Ordinance") and that said issue of Bonds, together with all other indebtedness of the County, is within every debt and other limit prescribed by the Constitution and laws of said State.

IN WITNESS WHEREOF, the County has caused this Bond to be executed in its name by the President of the Board of County Commissioners of Frederick County and attested by its County Manager, and has also caused its corporate seal to be printed hereon.

ATTEST:

COUNTY COMMISSIONERS OF FREDERICK COUNTY

By:

Douglas D. Browning
County Manager

Douglas D. Browning
County Manager

Douglas D. Browning
County Manager

-4-

## ASSIGNMENT

FOR VALUE RECEIVED, the undersigned hereby sells, assigns and transfers unto (Tax Iden hereunder, and does hereby constitute and appointattorney substitution in the premises.	tification or Social Security No) the within bond and all rights to transfer the within bond on the books kept for the registration thereof, with full power of
Dated:	
Signature Guaranteed:	
NOTICE: Signatures must be guaranteed by a member firm of the New York Stock Exchange or a commercial bank or trust company	(Signature of Registered Owner)  NOTICE: Signature must correspond with the name of the Registered Owner of the within bond as it appears on the face of the within bond in every particular, without alteration or enlargement or any change whatever
	-5-

## SCHEDULE A

## BOND SCHEDULE

(i) Bond Identifying Number: R-I

(ii) Company Name: EMERGENT BIOLOGICS INC.

(iii) Property Address: 7114, 7116 and 7118 Geoffrey Way, Frederick, Maryland 21701

(iv) (a) Original Loan Term: 5 years

(v)

(b) Original Final Maturity: December 1, 2010

Bond Interest Rate: 4.08% per annum

(vi) First Monthly Payment Due Date: December 1, 2005

(vii) Annual Payment Amount: 12/01/05 \$64,113.84; each 12/01 thereafter \$67,649.84 [+ Annual Servicing Fee \$0]

(viii) Original Principal Balance: \$300,000.00

# EXHIBIT C

# BOND OPINION

VENABLELLP

210 Allegheny Avenue Post Office Box 5517 Towson, Maryland 21285-5517 Telephone 410-494-6200 Facsimile 410-821-0147 www.venable.com

March , 2005

County Commissioners of Frederick County Winchester Hall 12 E. Church Street Frederick, Maryland 21701 Mercantile Potomac Bank 702 Russell Avenue — Suite 200 Gaithersburg, Maryland 20877

\$300,000 Frederick County, Maryland

Tax Increment Financing Bond

(Dudrow Industrial Park Lot Three Development District) Series 2005

## Ladies and Gentlemen:

We have acted as bond counsel to County Commissioners of Frederick County, a body politic and corporate and a political subdivision of the State of Maryland (the "Issuer"), in connection with the issuance of the above-referenced bonds which are issued as a single, fully registered bond in the amount of \$300,000 (the "Bond") dated the date hereof.

In such capacity, we have examined the law and such certified proceedings and other papers as we deem necessary to render this opinion.

The scope of our engagement as bond counsel extends solely to an examination of the facts and law incident to rendering the opinion specifically expressed herein.

Unless the context clearly indicates otherwise, each capitalized term used in this opinion shall have the same meaning as set forth in the Bond and in the Purchase Agreement.

The Bond has been authorized and issued pursuant to the Tax Increment Financing Act, Sections 14-201 through 14-214 of Article 41 of the Annotated Code of Maryland, as amended (the "Act"), Resolution No. 04-38 of the Issuer adopted on October 5, 2004 (the "Resolution"), Ordinance No. 05-02-363 enacted on March 1, 2005 (the "Ordinance"), a Written Order dated of even date herewith executed by the President of the Board of County Commissioners of Frederick County (the "Written Order") and under a Bond Purchase Agreement among the Issuer, Emergent BioLogics Inc. (the "Developer") and Mercantile Potomac Bank (the "Purchaser") dated as of even date herewith (the "Purchase Agreement"). The Bond is a limited obligation of the Issuer payable solely from tax revenues of the Issuer allocated and paid to the Special Fund (as defined in the Resolution).

## VENABLELLP

County	Commissioners of Frederick County
March	, 2005
Page 2	

We refer you to the Bond, the Written Order and the Purchase Agreement for a description of the purposes for which the Bond is issued, the security for the Bond, the manner in which and times at which the principal of, premium (if any), and interest on, the Bond are payable, the interest rate or rates payable on the Bond, the provisions under which the Bond may be redeemed, and all other details of the Bond.

Mercantile Potomac Bank, as servicer (the "Servicer") will administer the Bond and the collection of moneys for the payment thereof as fiscal agent for the Issuer pursuant to a Servicing Agreement dated of even date herewith among the Issuer, the Servicer, the Developer and the Purchaser.

Proceeds of the Bond will be applied by the Issuer to reimburse the Developer for costs incurred by the Developer in connection with certain improvements to the Dudrow Industrial Park Lot Three Development District created by the Resolution, pursuant to a Development Agreement dated of even date herewith among the Issuer and the Developer (the "Development Agreement").

We have not reviewed or examined any financial information or other information with respect to the Developer or any offering material relating to the Developer, and we express no opinion relating thereto

We have made no investigations of, and are rendering no opinion regarding, title to, liens on or security interests in real or personal property, and we express no opinion as to the creation, validity or priority of any lien upon, assignment of, pledge of or security interest in any real or personal property. It is the responsibility of the Servicer to continue to maintain the perfection, priority or validity of any liens, assignments, security interests or pledges created as security for the Bond.

This opinion does not constitute or imply a recommendation of the market or financial value of the Bond or an assessment of the strength or appropriateness of the covenants by any of the parties to any of the documents relating to the issuance of, or securing, the Bond, the possibility of default (other than on account of the invalidity of the Bond), the eligibility or suitability of the Bond as an investment, or any other legal or financial aspect of the Bond not expressly addressed.

As to questions of fact material to our opinion, we have relied on representations of the Developer, the Purchaser and the Issuer Documents (as defined below), the certified proceedings and other certifications of public officials furnished to us without undertaking to verify the same by independent investigation.

# $VENABLE_{\mathsf{LLP}}$

County	Commissioners of Frederick County
March	, 2005
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We have assumed the authenticity of all documents submitted to us as originals, the genuineness of all signatures, the conformity to original documents of all documents submitted to us as certified or photostatic copies and the authenticity of the originals of such latter documents.

We do not express any opinion herein concerning any law other than the law of the State of Maryland and the federal law of the United States of America.

Based on the foregoing, we are of the opinion that, under existing law and as of the date hereof:

- 1. The Issuer is duly created and validly existing as a body politic and corporate and a political subdivision of the State of Maryland and has full power and authority under the laws of the State, including the Act, to issue the Bond and to execute and deliver, and perform its obligations under, the Purchase Agreement, the Development Agreement and the Servicing Agreement (the "Issuer Documents").
  - 2. The Resolution has been validly adopted by the Issuer and has not been amended, rescinded or revoked and is in full force and effect.
  - 3. The Ordinance has been validly enacted by the Issuer and has not been amended, rescinded or revoked and is in full force and effect.
  - 4. The Written Order has been duly authorized, executed and delivered by the Issuer and has not been amended, rescinded or revoked and is in full force and effect.
- 5. The Bond has been duly authorized, executed and delivered by the Issuer, constitutes the valid and legally binding limited obligation of the Issuer and is enforceable against the Issuer in accordance with its terms. The Bond, the premium (if any), and the interest thereon, are limited obligations of the Issuer, the principal of, premium (if any), and interest on, which are payable solely from tax revenues of the Issuer allocated and paid to the Special Fund (as defined in the Resolution). The Bond, the premium (if any) and the interest thereon shall never constitute an indebtedness or a charge against the general credit or taxing powers of the Issuer, the State of Maryland, or any other public body within the meaning of any constitutional or charter provision or statutory limitation, and shall never constitute or give rise to any pecuniary liability of the Issuer, the State of Maryland, or any other public body. The Bond does not constitute an indebtedness to which the faith and credit of the Issuer, the State of Maryland or any public body is pledged.

VENABLELLP	

County	Commissioners of Frederick County
March	, 2005
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- 6. The Issuer Documents have been duly authorized, executed and delivered by the Issuer and, assuming due authorization, execution and delivery of such agreements by the other parties thereof, constitute legal, valid and binding agreements of the Issuer, enforceable against the Issuer in accordance with their respective terms.
- 7. In accordance with the Act, the principal amount of the Bond, the interest payable thereon, its transfer, and any income derived therefrom, including any profit made in the sale or transfer thereof, shall be exempt from taxation by the State of Maryland and by the several counties and municipalities of this State, but no opinion is expressed as to estate or inheritance taxes, Maryland franchise taxes on certain financial institutions measured by income, or to any other taxes not levied or assessed directly on the Bond or the interest thereon.
- 8. Interest on the Bonds is excluded from gross income for federal income tax purposes, and interest on the Bonds is not an item of tax preference for purposes of the federal alternative minimum tax imposed on individuals and corporations; it should be noted, however, that such interest is taken into account in determining adjusted current earnings for the purpose of computing the alternative minimum tax imposed on certain corporations (as defined for federal income tax purposes). The opinion set forth in the preceding sentence is subject to the condition that the County comply with all requirements of the Internal Revenue Code of 1986, as amended, that must be satisfied subsequent to the issuance of the Bonds in order that interest thereon be, or continue to be, excluded from gross income for federal income tax purposes. The County has covenanted to comply with all such requirements. Failure to comply with certain of such requirements may cause interest on the Bonds to be included in gross income for federal income tax purposes retroactively to the date of issuance of the Bonds. In addition interest on the Bonds may be subject to the branch profits tax imposed on foreign corporations engaged in a trade or business in the United States.

Other than as set forth in the preceding paragraphs 7 and 8, we express no opinion regarding the federal or state income tax consequences arising with respect to the Bonds.

The rights of any holder of the Bond and the enforceability of the Bond and the Issuer Documents are subject to: (a) the exercise of judicial discretion in accordance with general principles of equity (whether applied by a court of law or a court of equity), including judicial limitations on rights to specific performance; (b) the valid exercise of the constitutional powers of the United States of America and of the sovereign police and taxing powers of state or other governmental units having jurisdiction; and (c) bankruptcy,

# VENABLE<sub>LLP</sub> County Commissioners of Frederick County March\_\_\_\_\_\_, 2005 Page 5

insolvency, reorganization, moratorium or other similar laws heretofore or hereafter in effect affecting creditors' rights, to the extent constitutionally applicable.

Very truly yours,

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

Dated May 6, 2006

## EMERGENT EUROPE LIMITED

and

## SANOFI PASTEUR, S.A.

## LICENCE AND CO-DEVELOPMENT AGREEMENT

# COVINGTON & BURLING

265 Strand London WC2R 1BH Tel: +44 (0)20 7067 2000 Fax: +44 (0)20 7067 2222

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THIS AGREEMENT is dated 2006

#### BETWEEN:

**EMERGENT EUROPE LIMITED**, a company organised and existing under the laws of England (Company number 03270465) and having its registered office at 545 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire, RG41 5TU ("**Emergent**");

## AND

1.1

**SANOFI PASTEUR, S.A.**, a *Société Anonyme* organised and existing under the laws of France (Company registration number 349 505 370 Lyon) and having its registered head office at 2, avenue pont pasteur, Lyon 69007 France ("sanofi pasteur").

#### WHEREAS:

- (A) Emergent has intellectual property and related ongoing research activity directed towards the development of a vaccine to prevent Neisseria meningitidis serogroup B infections.
- (B) sanofi pasteur has expertise in clinical development and registration of meningitis and paediatric vaccines.
- (C) Emergent and sanofi pasteur agree that a collaboration between them will accelerate the pre-clinical, and early clinical development of a prophylactic vaccine against *Neisseria meningitidis* infections and wish to enter into such collaboration on the terms and conditions of this Agreement.

## IT IS AGREED as follows:

#### DEFINITIONS AND INTERPRETATION

- In this Agreement the following definitions shall have the following meanings unless otherwise expressly provided or unless the context otherwise requires:
  - "Activity Forms" means the activity forms to be completed by Emergent employees and consultants engaged in Emergent Activities in the form set out in Schedule 7.
  - "Additional Antigen" means a sanofi pasteur Antigen or a Third Party Antigen that satisfies the Inclusion Criteria.
  - "Adjusted Combination Net Sales" has the meaning set out in the definition of Net Sales.
  - "Adolescent" means a young adult between 11 and 18 (inclusive) years of age.
  - "Adverse Event" means any untoward medical occurrence in a patient or clinical investigation subject administered a Clinical Candidate or Product, whether or not caused by the treatment, including any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease (including clinically significant worsening of a disease or pre-existing condition) temporally related to a Clinical Candidate or Product. Adverse Event also means any report of lack of efficacy of a

Clinical Candidate or Product and any treatment of a pregnant woman, any abuse or overdose (accidental or intentional), any other accidental exposure and lack of expected pharmacological action temporally related to a Clinical Candidate or Product.

- "Affiliate" means any company or other business entity which controls, is controlled by, or is under common control with, either Emergent or sanofi pasteur (as the context requires). For the purpose of this definition, "control" means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting share capital in such company or other business entity.
- "Annual Budget" has the meaning set out in Clause 5.3.
- "Annual Development Plan" means the detailed plan setting out the activities to be conducted by Emergent and sanofi pasteur in any Year (or such other period as the SC may decide) as part of the Development Programme.
- "Antigen" means a distinct and uniquely identifiable protein (including glycoproteins and lipoproteins), peptide, polysaccharide, or protein-polysaccharide conjugate, capable of eliciting a specific immune response and reacting with the products of that response and in respect of which a Party has provided to the other complete details of (a) in the case of a protein, the amino acid sequence or (b) in the case of other molecules, the chemical structure of such molecule, in each case sufficient to identify such molecule. For the purpose of this Agreement in the case of: (i) a protein Antigen encoded by a given gene, any antigenic determinants or epitope containing portions of such protein, and all fragments, derivatives and variants of any such protein, shall all be deemed to be one Antigen; (ii) a polysaccharide Antigen from a given serogroup of Neisseria meningitidis or another bacterial pathogen, any antigenic determinants or epitope containing portions of such polysaccharide, and all fragments, derivatives and variants of any such polysaccharide, shall all be deemed to be one Antigen; and (iii) a protein-polysaccharide conjugate where each of the protein and polysaccharide components would individually meet the definition of Antigen as defined above and each component separately contributes to protection against Neisseria meningitidis serogroup B infections, such protein and polysaccharide components will each be deemed to be one Antigen (each of which will be deemed to be the same Antigen as the relevant protein or polysaccharide and any antigenic determinants, epitope containing portions, fragments, derivatives and variants of such protein or polysaccharide conjugate will in such circumstances be considered two (2) Antigens.
- "Applicable Law" means the applicable laws, rules and regulations (including any rules, regulations, guidelines or other requirements of national and international patent offices and of the Regulatory Authorities, including GMP, GLP and GCP) that may be in effect from time to time in the Territory, to the extent applicable.
- "Business Day" means a day other than a Saturday or Sunday on which banking institutions in both Paris, France and London, England are open for business.
- "Candidate Antigen" means any of the [\*\*] candidate Antigens identified by Emergent prior to the Effective Date as more particularly described in Schedule 3.

- "Change of Control" means, with respect to Emergent, (a) a merger, consolidation, share exchange or other similar transaction involving Emergent and any Third Party which results in the holders of the outstanding voting securities of Emergent immediately prior to such transaction ceasing to hold more than fifty percent (50%) of the combined voting power of the surviving, purchasing or continuing entity immediately after such transaction; or (b) any transaction or series of related transactions in which any person becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of Emergent; provided that, for the avoidance of doubt a public offering of shares in Emergent or any Affiliate thereof shall not constitute a transaction capable of triggering a Change of Control.
- "Clinical Candidate" means any Candidate Antigen or other Programme Antigen selected by the SC for clinical Development in accordance with this Agreement and the Development Plan (and in particular the Outline Candidate Evaluation and Selection Plan). A Clinical Candidate is a Programme Antigen.
- "Clinical Study" means any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of any Antigen or Meningitis B Product, or to identify any adverse reactions to any Antigen or Meningitis B Product and/or to study absorption, distribution, metabolism and excretion of any Antigen or Meningitis B Product with the object of ascertaining its safety and/or efficacy. Clinical Study includes any Phase I Study, Phase II Study, Phase II Study, Phase IV Study or any other investigation in human subjects involving a Clinical Candidate or Product that a Regulatory Authority may require that either Party performs for inclusion in Regulatory Documentation or as a condition of a Regulatory Approval.
- "Clinical Study Application" means an investigational new drug application filed with a Regulatory Authority for any Regulatory Approval required to supply or use a Clinical Candidate or Product for the purposes of a Clinical Study in a country or jurisdiction in the Territory.
- "Co-Exclusive Antigen" has the meaning set out in Clause 5.12.5.
- "Combination Product" means a product developed and administered as a single product pursuant to a single Marketing Authorisation that comprises a Unitary Product combined with another product that is not a Meningitis B Product and does not contain a Programme Antigen or an Additional Antigen. For the avoidance of doubt a Unitary Product will not constitute a Combination Product merely because it is packaged with another product and sold as one product or is sold as a "bundle" with one or more products.
- "Commercialisation" or "Commercialise" means any and all lawful activities directed to the commercialisation of a Product (whether before or after Marketing Authorisation has been obtained), including marketing, manufacturing for commercial sale, promoting, detailing, distributing, offering to sell and selling a Product, importing a Product for sale, conducting additional human clinical studies with respect to an indication for which Marketing Authorisation has been obtained and interacting with Regulatory Authorities regarding the foregoing. When used as a

verb, "Commercialising" means to engage in Commercialisation and "Commercialised" has a corresponding meaning.

- "Commercialisation Plan" means the written plan for the Commercialisation of a Product in the Territory (including detailed strategy, budget and proposed timelines), as more particularly described in Clause 6.3 as may be amended or updated in accordance with Clause 6.3.
- "Commercially Reasonable Efforts" means, with respect to the Development or Commercialisation of any Programme Antigen or Product, the level of efforts and resources customarily applied in the research-based pharmaceutical industry in the development of a product candidate or the commercialisation of a product of similar commercial potential at a similar stage in its lifecycle, taking into consideration its safety and efficacy, its cost to develop, the competitiveness of alternative products, its proprietary position, the likelihood of regulatory approval, its profitability (provided that in assessing such profitability sanofi pasteur shall not be entitled to take into account the royalties, milestones or other payments due or potentially due to Emergent with respect to such Programme Antigen or Product pursuant to this Agreement), and all other relevant factors.
- "Competitive Product" means a Meningitis B Product or potential Meningitis B Product (in each case, other than a Product) Exploited by sanofi pasteur or any of its Affiliates or Sub-Licensees.
- "Confidential Information" means either the Emergent Confidential Information or the sanofi pasteur Confidential Information, or both the Emergent Confidential Information and the sanofi pasteur Confidential Information, as the context requires.
- "Control" means, with respect to any Antigen or other Materials, or Patent Rights, item of Know How, Regulatory Documentation, Trademark or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, licence or otherwise (other than pursuant to this Agreement), to grant access to such Antigen, other Materials or Regulatory Documentation or to assign, or grant a licence, sub-licence or other right to or under, such Patent Rights, Know How, Regulatory Documentation, Trademark or other intellectual property right as provided for herein, without violating the terms of any agreement with any Third Party or any other arrangement with any Third Party.
- "Demonstration of Presence of SBAs" has the meaning set out in Clause 5.6.3.
- "Development" and, with correlative meaning, "Develop", means all activities related to preclinical research, discovery and testing, toxicology, process development, stability studies, formulation development, manufacturing scale-up, production of clinical product batches, development of quality assurance/quality control testing, clinical studies and regulatory affairs, including the conduct of Clinical Studies, for a Product in connection with obtaining Regulatory Approvals of such Product.
- "Development Activities" means the activities of the Parties relating to the Development of Programme Antigens and Products as set out in the Development Plan or any Annual Development Plan.

- "Development Plan" means the plan detailing the pre-clinical and clinical activities to be conducted by the Parties in the course of the Development Programme and, as the Development Programme progresses, to the extent not already included, the matters referred to in Clause 5.2. The first Development Plan, incorporating the Outline Candidate Evaluation and Selection Plan (Appendix 1), the Phase I Product and Clinical Development Plan (Appendix 2) and the Later Stage Clinical Development Plan (Appendix 3), is attached hereto at Schedule 1.
- "Development Programme" has the meaning set out in Clause 2.1.
- "Early Development Phase" means the period from the Effective Date until the Transition Date.
- "Effective Date" means 1 April 2006.
- "Emergent Activities" means the Development Activities allocated to Emergent in the Development Plan or any Annual Development Plan.
- "Emergent Combined Improvements" means any patentable improvement, enhancement or modification, which is made, developed or conceived by employees or consultants of Emergent, solely or jointly with Third Parties, in the conduct of the Development Programme, that relates to any subject matter that is covered both by Emergent Independent Patent Rights and sanofi pasteur Independent Patent Rights, such that the Exploitation of such improvement, enhancement or modification without consent would infringe both Emergent Independent Patent Rights and sanofi pasteur Independent Patent Rights.
- "Emergent Confidential Information" means Emergent Independent Know How, non-patented Emergent Programme Technology and trade secrets and any other confidential information relating to the business affairs or finances of Emergent or its Affiliates.
- "Emergent Expenses" means (i) costs or expenditures incurred by Emergent (or for its account by an Affiliate) in connection with the engagement of any Third Party to conduct work in connection with Emergent Activities; and (ii) any capital expenditures incurred by Emergent (or for its account by an Affiliate of Emergent) in connection with the Development Programme; and (iii) any other costs or expenses incurred by Emergent (or for its account by an Affiliate of Emergent), in each case as provided for in an Annual Budget and without any mark-up.
- "Emergent Independent Know How" means all Know How that (i) as of the Effective Date is in the Control of Emergent, (ii) Emergent is free to disclose to a Third Party and (iii) is necessary or reasonably useful to the Development Programme or to the Exploitation of a Product.
- "Emergent Independent Patent Rights" means those Patent Rights Controlled by Emergent as of the Effective Date that are set out in Schedule 5.
- "Emergent Independent Technology" means Emergent Independent Patent Rights and Emergent Independent Know How.

- "Emergent Patent Rights" means the Emergent Independent Patent Rights and the Emergent Programme Patent Rights.
- "Emergent Programme Patent Rights" means the Patent Rights Controlled by Emergent that claim or otherwise cover Emergent Programme Technology.
- "Emergent Programme Technology" means any Technology made, developed or conceived by employees or consultants of Emergent, alone or jointly with Third Parties, in the conduct of the Development Programme other than Emergent Combined Improvements.
- "Emergent Project Leader" means the Project Leader appointed by Emergent pursuant to Clause 2.2.
- "Emergent Technology" means the Emergent Independent Technology and the Emergent Programme Technology.
- "European Union" or "EU" means the countries of the European Union as constituted from time to time during the term of this Agreement.
- "Exploit" means to make, have made, import, use, sell, or offer for sale, including to discover, research, develop, register, modify, enhance, improve, manufactured, hold/keep (whether for disposal or otherwise), formulate, optimise, have used, export, transport, distribute, promote, market or have sold or otherwise dispose or offer to dispose of, a product or process and "Exploitation" means the act of Exploiting a product or process.
- "FDA" means the United States Food and Drug Administration and any successor agency or authority thereto.
- "Field" means the prophylactic immunisation of human populations to prevent Neisseria meningitidis infections.
- "First Commercial Sale" means the first commercial sale by or on behalf of sanofi pasteur, its Affiliates or Sub-Licensees of a Product in each country of the Territory after Marketing Authorisation has been granted by the appropriate Regulatory Authority in that country.
- "First Year" means the period commencing on the Effective Date and ending on 31 December 2006.
- "FTE" means a Full Time Equivalent of one thousand, five hundred and eighty nine (1,589) hours of work per year (based on a thirty-five (35) hour working week and standard vacations and holidays), devoted to or in support of the Emergent Activities that is carried out by employees, contract personnel or consultants of Emergent as recorded on Activity Forms.
- "FTE Cost" means, for any period, the FTE Rate multiplied by the applicable number of FTEs in such period. The FTE Cost shall be denominated in pounds sterling (£).
- "FTE Rate" means an amount reflecting the average annual gross salary, social charges and benefits (including for notice periods in compliance with applicable

employment law) of Emergent employees, contract personnel and consultants engaged or to be engaged in Emergent Activities together with provisions, allocations of general and administrative charges, amortization, depreciation, overhead, and normal laboratory expenses, which amount is at the Effective Date [\*\*] pounds (£[\*\*]) per FTE. For the avoidance of doubt the FTE Rate may only be amended with the agreement of both Parties.

- "GAAP" means in relation to Emergent, United Kingdom, and in relation to sanofi pasteur, French, generally accepted accounting principles consistently applied, or such other generally accepted accounting principles, consistently applied, as may be applicable to the relevant Party or Third Party at the relevant time.
- "GCP" means the then-current standards for Clinical Studies involving pharmaceuticals as are required by the Regulatory Authorities in Europe, the United States and Japan and other organisations and governmental agencies in countries in which any Product is intended to be sold or tested, to the extent such standards are not less stringent than ICH Topic E6: Good Clinical Practice Consolidated Guideline.
- "GLP" means the then-current standards for laboratory activities for pharmaceuticals, as are required by the Regulatory Authorities of Europe, the United States and Japan, including 21 C.F.R. part 58 and EC Directives 87/18/EEC, 88/320/EEC and 1999/11/EC, in each case, as amended from time to time and any relevant international standards or principles such as those adopted by the Organisation for Economic Co-operation and Development.
- "GMP" means the then-current standards for good manufacturing practices as are required by the Regulatory Authorities in Europe, the United States and Japan and other organisations and governmental agencies in countries in which any Product is intended to be manufactured or sold, to the extent such standards are not less stringent than standards of good manufacturing practice in Europe, the United States and Japan.
- "ICH" means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.
- "Inclusion Criteria" means the criteria set out in Schedule 8 for the inclusion of an Antigen into a Meningitis B Product.
- "Indicative Cost Schedule" means the indicative FTE Costs and Emergent Expenses set out in Schedule 2.
- "Joint Patent Rights" means the Patent Rights that claim or otherwise cover Joint Technology.
- "Joint Project Team" or "JPT" means the committee of Emergent and sanofi pasteur representatives established in accordance with Clause 4.1.
- "Joint Technology" means any and all Technology conceived, discovered, developed or otherwise made jointly by or on behalf of Emergent (or its Affiliates or, to the extent permitted by their agreements therewith, their respective licensees and sub-licensees), on the one hand, and sanofi pasteur (or its Affiliates or, to the extent permitted by their agreements therewith, their respective licensees and sub-licensees)

on the other hand, in connection with the work conducted under or in connection with this Agreement, whether or not patented or patentable, together with any Emergent Combined Improvements.

- "Know How" means unpatented technical and other information which is not known to the public, including information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, experience, inventions, improvements, methods, models, assays, research plans, procedures, designs or experiments and tests and results of experimentation and testing, including results of research or development, together with processes, including manufacturing processes, specifications, techniques, chemical, pharmacological, toxicological, clinical, analytical and quality control data, trial data, case report forms, data analyses, reports or summaries and information contained in submissions to and information from ethical committees and regulatory authorities. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, or a development related to the item, is (or remains) not known to the public.
- "Late Development Phase" means the period commencing on the Transition Date and continuing for so long as any Product is in Development including, if applicable, any period(s) during which the Development Programme is continuing pursuant to Clause 5.9.
- "Later Stage Clinical Development Plan" means the plan set out in Appendix 3 to the Development Plan.
- "Liabilities" has the meaning set out in Clause 13.1.
- "Major Market Country" means each country in the European Union, the United States, Japan, Australia, Canada, China, New Zealand, Norway, Russia, Singapore, Hong Kong, India and South Korea.
- "Marketing Authorisation" means a Biologics License Application (as defined in the United States Federal Food Drug and Cosmetic Act (as amended from time to time) and the regulations promulgated thereunder), and any corresponding Regulatory Approval necessary to import, market, transfer, supply or sell a product in any country, but not including pricing and reimbursement approvals.
- "Materials" means biological and chemical materials including Antigens, screens, cell lines, cells, vectors, nucleic acids and reagents, and any progeny or derivatives thereof.
- "Meningitis B Product" means a product or potential product for the prophylactic immunisation of human populations to prevent Neisseria meningitidis serogroup B infections (whether or not such product confers protection against any other meningococcal serogroup infection).
- "Net Sales" means the gross invoice price of Products sold by sanofi pasteur, its Affiliates and Sub-Licensees to the first Third Party less, to the extent specifically allocable to the Product and actually incurred or allowed and if not already deducted in the amount invoiced:

- (a) normal and customary trade or quantity discounts to the extent included on the invoice as a separate item, credits, allowances, rebates, returns (including wholesaler and retailer returns);
- (b) retroactive price reductions;
- (c) excise taxes, other consumption taxes, customs duties and compulsory payments made to governmental authorities to the extent included on the invoice as a separate item;
- (d) normal and customary sales commissions that are actually paid to Third Party distributors and Third Party selling agents to the extent included on the invoice as a separate item; and
- (e) transportation, transit and insurance for transportation each to the extent separately invoiced and paid by sanofi pasteur.

Any of the deductions listed above that involves a payment by sanofi pasteur, its Affiliates or its Sub-Licensees, as the case may be, shall be taken as a deduction in the Quarter in which the payment is accrued by such entity. For purposes of determining Net Sales, any Product shall be deemed to be sold when invoiced. For purposes of calculating Net Sales, sales between or among sanofi pasteur, its Affiliates, and its Sub-Licensees shall be excluded from the computation of Net Sales, but sales by sanofi pasteur, its Affiliates or its Sub-Licensees to Third Parties (other than its Sub-Licensees) shall be included in the computation of Net Sales. If, in any country, any Product is sold or otherwise disposed of for any consideration other than an exclusively monetary consideration on bona fide arm's length terms, such Product shall be deemed to have been sold exclusively for money at the average sales price during the applicable Quarter generally achieved for such Product in the country in which such sale or other disposition occurs or if there is no average sales price in that country, the average sales price in comparable countries

Adjusted Combination Net Sales. In the event that a Product is sold in any country in any Quarter in the form of a Combination Product, Net Sales of such Combination Product shall be adjusted to represent the contribution of each product to the value of the Combination Product by multiplying actual Net Sales of such Combination Product in such country in such Quarter calculated as set out above by the fraction A/(A+B) (such adjusted amount the "Adjusted Combination Net Sales") where A and B are determined as follows:

- (i) if sanofi pasteur has already launched a Unitary Product in such country, A shall be the highest official list price of the Unitary Product in that country in the relevant Quarter;
- (ii) if sanofi pasteur has not already launched a Unitary Product in such country, but a unitary product for exactly the same indications as the Unitary Product is already on the market in such country, A shall be the highest official list price of such competitive unitary product in such country in such Quarter. For the avoidance of doubt, if there is more than one competitive unitary product on the relevant market, then

A shall be referenced to the competitive unitary product with the highest official list price in such country in such Quarter;

- (iii) B shall be the highest official list price in such country in such Quarter of the other product included in the Combination Product;
- if when sanofi pasteur first submits an application for Marketing Authorisation for a Combination Product in a country or at any time subsequently it is not possible to determine (iv) A or B in accordance with paragraphs (i) to (iii) above, the Parties shall seek to agree A or B (as required) but failing such agreement within thirty (30) days (or such longer period as the parties may agree) of either Party notifying the other that such values are to be determined in accordance with this paragraph (iv) either Party can require an independent third party expert to determine such values so that application of the formula A/(A+B) fairly reflects the contribution of the Unitary Product to the value of the Combination Product in that country. Within fifteen (15) days of either Party notifying the other that an expert determination is required, the Parties shall appoint an independent expert with expertise in the field of vaccine development and commercialisation reasonably acceptable to both Parties. If the Parties are unable to agree on the identity of the independent expert within such period, the independent expert shall be appointed by Emergent, and approved by sanofi pasteur, which approval shall not be unreasonably withheld, conditioned or delayed. Within thirty (30) days of such appointment, each of the Parties shall furnish to the expert (subject to such obligations of confidentiality and non-use as may be reasonably required by them), with a copy to the other Party, a written summary of such Party's position as to the values of A and B in such country and any relevant evidence supporting such position. Any such written summary and evidence shall not, unless the Parties otherwise agree, exceed 15,000 words. Within fifteen (15) days of receipt of the other Party's summary (or such longer period as may be required to ensure the presence of the expert) there shall be a one-day oral hearing before the expert at which each Party shall be given an equal opportunity to present its own position and hear and respond to the oral presentation given by the other Party. Within fifteen (15) days of such oral hearing each Party may submit a written rebuttal of the other Party's summary, providing that any rebuttal shall not exceed 5,000 words, and amend its final position with regard to the values of A and B. The expert shall be required by the Parties to select the resolution proposed by one of the Parties that as a whole most fairly and reasonably reflects the relative contributions of the Unitary Product and the other product to the Combination Product and shall provide the Parties with a written statement setting forth the basis of such determination. For the avoidance of doubt, the expert shall only have the right to select a resolution proposed by one of the Parties in its entirety and without modification. The expert shall be required by the Parties to use all reasonable efforts to render his decision within sixty (60) days of his appointment or, if earlier, within thirty days following his receipt of all

such information and such decision shall be final and binding upon each of the Parties unless and until it becomes possible to determine A and B in accordance with paragraphs (i) to (iii) above. If the expert adopts the resolution proposed by Emergent, then sanofi pasteur shall pay the fees and expenses of the expert. If the expert adopts the resolution proposed by sanofi pasteur, then Emergent shall pay the fees and expenses of the expert. If due to any act or omission by one of the Parties, the Parties have not agreed, or the expert has not determined, the values of A and/or B (as required) in any country before launch of the Combination Product in that country, A and/or B (as required) shall be as determined by the other Party.

Minimum royalties payable to Emergent on a Combination Product in any country: If the Product is sold as a Combination Product, the royalty payable to Emergent on sales of the Combination Product in the relevant country in the applicable Quarter shall be the higher of:

- (1) the royalty payable to Emergent pursuant to Clause 7.3 (as adjusted pursuant to Clause 7.4.1 or Clause 7.4.2 if applicable) for such country and Quarter;
- (2) [\*\*] per cent ([\*\*]%) X the royalty rate applicable to the Unitary Product X A/C X Net Sales of the Combination Product (before application of the formula A/(A+B)) where C is the highest official list price of the Combination Product in that country and Quarter and A for that country and Quarter is determined in accordance with paragraphs (i) to (iv) above (as applicable): and
- (3) if the royalty would otherwise be payable pursuant to Clause 7.3(a), [\*\*] per cent ([\*\*]%) X actual Net Sales of the Combination Product in that country and Quarter (before application of the formula A/(A+B)); or if the royalty would otherwise be payable pursuant to Clause 7.3(b), [\*\*] per cent ([\*\*]%) X actual Net Sales of the Combination Product in that country and Quarter (before application of the formula A/(A+B)).

**Bundled products:** If, in any country, a Product and one or more products capable of separate sales are "bundled" and sold without separate pricing for each product within the bundle, Net Sales per unit of such Product shall be deemed to be the average sales price at which that Product has been sold unbundled in such country during the applicable Quarter.

- "Outline Candidate Evaluation and Selection Plan" means the plan for the screening, selection and progression of Programme Antigens prior to clinical Development as set out in Appendix 1 to the Development Plan.
- "Outline Commercialisation Plan" means the Outline Commercialisation Plan set out in Schedule 4.
- "Party" means either Emergent or sanofi pasteur and "Parties" means Emergent and sanofi pasteur.
- "Patent Rights" means any and all (a) patents, (b) pending patent applications, including all provisional applications, continuations, continuations-in-part, divisions,

reissues, renewals, and all patents granted thereon, and (c) all patents-of-addition, reissue patents, re-examinations and extensions or restorations by existing or future extension or restoration mechanisms, supplementary protection certificates or the equivalent thereof, and (d) any equivalent of any of the foregoing in any jurisdiction.

- "Phase I Product and Clinical Development Plan" means the plan set out as Appendix 2 to the Development Plan.
- "Phase I Study" means a Clinical Study in any country that is intended to initially evaluate the safety or pharmacological effect of an Antigen or Meningitis B Product in subjects or that would otherwise satisfy requirements of 21 C.F.R. 312.21(a), or its equivalent outside the United States.
- "Phase II Study" means a Clinical Study in any country that is intended to initially evaluate the effectiveness of an Antigen or Meningitis B Product for a particular indication or indications in patients with the disease or indication under study or that would otherwise satisfy requirements of 21 C.F.R. 312.21(b), or its equivalent outside the United States.
- "Phase III Study" means a pivotal Clinical Study, the principal purpose of which is to establish safety and efficacy in patients with the disease or indication under study as required in 21 C.F.R. 312.21(c), or similar clinical studies prescribed by the Regulatory Authorities in a country other than the United States whether or not such study is a traditional Phase III Study.
- "Phase IV Study" means a Clinical Study that is required or requested by a Regulatory Authority as a condition of or in connection with obtaining or maintaining a Regulatory Approval (whether commenced either prior to or after receipt of such Regulatory Approval).
- "Pre-Clinical Study" means any investigation in animals or in vitro intended to discover or verify the pharmacological or other pharmacodynamic effects of any Programme Antigen or Product, or to study absorption, distribution, metabolism and excretion of any Programme Antigen or Product with the object of ascertaining its safety.
- "Primary Inclusion Criteria" means the criteria set out in Schedule 8 Part I for the progress of Antigens into Phase II Studies.
- "Product" means a vaccine or potential vaccine containing one or more Programme Antigens. Unitary Products and Combination Products are Products.
- "Product Trademark" has the meaning set out in Clause 6.5.
- "Programme Antigen" means any Candidate Antigen, including any Antigen derived from a Candidate Antigen by either Party, or any other Antigen (other than a Terminated Antigen or a Repatriated Antigen) claimed or otherwise covered by Emergent Patent Rights or Joint Patent Rights.
- "Project Leader" has the meaning set out in Clause 2.2.

- "Quarter" means a period of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31 and "Quarterly" shall be construed accordingly.
- "Regulatory Approval" means any and all approvals (including any applicable supplements, amendments, pre- and post-approvals, governmental price and reimbursement approvals and approvals of applications for regulatory exclusivity), licences, registrations, or authorisations of any federal, national, multinational, international, state, provincial or local regulatory agency, department, bureau, commission, council or other governmental entity necessary for the manufacture, distribution or other transfer of possession, use, holding, storage, import, export, transport, promotion, marketing, supply or sale of a product in a country or jurisdiction in the Territory, or the use of a product or Antigen in any Pre-Clinical Study or Clinical Study. For clarity, a compendia listing shall not be deemed to be a Regulatory Approval.
- "Regulatory Authority" means the FDA or any counterpart of the FDA outside the United States, or other national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport, pre-clinical or clinical testing or sale of a Meningitis B Product or Antigen.
- "Regulatory Documentation" means all applications, registrations, governmental licences, authorisations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities and all supporting documents and all clinical studies and tests, relating to a Programme Antigen or Product, and all data contained in any of the foregoing.
- "Repatriated Antigen" means a Programme Antigen repatriated to Emergent in accordance with Clause 5.12.3(f). An Antigen shall cease to be a Programme Antigen on becoming a Repatriated Antigen.
- "Royalty Burden" has the meaning set out in Clause 7.4.1.
- "sanofi pasteur Antigen" means an Antigen Controlled by sanofi pasteur that is not either a Third Party Antigen or a Programme Antigen.
- "sanofi pasteur Confidential Information" means sanofi pasteur Independent Know How, unpatented sanofi pasteur Programme Technology and trade secrets and any other confidential information relating to the business affairs or finances of sanofi pasteur or an Affiliate.
- "sanofi pasteur Independent Know How" means all Know How which either at the Effective Date or subsequently during the Term is in the Control of sanofi pasteur or its Affiliates (other than any Know How that constitutes unpatented Joint Technology or unpatented sanofi pasteur Programme Technology) and which sanofi pasteur is free to disclose to a Third Party which is necessary or reasonably useful to the Development Programme or to the Exploitation of a Product.

- "sanofi pasteur Independent Patent Rights" means (a) any Patent Rights Controlled by sanofi pasteur pursuant to a sanofi pasteur In-Licence at any time during the Term and (b) any other Patent Rights Controlled by sanofi pasteur at any time during the Term otherwise than pursuant to a sanofi pasteur In-Licence necessary or reasonably useful to the Development Programme or to the Exploitation of a Product; in each case excluding, for the avoidance of doubt, sanofi pasteur Programme Patent Rights and Joint Patent Rights
- "sanofi pasteur Independent Technology" means sanofi pasteur Independent Patent Rights and sanofi pasteur Independent Know How.
- "sanofi pasteur In-Licence" means any licence deemed to be a sanofi pasteur In-Licence pursuant to Clause 5.8.1.
- "sanofi pasteur Patent Rights" means the sanofi pasteur Independent Patent Rights and the sanofi pasteur Programme Patent Rights.
- "sanofi pasteur Programme Patent Rights" means the Patent Rights Controlled by sanofi pasteur that claim or otherwise cover sanofi pasteur Programme Technology.
- "sanofi pasteur Programme Technology" means any Technology made, developed or conceived by employees or consultants of sanofi pasteur, alone or jointly with Third Parties, in the conduct of the Development Programme.
- "sanofi pasteur Project Leader" means the Project Leader appointed by sanofi pasteur pursuant to Clause 2.2.
- "sanofi pasteur Technology" means the sanofi pasteur Independent Technology and the sanofi pasteur Programme Technology.
- "SBA" means a serum bactericidal antibody, i.e., an antibody or antibodies which, in the presence of an exogenous source of complement, has the ability to kill *Neisseria meningitidis* bacteria. For clarity, the source of the complement used in the SBA assay shall be appropriate to the serum being measured, for example, for human sera, a human complement source obtained from a donor without bactericidal activity against the test strain shall be utilised.
- "SBA Activity" means measurement of SBA titres in serum.
- "Selection Criteria" means the technical selection criteria set out in the Outline Candidate Evaluation and Selection Plan and included in Appendix 1 to the Development Plan for the selection of Candidate Antigens to progress into Phase I Studies.
- "Senior Officer" has the meaning set out in Clause 3.5.1.
- "Serious Adverse Event" means an Adverse Event that at any dose: (a) results in death, (b) puts the patient at risk of death at the time of the event or occurrence, (c) requires inpatient hospitalisation or prolongation of existing hospitalisation, (d) results in persistent or significant disability or incapacity, (e) is a congenital anomaly/birth defect or (f) based upon reasonable medical scientific judgment, places a patient in jeopardy or may require intervention to prevent any of the events or occurrences

described in (a) through (e). In the event of doubt as to whether an Adverse Event is a Serious Adverse Event, the Adverse Event shall be treated as if it is a Serious Adverse Event.

- "Steering Committee" or "SC" means the committee of Emergent and sanofi pasteur representatives established in accordance with Clause 3.1.
- "Sub-Licensee" means a person (other than an Affiliate of sanofi pasteur) that is authorised by sanofi pasteur (with the express prior written consent of Emergent) to manufacture and sell a Product in the Field in the Territory (including any Third Party acting in collaboration with sanofi pasteur or its Affiliates). For clarity, a Sub-Licensee shall not include a Third Party to whom sanofi pasteur sells bulk Product together with a right to fill/finish, label, market and distribute such Product, provided that sanofi pasteur is not entitled to any additional consideration upon the Exploitation of such Product.
- "Technology" means inventions, discoveries, improvements, trade secrets and proprietary methods, whether or not patentable, including Know How.
- "Term" means the term of this Agreement, which term shall be the period commencing on the Effective Date and ending either on the date on which the final obligation of sanofi pasteur to make royalty payments under Clause 7.3 expires or, if earlier, the date on which this Agreement is terminated in accordance with Clause 14.2.
- "Terminated Antigen" means the Antigens listed on Schedule 11 and each Programme Antigen determined by the SC to be a Terminated Antigen in accordance with Clause 5.15. An Antigen shall cease to be a Programme Antigen on becoming a Terminated Antigen.
- "Territory" means all countries of the world.
- "Third Party" means any corporation, unincorporated organisation, person or other legal entity other than Emergent or sanofi pasteur or their respective Affiliates.
- "Third Party Antigen" means any Antigen Controlled by sanofi pasteur the Exploitation of which as a constituent of any Unitary Product would, but for a sanofi pasteur In-Licence infringe the Patent Rights of a Third Party.
- "Trademark" means any corporate name, trade name, trade dress, service mark, logos and trademarks (whether or not registered) and all applications for, and registrations of, and all renewals, extensions or modifications to, and any goodwill associated with, any of the foregoing in the Territory.
- "Transition Date" means the date on which all Pre-Clinical Studies and Phase I Studies involving a Programme Antigen and described in any Development Plan or Annual Development Plan have been completed or, if later, the date on which all Transition Plans in effect at such date are fully implemented to the satisfaction of the Parties.
- "Transition Plan" has the meaning set out in Clause 5.5.1.

"Unitary Product" means a Product for use in the prevention of meningococcal serogroup B infections (whether or not such Product confers protection against any other meningococcal serogroup infection) in which Programme Antigens and Additional Antigens are the only Antigens. For the avoidance of doubt, a Product that is not a Combination Product is a Unitary Product

"Valid Claim" means a claim of (i) an issued and unexpired patent, (ii) a patent the term of which has been extended pursuant to an extension of term or equivalent right anywhere in the world, (iii) a patent listed in a supplementary protection certificate or equivalent instrument anywhere in the world, (iv) a pending patent application providing that such application has been pending for no longer than ten (10) years, in each case which has not been withdrawn, cancelled, abandoned, disclaimed, revoked or held unpatentable, invalid or unenforceable by final decision of a court or other governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal.

"Year" means the First Year and thereafter each successive period of twelve (12) months ending on the last day of December.

- 1.2 In this Agreement, unless the context otherwise requires:
  - (a) references to "this Agreement" shall mean this Agreement and any and all Schedules to it, each as amended from time to time in accordance with the provisions of this Agreement;
  - (b) references to a particular Clause, Schedule or paragraph shall be a reference to that clause, schedule or paragraph in this Agreement;
  - (c) words in the singular shall include the plural and vice versa and references to the masculine gender shall include the feminine gender and vice versa;
  - (d) headings are for convenience only and shall be ignored in interpreting this Agreement;
  - (e) reference to a person shall mean any individual, partnership, company, corporation, joint venture, trust, association, organisation or other entity, in each case whether or not having separate legal personality;
  - (f) the words "include", "including" or "in particular" are to be construed without limitation to the generality of the preceding words;
  - (g) references to a statute include any statutory modification, extension or re-enactment of that statute;
  - (h) any reference to "writing" includes a reference to any communication effected by facsimile transmission or similar means;
  - (i) the word "or" has the inclusive meaning represented by the phrase "and/or"; and

- (j) any covenant by a Party not to do an act or thing shall be deemed to include an obligation not to permit or suffer such act or thing to be done by another person.
- 1.3 If there is any inconsistency between Clauses 1 to 28 (inclusive) of this Agreement and any Schedule, such Clauses shall prevail.

### 2. COLLABORATION

#### 2.1 Objectives and Overview

The Parties wish to evaluate and screen the Candidate Antigens, select Clinical Candidates and Develop a Product for use in the Field (the "Development Programme"). The Development Programme shall comprise all activities relating to Development. It is anticipated that the majority of Pre-Clinical Studies and Phase I Studies relating to Programme Antigens will be undertaken by Emergent during the Early Development Phase, at sanofi pasteur's cost, and that the majority of Phase II Studies relating to Programme Antigens and the subsequent Development of Programme Antigens (whether during the Early Development Phase or the Late Development Phase) will be undertaken by sanofi pasteur, at its own cost. The SC shall oversee the overall execution of the objectives of the Development Programme and the JPT shall manage the day-to-day running of the collaboration in the Early Development Phase. The Project Leaders shall facilitate the flow of information and otherwise promote communications and collaboration within and among the Parties, the SC, JPT and any other sub-committees or teams that the SC may appoint or constitute.

#### 2.2 Project Leaders

Within sixty (60) days of the Effective Date, each Party shall appoint a senior representative with a good general understanding of the vaccine development process to act as a co-ordinator and project leader ("**Project Leader**"). Each Party may replace its Project Leader with another suitably qualified individual, on written notice to the other Party. Each Project Leader shall be primarily responsible for the day-to-day management of each Party's activities within the collaboration.

### 2.3 Intellectual Property Strategy

The Parties acknowledge the importance of effectively securing and managing the intellectual property relating to Programme Antigens and any Product. The Parties shall, consistent with Clause 9 and Schedule 9, seek to obtain and maintain the broadest patent protection that is commercially reasonable across the Territory, extending this protection through additional filings and the use of supplementary protection certificates where appropriate, and to protect the confidentiality of all Know How relating to the Programme Antigens and any Product.

#### 2.4 Exclusivity

Emergent shall not and shall procure that none of its Affiliates shall, other than pursuant to this Agreement, conduct any activity, either on its own, or with, for the benefit of, or sponsored by, any Third Party, that is designed to research, develop or

commercialise, or grant any licence or other rights to any Third Party to utilise, the Programme Antigens for the purpose of researching, developing, commercialising or otherwise Exploiting any product in the Territory provided that this shall not prevent Emergent from Exploiting, or granting a Third Party the right to Exploit, any Co-Exclusive Antigen.

### 2.5 Co-operation

Emergent and sanofi pasteur shall co-operate in the performance of the Development Plan and each Annual Development Plan and, subject to the terms of this Agreement and any confidentiality obligations to Third Parties, each shall at its own cost (providing that such costs are not substantial), if requested by the other Party, exchange such Materials, data and information in its Control as are reasonably necessary for the other Party to perform its obligations under any Annual Development Plan.

### 3. STEERING COMMITTEE

### 3.1 Establishment and Membership of SC

Within sixty (60) days of the Effective Date, Emergent and sanofi pasteur shall establish a Steering Committee ("SC") comprising not less than six (6) members, with at least three (3) being appointed and replaced by Emergent, of which one shall be the Emergent Project Leader, and at least three (3) being appointed and replaced by sanofi pasteur, of which one shall be the sanofi pasteur Project Leader. All such representatives shall be individuals of suitable authority and seniority with significant experience and expertise in vaccine development, commercialisation or marketing commensurate with the responsibilities and activities of the SC from time to time. Any appointment or replacement shall be notified to the other Party in writing. Any member of the SC may designate a substitute of equal experience and seniority to attend and perform the functions of such member at any meeting of the SC.

#### 3.2 Meetings

The first meeting of the SC shall take place within seventy-five (75) days of the Effective Date. The SC shall meet Quarterly during the Development Programme and thereafter bi-annually and in addition within fifteen (15) days of a request by any SC member to have such a meeting. Meetings may take place by video conference or telephone conference or such other means as the SC shall decide and all members participating in the meeting by video link, telephone or such other means shall be deemed to be present at the meeting, provided however, that the SC shall meet in person at least twice per Year, unless otherwise agreed by the SC. Meetings held in person shall alternate between Emergent and sanofi pasteur designated locations. The first meeting shall be held at sanofi pasteur's facilities. The chair of the SC shall rotate between Emergent and sanofi pasteur from meeting to meeting. The first meeting shall be chaired by a sanofi pasteur representative. The quorum for meetings shall be one sanofi pasteur representative. Decisions and determinations of the SC shall be made by unanimous agreement of the members present. Each Party may invite additional employees, or consultants to attend SC meetings but any such additional attendees shall not have any right to vote. The principal business and any decisions of any meeting shall be recorded in minutes

which shall be circulated by the chair to the members of the SC promptly following the meeting for review, comment and adoption.

## 3.3 Responsibilities of the SC

Except as otherwise provided in this Agreement, the SC shall have authority to make all necessary strategic decisions relating to the Development of a Product and the implementation of the Development Plan. Specifically, and in addition to any other responsibilities assigned to the SC elsewhere in this Agreement, the SC shall be responsible for:

- (a) reviewing and approving any major amendments to the Development Plan (including the Outline Candidate Evaluation and Selection Plan, the Phase I Product and Clinical Development Plan and the Later Stage Clinical Development Plan);
- (b) reviewing and approving each Annual Development Plan and any major amendments thereto;
- (c) reviewing and resolving all significant strategic issues relating to the Development of Unitary Products including the review and approval of:
  - (i) the target product profile of a Product;
  - (ii) any go/no go decision points relating to Development;
  - (iii) prioritising Candidate Antigens, selecting Clinical Candidates and designating Terminated Antigens;
  - (iv) Clinical Study endpoints and success criteria;
  - (v) insurance coverage for Clinical Studies;
  - (vi) the regulatory strategy for a Product;
  - (vii) patent, trademark and other intellectual property strategy and, to the extent applicable, patent, trademark and other intellectual property litigation strategy;
- (d) reviewing all significant strategic issues (including, as applicable, those matters listed in paragraph c above) relating to the Development of any Combination Product;
- (e) reviewing and approving each Transition Plan;
- (f) reviewing and commenting on the Commercialisation Plan;
- (g) reviewing the efforts of the Parties in performing their respective responsibilities under the Development Plan, any Annual Development Plan, each Transition Plan and the Commercialisation Plan;
- (h) reviewing the implementation of each Transition Plan; and

(i) reviewing and approving any external corporate communication regarding the Development Programme.

For the avoidance of doubt, if this Agreement provides that any matter is to be determined by the Parties or either of them, such matter shall not be considered to be the responsibility, or within the authority, of the SC.

#### 3.4 Role of the Project Leader within the SC

Within the framework of the SC, each Project Leader shall facilitate the execution of the SC's responsibilities and in particular shall be responsible for:

- (a) facilitating coordination among the various functional representatives of either Emergent or sanofi pasteur, as appropriate;
- (b) seeking consensus both internally within the respective Party's organisation and together regarding key global Development and Commercialisation strategy and issues concerning the Development Plan, each Annual Development Plan, each Transition Plan and each Commercialisation Plan, as appropriate, including facilitating review of external corporate communications;
- (c) raising to the SC in a timely manner cross-Party or cross-functional disputes, or proposed modifications to any Development Plan, Annual Development Plan, Transition Plan or Commercialisation Plan;
- (d) providing a single point of communication between the SC, the JPT and any subcommittee created pursuant to Clause 3.6;
- (e) submitting to the SC the reports referred to in Clause 5.10; and
- (f) such other matters as the SC may consider appropriate.

#### 3.5 SC Dispute Resolution

3.5.1 **Escalation of Disputes within the SC**. If the SC is unable to resolve any dispute with respect to a matter within the scope of Clause 3.3 within thirty (30) days (or fourteen days (14) days if the matter is expedited in accordance with Clause 3.5.3) after such matter was first referred to or considered by the SC, whichever is earlier, or in such longer period of time as the Parties may agree such matter shall, at the written request of either Party, be referred to the Chief Executive Officer of Emergent and the sanofi pasteur Head of Research and Development (the "Senior Officers") as soon as practicable but in any event no later than fifteen (15) days after such request. Each Senior Officer shall have the right to engage the services of any number of independent experts in the field in question (such independent expert(s)) to be engaged under obligations of confidentiality and non-use equivalent to those set out in Clause 10 and at the expense of the Party so engaging such expert(s)) to assist the Senior Officers in making a determination on the unresolved dispute, and each Senior Officer shall consider in good faith the analyses and opinions of any such experts engaged by either of them in making a determination. Subject to Clause 3.5.2, if the Senior Officers are unable to resolve the dispute within thirty (30) days after such referral, or

such longer period as the Senior Officers may agree, the sanofi pasteur Head of Research and Development shall be entitled to determine the matter. Any such determination shall be commercially reasonable and consistent with Applicable Law. Prior to resolving any such dispute unilaterally, sanofi pasteur shall consider in good faith Emergent's position and the analyses and opinions of any independent expert engaged by Emergent. For the avoidance of doubt, in reaching any such decision sanofi pasteur shall act in good faith and in the best interests of the Development and Commercialisation of a Product but shall not be bound to follow the recommendations of any such expert. For the avoidance of doubt, all other disputes arising under or in connection with this Agreement shall, unless subject to final and binding expert determination in accordance with this Agreement, be resolved in accordance with Clause 25.2 and, if necessary, Clause 25.3.

- 3.5.2 Notwithstanding Clause 3.5.1, the sanofi pasteur Head of Research and Development shall not be entitled to determine a dispute with respect to a matter within the scope of Clause 3.3, if such decision relates to any of the following matters and no such proposal or decision with respect to any such matter shall be effective unless and until agreed by Emergent:
  - (a) any proposal to amend the Development Plan, adopt or amend any Annual Development Plan (including any Annual Budget), or adopt or amend any Transition Plan in a manner that alters an existing obligation of Emergent or imposes a new obligation on Emergent;
    - (b) any proposal to amend the Outline Candidate Evaluation and Selection Plan (including the Selection Criteria);
    - (c) any proposal to amend the standard assay system for measurement of SBA Activity set out in the Development Plan;
    - (d) any proposal to use an Alternative Assay to demonstrate the presence of SBAs with a Clinical Candidate or Product unless such proposal is consistent with Clause 5.6.3.
    - (e) any proposal to incorporate an Additional Antigen in a Product or include an Additional Antigen in the Development Programme unless such proposal is consistent with the decision of the expert appointed pursuant to Clause 5.7.2;
  - (f) any proposal relating to the patent strategy for Emergent Patent Rights or Joint Patent Rights or any proposal to seek patent term extensions regarding the Emergent Patent Rights, the sanofi pasteur Patent Rights or the Joint Patent Rights with respect to any Product in each country in the Territory;
  - (g) any decision that would constitute a deviation from any of the terms of, or would require an amendment to, this Agreement (other than an amendment to the Development Plan as expressly permitted in accordance with this Agreement); and
  - (h) any proposal that would affect when a milestone payment under Clause 7.2 would be payable.

3.5.3 **Expedited Escalation.** If either the SC or JPT is unable to resolve a dispute relating to a matter for which it is responsible, either Party may designate such dispute an urgent matter. The SC shall resolve such issue within fourteen (14) days after such matter was first designated an urgent matter. The Parties shall ensure that the SC meets (by teleconference/videoconference as necessary) to discuss and resolve such urgent matter within such period. If the SC does not resolve such matter within such fourteen (14) day period, the matter will be referred to the Senior Officers in accordance with Clause 3.5.1.

#### 3.6 Subcommittees

The SC is empowered to create such sub-teams or subcommittees of itself as it may deem appropriate or necessary. Each such sub-team or subcommittee shall report to the SC, which shall have authority to approve or reject recommendations or actions proposed subject to the terms of this Agreement. No sub-team or subcommittee shall have authority to make any decision binding upon the SC or the Parties. For the avoidance of doubt, a Party may appoint the same individual as its representative on more than one committee.

#### 4. JOINT PROJECT TEAM

#### 4.1 Establishment and Membership of JPT

Within sixty (60) days of the Effective Date Emergent and sanofi pasteur shall establish a Joint Project Team ("JPT") comprising up to six (6) members, with up to three (3) being appointed and replaced by Emergent, of which one shall be the Emergent Project Leader, and up to three (3) being appointed and replaced by sanofi pasteur, of which one shall be the sanofi pasteur Project Leader. All such representatives shall be individuals of suitable authority and seniority with significant experience and expertise in vaccine research and development to commensurate with the responsibilities of the JPT. Any appointment or replacement shall be notified to the other Party in writing. Any member of the SC may designate a substitute of equal experience and seniority to attend and perform the functions of such member at any meeting of the JPT. Any changes to the size of the JPT shall be decided by the SC. Unless otherwise decided by the Parties, the JPT shall be disbanded on the Transition Date and have no further responsibilities thereafter; provided that if the SC determines that pre-clinical Development activities, or a Phase I Study, are to be undertaken with or in connection with a Programme Antigen and it is proposed that all or any of such activities are commenced or continued after the Transition Date or the anticipated Transition Date the JPT shall not be disbanded, or if it has been disbanded it shall be reconstituted before commencement of any such activities. The JPT shall prepare the amendments to the Development Plan and any Annual Development Plan required in connection with such proposed activities and shall not be disbanded until all pre-clinical Development activities and any Phase I Studies for such Programme Antigen are complete or discontinued.

### 4.2 Meetings

The first meeting of the JPT shall take place within seventy-five (75) days of the Effective Date and thereafter the JPT shall meet monthly or as otherwise determined by the Parties. Meetings may take place by video conference or telephone conference

or such other means as the SC shall decide and all members participating in the meeting by video link, telephone or such other means shall be deemed to be present at the meeting, provided however, that the JPT shall meet in person at least once per Quarter, unless otherwise agreed by the SC. Meetings held in person shall alternate between Emergent and sanofi pasteur designated locations. The first meeting shall be held at Emergent's facilities. The chair of the JPT shall rotate between Emergent and sanofi pasteur from meeting to meeting, the first meeting shall be chaired by a sanofi pasteur representative. The quorum for meetings shall be one sanofi pasteur representative and one Emergent representative. Decisions and determinations of the JPT shall be made by unanimous agreement of the members present. Each Party may invite additional employees, or consultants to attend JPT meetings but any such additional attendees shall not have any right to vote. The principal business of any meeting shall be recorded in minutes, which minutes shall be circulated by the chairperson to the members of the JPT promptly following the meeting for review, comment and adoption.

### 4.3 Responsibilities of the JPT

Until the Transition Date (or such later date as the Parties may agree) and during any subsequent period during which the JPT is reconstituted pursuant to Clause 4.1, the JPT shall have the general responsibility for the day-to-day management of the collaboration, including co-ordinating the Development Activities of each of the Parties and making recommendations and referring strategic issues to the SC. Specifically, the JPT shall be responsible for:

- (a) preparing Annual Development Plans in accordance with Clause 5.3, and submitting such Annual Development Plan to the SC for approval;
- (b) preparing each Transition Plan and submitting such plan to the SC for approval;
- (c) proposing to the SC any amendments to the Development Plan or any Annual Development Plan, including proposals relating to Product Development, the Outline Candidate Evaluation and Selection Plan, and clinical, regulatory and intellectual property strategy, in each case as appropriate to the stage of the Development Programme;
- (d) overseeing and managing the implementation of the Development Plan, and each Annual Development Plan and Transition Plan;
- (e) facilitating the exchange of information and data between the Parties and the Parties' representatives engaged in the day-to-day conduct of the Development Activities;
- (f) referring any significant strategic issues relating to the Development Programme, including any issues that have a material effect on quality, cost and time needed to undertake any Development Activities, to the SC;
- (g) making recommendations to the SC with respect to:
  - (i) Development go/no go decision points;

- (ii) amendments to the Outline Candidate Evaluation and Selection Plan;
- (iii) the prioritisation of Candidate Antigens, the selection of Clinical Candidates and the designation of Terminated Antigens;
- (iv) Clinical Study endpoints, success criteria and protocols for Clinical Studies;
- (v) insurance requirements for Clinical Studies;
- (h) co-ordinating and monitoring the regulatory strategy and intellectual property strategy with respect to any Programme Antigen or Product;
- (i) recommending the appointment of any necessary additional subcommittees;
- (j) preparing and submitting to the SC the Transition Plans in accordance with Clause 5.5.1;
- (k) reviewing and then reporting on the efforts of the Parties in performing their respective Development Activities to the SC; and
- (l) such other activities consistent with this Agreement as determined by the SC.

### .4 Role of the Project Leader within the JPT

Within the framework of the JPT, each Project Leader shall facilitate the execution of the JPT's responsibilities and in particular shall be responsible for:

- (a) providing a single point of communication between the Parties concerning the day-to-day operation of the collaboration;
- (b) seeking consensus both internally within the respective Party's organisation and together regarding the preparation or implementation of the Development Plan, each Annual Development Plan and Transition Plan and any recommendations to be made by the JPT to the SC; and
- (c) raising to the JPT in a timely manner cross-Party or cross-functional disputes.

## 4.5 **Dispute Resolution**

- 4.5.1 **Referral to the SC**. If the JPT is unable to resolve any dispute with respect to a matter within the scope of Clause 4.3, within thirty (30) days after such matter was first referred to or considered by the JPT, whichever is earlier, then such matter shall, at the written request of either Party, be referred to the SC for resolution. The referral shall be made in writing and if the form of such referral is not agreed each Party may make written submissions to the SC.
- 4.5.2 **Expedited Referral.** Either Party may designate a dispute within the JPT an urgent matter and, if the JPT is unable to resolve such dispute within fourteen (14) days of such matter first being designated an urgent matter, either Party may immediately refer such matter to the SC for resolution.

#### 5. CONDUCT OF THE DEVELOPMENT PROGRAMME

# 5.1 The Development Programme

The Development Programme shall be conducted in accordance with this Agreement, the Development Plan and any Annual Development Plan. Each Party shall conduct the Development Activities allocated to it in the Development Plan diligently, in good scientific manner and in compliance with this Agreement, the Development Plan, the relevant Annual Development Plan and Applicable Law. As part of the Development Programme, the Parties will seek to evaluate and screen the Programme Antigens, select Clinical Candidates and Develop a Product.

### 5.2 The Development Plan

The overall strategy and anticipated budget for the Development of any Product are set out in the first Development Plan attached as Schedule 1. The Development Plan, including the Outline Candidate Evaluation and Selection Plan, Phase I Product and Clinical Development Plan and Later Stage Clinical Development Plan, shall be revised and updated by the SC as and when necessary during the course of the Development Programme with the intent that the Development Plan shall:

- (a) identify Development Activities to be conducted by each of the Parties and the anticipated timelines for such activities;
- (b) specify the standards applicable to any Development Activities including whether particular Development Activities are to be conducted in accordance with GLP, GMP or GCP;
- (c) include and, if necessary, update the criteria for the selection of Clinical Candidates;
- (d) describe the clinical and regulatory strategy for any Clinical Candidate or Product;
- (e) describe the intellectual property strategy for Emergent Patent Rights and Joint Patent Rights;
- (f) incorporate a manufacturing plan for clinical supplies of Clinical Candidates and any Product; and
- (g) include such other matters as the SC consider appropriate in relation to the Development Programme.

During the Early Development Phase and during any other period during which the JPT has responsibilities pursuant to Clause 4.3, the JPT, and at any other time, sanofi pasteur, shall be responsible for proposing amendments to the Development Plan. No major amendment to the Development Plan shall be effective until approved by the SC. For the purpose of this Agreement any change to the Development Plan or an Annual Development shall be considered major if the change affects Emergent's obligations under the Development Plan or any Annual Development Plan, or, in isolation or in aggregate with any other changes not previously approved by the SC, represents a material change to the resources engaged or to be engaged by sanofi

pasteur in the Development of a Product, or affect or might be reasonably expected to affect the anticipated timetable for Development of a Product. sanofi pasteur shall provide Emergent with an up to date summary of the Development Plan and any Annual Development Plan within thirty (30) days of the commencement of each Quarter which summaries shall highlight any amendments (whether or not major amendments) made to such plan in the previous Quarter. sanofi pasteur shall promptly answer any queries raised by Emergent in connection with any such summary.

#### 5.3 Annual Development Plan and Budget

As soon as practicable following the Effective Date, and in any event within sixty (60) days following the Effective Date, the JPT shall submit to the SC, and the SC shall review and agree to, the Annual Development Plan for the First Year (or such other period as the SC may decide). For each subsequent Year (or such other period as the SC may decide) prior to or including the anticipated Transition Date and during any other period during which the JPT has responsibilities pursuant to Clause 4.3, the JPT shall prepare a draft Annual Development Plan. For each Year during the Late Development Phase, sanofi pasteur shall prepare a draft Annual Development Plan (unless the JPT has been reconstituted pursuant to Clause 4.1, in which case the JPT shall prepare the draft Annual Development Plan). Each draft Annual Development Plan shall be submitted to the SC for review, modification and if appropriate, as determined by the SC, approval. The JPT or sanofi pasteur, as the case may be, shall manage the preparation and submission of each draft Annual Development Plan (other than the Annual Development Plan for the First Year) in a manner designed to result in approval of such plan, if there is no dispute within the SC, by no later than thirty (30) days prior to the end of the then-current Year or such other date (taking into account the budget cycle of sanofi pasteur) as the SC may decide. Each Annual Development Plan shall describe with reasonable specificity the Development objectives for, and activities to be performed in, the applicable Year (or other period covered by the Annual Development Plan) and an estimated timeline for such activities. During the Early Development Planse and thereafter if and for so long as the Parties agree that any Development Activities shall be conducted by Emergent, each Annual Development Plan shall identify which Development Activities are Emergent Activities and with respect to such Emergent Activities the number of FTEs estimated to be required to perform such activities, the corres

## 5.4 The Early Development Phase

5.4.1 **Conduct**. During the Early Development Phase each Party shall undertake the Development Activities allocated to it in the relevant Annual Development Plan. It is anticipated that the majority of Pre-Clinical Studies and Phase I Studies will be

undertaken by Emergent. In particular, Emergent shall, with assistance from sanofi pasteur and at sanofi pasteur's cost, (i) evaluate and screen the Candidate Antigens and the SC shall select Clinical Candidates as more particularly described in the Outline Candidate Evaluation and Selection Plan; and (ii) Develop Clinical Candidates and undertake Phase I Studies as more particularly described in the Phase I Product and Clinical Development Plan.

- Role of the JPT. The JPT shall be responsible for day-to-day management of the Development Programme during the Early Development Phase and any subsequent period during which pre-clinical Development Activities or a Phase I Study are to be undertaken with or in connection with a Programme Antigen, and in particular shall have the responsibilities set out in Clause 4.3. Each of sanofi pasteur and Emergent shall cause its representatives on the JPT to collaborate with the other Party's representatives in the discharge of those responsibilities. In addition to the reports prepared pursuant to Clause 5.10, each of Emergent and sanofi pasteur shall keep the other informed of the conduct of their respective Development Activities through the JPT and their respective Project Leaders.
- 5.5 Transition from Early Development to Late Development
- 5.5.1 **Transition Plans.** If sanofi pasteur notifies Emergent that it intends to progress a Clinical Candidate into a Phase II Study, the JPT shall prepare and submit to the SC a transition plan for such Clinical Candidate (each a "**Transition Plan**"), which plan shall provide for the smooth, orderly and cost-effective transfer of principal responsibility for the conduct of Development Activities relating to that Clinical Candidate from Emergent to sanofi pasteur and shall include each Party's responsibilities (and, with respect to any responsibilities allocated to Emergent, the estimated FTE Costs and Emergent Expenses) and a timetable for such transfer. The Transition Plan shall provide for:
  - (a) securing supplies of any Clinical Candidate as required for planned Clinical Studies involving that Clinical Candidate;
  - (b) the transfer of copies of all relevant information, files or data relating to the Clinical Candidate;
  - (c) the assignment and transfer from Emergent to sanofi pasteur of all of Emergent's rights, title or interest in or to any Regulatory Documentation and Regulatory Approvals relating to that Clinical Candidate then in Emergent's name; provided that if the Clinical Candidate is a Co-Exclusive Antigen Emergent shall only be required to grant sanofi pasteur co-exclusive rights in such Regulatory Documentation and Regulatory Approvals; and
  - (d) such other matters as the SC may consider appropriate.
- 5.5.2 **Assignment of Regulatory Documentation**. Emergent shall, at sanofi pasteur's cost, duly execute and deliver, or cause to be duly executed and delivered, such instruments and shall do and cause to be done such acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary to give effect to Clause 5.5.1(c).

- 5.5.3 Transition Costs. All FTE Costs and Emergent Expenses incurred by Emergent in implementing each Transition Plan shall be paid by sanofi pasteur in accordance with Clause 5.13.
- 5.6 The Late Development Phase
- 5.6.1 Conduct. During the Late Development Phase each Party shall undertake the Development Activities allocated to it in the Development Plan and the relevant Annual Development Plan. It is anticipated that the majority of such Development Activities will be undertaken by sanofi pasteur. In particular, sanofi pasteur shall, with such assistance from Emergent as may be described in any Annual Development Plan, undertake further research and Development and Clinical Studies as described in the Later Stage Clinical Development Plan including all clinical, regulatory, manufacturing and other work that is required to conduct Phase II Studies and Phase III Studies and as may be necessary to obtain Marketing Authorisation for a Unitary Product in each Major Market Country. In addition to the reports to be provided pursuant to Clause 5.10, sanofi pasteur shall keep the Emergent Project Leader regularly updated as to progress under the Development Plan or any Annual Development Plan.
- 5.6.2 Additional sanofi pasteur Responsibilities. The JPT shall be disbanded on the Transition Date or on such later date as the Parties may agree. Thereafter, except during such periods as the JPT is reconstituted pursuant to Clause 4.1, sanofi pasteur shall be responsible for proposing and submitting to the SC for review and, where required by this Agreement, approval as to:
  - (a) any amendments to the Development Plan or any Annual Development Plan including proposals relating to clinical, regulatory and intellectual property strategy, in each case as appropriate to the stage of the Development Programme; and
  - (b) any strategic issues relating to the Development Programme including the progression of Clinical Candidates and the Development of Combination Products.
- 5.6.3 Demonstration of Presence of SBAs. Subject to this Clause 5.6.3, sanofi pasteur shall commence a Clinical Study with a Clinical Candidate or Product to demonstrate the presence of SBAs in Adolescents within six (6) months of receipt of a final clinical study report demonstrating, in adults, the presence of SBAs in connection with use of a Clinical Candidate or Product. For the purpose of this Agreement, presence of SBAs will be deemed to have been demonstrated against Neisseria meningitidis serogroup B ("Demonstration of Presence of SBAs"), if a Programme Antigen or a Product (i) elicits a [\*\*] fold increase in SBA Activity, as measured with a standard assay system, as identified in the Development Plan, which utilises human complement as the exogenous complement source, against at least [\*\*] percent ([\*\*]%) of a representative panel of Neisseria meningitidis serogroup B strains, in at least [\*\*] percent ([\*\*]%) of the subjects allocated to receive one test vaccine (i.e. at least one dosage with or without adjuvant) (the "Response Rate"); and (ii) satisfies the safety endpoints of that Clinical Study with the very same formulation. Without prejudice to the generality of the foregoing, following the design of the relevant Clinical Study, the Steering Committee will agree the statistical analysis to be

performed on the Clinical Study results, including possible determination of the confidence intervals or other statistical measures for the Response Rate endpoint. If the Steering Committee agree statistical limits around the Response Rate endpoint and Demonstration of Presence of SBAs shall also be deemed to have occurred if the Clinical Study results are within these agreed limits and Clause 5.6.3 (ii) is also satisfied. If either the FDA or the European Agency for the Evaluation of Medicinal Products establishes a functional assay other than SBA Activity (an "Alternative Assay") as an alternative efficacy endpoint for the grant of a Marketing Authorisation for a Meningitis B Product, the Parties shall adopt such Alternative Assay and Demonstration of Presence of SBAs will be deemed satisfied if there is a successful demonstration of such functional activity using the Alternative Assay.

### 5.7 Incorporation of Additional Antigens

- 5.7.1 **Proposal to incorporate Additional Antigens**. The Parties each acknowledge and agree that, although the primary objective of the Development Programme is to Develop a Product comprising only Programme Antigens, the effectiveness of a potential Product for the prevention of *Neisseria meningitidis* serogroup B may be enhanced by the incorporation of one or more Additional Antigens. Subject to Clause 5.8, sanofi pasteur may propose any such addition (and any corresponding amendments to the Development Plan) during the Early Development Phase or the Late Development Phase provided that sanofi pasteur is able to demonstrate that the proposed Additional Antigen satisfies the Inclusion Criteria. Any such proposal by sanofi pasteur shall be in writing and shall include all information required to determine whether the Additional Antigen satisfies the Inclusion Criteria and shall either be submitted to Emergent or, if sanofi pasteur is not prepared to disclose such information to Emergent, sanofi pasteur shall confirm that such information is available for review by an independent expert in accordance with Clause 5.7.2. Emergent shall within thirty (30) days from the date of such submission notify sanofi pasteur whether it agrees to the inclusion of such Additional Antigen or alternatively that it wishes the matter to be referred to an independent expert in accordance with Clause 5.7.2. If Emergent fails to provide such notice within such thirty (30) day period, Emergent shall be deemed to have consented to the incorporation of such Antigen into the Product or potential Product.
- 5.7.2 **Expert Review**. If sanofi pasteur is unable to demonstrate to Emergent's reasonable satisfaction that any proposed Additional Antigen satisfies the Inclusion Criteria, the Parties shall appoint an independent expert with expertise in the field of vaccine development and licensing reasonably acceptable to both Parties to determine whether the Antigen satisfies the Inclusion Criteria. If the Parties are unable to agree on the identity of the independent expert within ten (10) days of Emergent's notifying sanofi pasteur that it desires the appointment of such expert, the independent expert shall be appointed by Emergent, and approved by sanofi pasteur, which approval shall not be unreasonably withheld, conditioned or delayed. Within twenty (20) days of such appointment, sanofi pasteur shall furnish to the expert (subject to such obligations of confidentiality and non-use as may be reasonably required by sanofi pasteur) all information necessary for the expert to make such determination with a copy to Emergent, provided that sanofi pasteur shall be entitled to redact sanofi pasteur Confidential Information from such copy. Emergent may also make submissions to the expert, with a copy to sanofi pasteur, within such period. Any such submission

shall not, unless the Parties otherwise agree, exceed 15,000 words. Within fifteen (15) days of receipt of the other Party's summary (or such longer period as may be required to ensure the presence of the expert), there shall be a one-day oral hearing before the expert at which each Party shall be given an equal opportunity to present its own position and hear and respond to the oral presentation given by the other Party. Within fifteen (15) days of such oral hearing each Party may submit a written rebuttal of the other Party's summary providing that any rebuttal shall not exceed 5,000 words. The expert shall be required by the Parties to use all reasonable efforts to render his decision within sixty (60) days of his appointment or if earlier within thirty days following his receipt of all such information and such decision shall be final and binding upon each of the Parties. Should the expert determine that the proposed Additional Antigen satisfies the Inclusion Criteria, then Emergent shall pay the fees and expenses of the expert. Should the expert determine that the proposed Additional Antigen does not satisfy the Inclusion Criteria, then sanofi pasteur shall pay the fees and expenses of the expert.

- 5.7.3 **Non-discrimination.** Whether or not any Additional Antigen satisfies the Inclusion Criteria, sanofi pasteur shall not in any event discriminate against any Programme Antigen and shall make all proposals and decisions relating to the prioritisation and screening of Antigens and the inclusion of any Antigen in a Unitary Product in good faith based on all available technical and scientific information. For the avoidance of doubt in making any such proposal or decision (including pursuant to Clause 3.5.1), sanofi pasteur shall not be entitled to take into account the royalties, milestones or other payments due or potentially due to Emergent with respect to any Programme Antigen or Product pursuant to this Agreement.
- 5.7.4 **sanofi pasteur activities with Programme Antigens.** For the avoidance of doubt, sanofi pasteur shall not conduct any activities in relation to the Development of Programme Antigens unless such activities are set out in the Development Plan or any Annual Development Plan and are conducted in accordance with this Agreement as part of the Development Programme.
- 5.8 Third Party Technology and sanofi pasteur Technology
- 5.8.1 Independent review of Technology. Prior to the incorporation of any Third Party Antigen into a Product or application to a Product of any Patent Rights licensed to sanofi pasteur, sanofi pasteur shall disclose such Antigen or technology to Emergent and shall, upon Emergent's request, allow an independent third party access to any relevant licenses granted to sanofi pasteur by Third Parties to verify the terms on which such Antigen or technology is licensed to sanofi pasteur (including any royalty obligations that would form part of the Royalty Burden). If sanofi pasteur incorporates or applies any such Antigen or technology in or to a Unitary Product the licence of such Antigen or technology to sanofi pasteur shall be deemed to be a sanofi pasteur In-Licence and Emergent will be provided with a schedule listing such sanofi pasteur In-License(s) and related Patent Rights. Except as expressly provided in Clause 7.4, no royalties or other consideration paid or payable by sanofi pasteur, its Affiliates or any Sub-Licensees to any Third Party pursuant to any sanofi pasteur In-Licence or any other licence shall be taken into consideration in the calculation of Net Sales hereunder or credited against any amounts owed by sanofi pasteur to Emergent hereunder.

5.8.2 **Disclosure of Technology**. From time to time throughout the Term, sanofi pasteur shall disclose to Emergent any sanofi pasteur Independent Technology and sanofi pasteur Programme Technology necessary for the conduct of the Emergent Activities.

#### 5.9 Combination Product

Without prejudice to Clause 6.2, sanofi pasteur may at any time after commencement of the Late Development Phase propose Development of a Combination Product. In such event, whether or not there are, at that time, any ongoing Development Activities, any such Development shall be considered to be part of the Development Programme and the Late Development Phase shall be extended or revived as required. Without prejudice to its obligations under this Agreement, sanofi pasteur shall be entitled to make all strategic decisions relating to the Development of Combination Products; provided that sanofi pasteur shall promptly inform Emergent of any such decisions and shall provide such further information and explanation for such decision as Emergent may reasonably request.

### 5.10 Reports of Development Activities

During the Development Programme, each Party (acting through its Project Leader) shall furnish to the SC:

- (a) within thirty (30) days after the end of each Quarter, summary reports describing its progress under the Annual Development Plan during that Quarter. The format and degree of detail required for such summary reports shall be defined and agreed by the SC with the objective of ensuring that each of the Parties provides an adequate amount of information to the other about its activities pursuant to the Annual Development Plan; and
- (b) within sixty (60) days after the end of each Year or at such other times as the Parties may determine, comprehensive written reports describing in detail the work accomplished by it under the Annual Development Plan during such Year and discussing and evaluating the results of such work.

### 5.11 Performance by Emergent

In performing the Emergent Activities, Emergent shall use such FTEs as are specified in the relevant Annual Development Plan. Emergent shall notify the SC promptly upon becoming aware of a scientific or technical problem that is likely to preclude Emergent from completing any Emergent Activity with the FTEs set out in the applicable Annual Budget for such Emergent Activity. As part of such notification, Emergent shall provide the SC with a reasonably detailed description of such problem, together with its good faith belief as to the steps necessary to complete such Emergent Activity, if practicable at all, in light of such problem. Upon receipt of such notification, the SC shall then meet within ten (10) days to determine what action to take and Emergent shall not be required to perform the relevant Emergent Activity unless and until the SC resolves how to proceed.

#### 5.12 Performance by sanofi pasteur

5.12.1 **Development of a Unitary Product**. sanofi pasteur shall use Commercially Reasonable Efforts to Develop a Unitary Product.

- 5.12.2 **sanofi pasteur Diligence**. sanofi pasteur warrants and undertakes that it shall at all times prior to the grant of a Marketing Authorisation for a Product in a Major Market Country have at least one Programme Antigen in active clinical Development provided that at least one Programme Antigen has met the Selection Criteria and provided further that:
  - (a) if all Programme Antigens have been tested in preclinical Development and none have met the Selection Criteria then sanofi pasteur will have no obligation to conduct clinical activities with any Programme Antigen and the absence of ongoing clinical activities by sanofi pasteur shall not constitute a lack of diligence; and
  - (b) if all Programme Antigens that have met the Selection Criteria have been tested in a Phase I Study, and none of the Programme Antigens that have met the Selection Criteria have been found to meet the Primary Inclusion Criteria, then sanofi pasteur will have no obligation to conduct further clinical activities with any such Programme Antigen and the absence of ongoing clinical activities by sanofi pasteur shall not constitute a lack of diligence.

sanofi pasteur shall be deemed to be actively Developing at least one Programme Antigen if a Programme Antigen is in a Phase I Study, a Phase II Study or a Phase III Study.

- 5.12.3 Clinical Development. Without limiting the generality of Clause 5.12.2:
  - (a) sanofi pasteur shall use Commercially Reasonable Efforts to screen all Candidate Antigens to determine whether they meet the Selection Criteria;
  - (b) sanofi pasteur shall use Commercially Reasonable Efforts to progress into a Phase I Study any Programme Antigen that meets the Selection Criteria unless there is already a Programme Antigen in a Phase I Study or a later stage of active clinical Development;
  - (c) any Programme Antigen in a Phase I Study will be assessed to determine whether it satisfies the Primary Inclusion Criteria;
  - (d) subject to paragraph (e) below, sanofi pasteur shall use Commercially Reasonable Efforts to progress into a Phase II Study any Programme Antigen that meets the Primary Inclusion Criteria unless there is already a Product in a Phase II Study or a later stage of active clinical Development;
  - (e) provided that if sanofi pasteur has another Programme Antigen in a Phase I Study, sanofi pasteur shall not be obliged to include a Programme Antigen in a Meningitis B Product going into a Phase II Study if each of the Antigens included in that product are superior to that Programme Antigen or the combination of those Antigens is superior to all combinations of all or some of those Antigens with that Programme Antigen;
  - (f) if sanofi pasteur (or one of its Affiliates or Sub-Licensees) has a Competitive Product in a Phase II Study or later clinical development or a Competitive Product has been granted a Marketing Authorisation, any Programme Antigen

that satisfies the Primary Inclusion Criteria shall be assessed to determine (i) whether it is superior to one or more Sanofi Pasteur Antigens or Third Party Antigens included in that Competitive Product, or (ii) whether a combination of that Programme Antigen with one or more of those Sanofi Pasteur Antigens or Third Party Antigens is superior to the combination of Antigens in the Competitive Product. Superiority shall be determined in accordance with Clause 5.12.4. If it is determined that a Programme Antigen is superior to one or more Antigens included in the Competitive Product or would provide a superior combination of Antigens for use in a Meningitis B Product, sanofi pasteur must either (i) commence a Phase II Study with a Meningitis B Product including the superior Programme Antigen and, if applicable, the best combination of Antigens from the Competitive Product and thereafter actively continue the clinical Development of such Meningitis B Product; or (ii) notify Emergent in writing that it is not progressing a Meningitis B Product including the superior Programme Antigen and, if applicable, the best combination of Antigens from the Competitive Product into a Phase II Study or, if later, that it is suspending the further clinical Development of such Programme Antigen. On sanofi pasteur serving such notice or, if sanofi pasteur does not serve such notice and does not, within three (3) months from the date on which it is determined that the Programme Antigen is superior, commence development activities leading to the commencement of a Phase II Clinical Study with a Meningitis B Product including the superior Programme Antigen and, if applicable, the best combination of Antigens from the Competitive Product, or having commenced such activities suspends active clinical Development of such Programme Antigen, on Emergent serving written notice on sanofi pasteur, all rights in that Programme Antigen (the "Repatriated Antigen") shall revert to Emergent and Emergent shall be entitled to Exploit such Repatriated

(g) if the Programme Antigen assessed pursuant to paragraph (f) above is not superior to the Antigens in the Competitive Product, sanofi pasteur shall be entitled to suspend further clinical Development of such Programme Antigen provided that, and for so long as, sanofi pasteur has another Programme Antigen in a Phase I Study or a later stage of active clinical Development.

For the avoidance of doubt, sanofi pasteur's obligations in relation to the clinical Development of Programme Antigens shall cease on the grant of a Marketing Authorisation for a Product in a Major Market Country.

5.12.4 Superiority of Antigens. For the purposes of this Agreement, a Programme Antigen will be deemed to be superior to a sanofi pasteur Antigen or Third Party Antigen (as the case may be) if that Programme Antigen, had its characteristics been known at the time sanofi pasteur decided which Antigens would be included in the Competitive Product, would, applying the principles of non-discrimination set out in Clause 5.7.3, have been included standing alone or with other Antigens in a Meningitis B Product. The assessment of the relative superiority of Antigens shall be made on the basis of the same tests or assessments for each Antigen, including protection coverage against the same representative panel of clinically relevant Neisseria meningitidis serogroup B strains for each Antigen, immunogenicity, potential synergistic effects when in combination with other Antigens and the optimum protection coverage obtained with

combinations of Antigens. The level of SBA or readout from any Alternative Assay considered to confer protection shall be applied equally to all Antigens. One Antigen shall not be considered superior to another on the basis of tests or assessments that may not be applied equally to both Antigens. Activities required to generate the data required to allow determination of the relative superiority of Antigens will be included in the Development Plan and Annual Development Plan and will be completed prior to the end of Phase I clinical development for the relevant Antigen.

- 5.12.5 Co-Exclusive Antigens. If prior to the grant of a Marketing Authorisation for a Product in a Major Market Country, sanofi pasteur suspends development of a Programme Antigen in accordance with Clause 5.12.3(g) and at the time of such suspension has or subsequently obtains a Marketing Authorisation for any Competitive Product, Emergent and sanofi pasteur shall have co-exclusive rights to Exploit such Programme Antigen (a "Co-Exclusive Antigen") unless sanofi pasteur has and continues to have a Product incorporating a Programme Antigen in a Phase II Study or later active clinical Development. A Co-Exclusive Antigen shall remain a Programme Antigen but once a Programme Antigen has become a Co-Exclusive Antigen it shall remain a Co-Exclusive Antigen even if sanofi pasteur subsequently commences a Phase II Study or any later clinical Development with it or a different Programme Antigen.
- 5.12.6 Expert Determination. If sanofi pasteur is unable to demonstrate to Emergent's reasonable satisfaction that a Programme Antigen is being Developed as required pursuant to this Clause 5.12, Emergent shall notify sanofi pasteur and the Parties shall appoint an independent expert with expertise in the field of vaccine development and licensure reasonably acceptable to both Parties to determine whether the Programme Antigen (i) satisfies the Selection Criteria and the Primary Inclusion Criteria; and (ii) is superior to any sanofi pasteur Antigen or Third Party Antigen in active clinical Development. If the Parties are unable to agree on the identity of the independent expert within ten (10) days of Emergent notifying sanofi pasteur that it wishes the appointment of such expert, the independent expert shall be appointed by Emergent, and approved by sanofi pasteur, which approval shall not be unreasonably withheld, conditioned or delayed. Within twenty (20) days of such appointment, each of the Parties shall furnish to the expert (subject to such obligations of confidentiality and non-use as may be reasonably required by them), with a copy to the other Party, a written summary of such Party's position and any relevant evidence supporting such position including all information necessary for the expert to make such determination. Any such written summary and evidence shall not, unless the Parties otherwise agree, exceed 15,000 words. Within fifteen (15) days of receipt of the other Party's summary (or such longer period as may be required to ensure the presence of the expert) there shall be a one-day oral hearing before the expert at which each Party shall be given an equal opportunity to present its own position and hear and respond to the oral presentation given by the other Party. Within fifteen (15) days of such oral hearing each Party may submit a written rebuttal of the other Party's summary providing that any rebuttal shall not exceed 5,000 words. The expert shall be required by the Parties to use all re

the expert find in favour of sanofi pasteur, then Emergent shall pay the fees and expenses of the expert.

## 5.13 **Development Funding**

sanofi pasteur shall pay Emergent (i) the aggregate FTE Cost for all FTEs, and (ii) the amount of all Emergent Expenses incurred by Emergent in accordance with the Indicative Cost Schedule, any Annual Budget or Transition Plan. On the date of this Agreement and on the first day of each subsequent Quarter, sanofi pasteur shall make a payment in pounds sterling (£) equal to the estimated FTE Cost and Emergent Expenses for the Quarter commencing on the Effective Date and thereafter each subsequent Quarter and, in relation to the payment to be made on the date of this Agreement, FTE Costs of  $\pounds[**]$  and Emergent Expenses of  $\pounds[**]$  incurred between 1 January 2006 and the Effective Date, as reflected in the then-current Indicative Cost Schedule, Annual Budget or Transition Plan provided that each such payment shall be made against an invoice issued by Emergent. Emergent acknowledges that sanofi pasteur may not be able to pay invoices received by sanofi pasteur in a particular month before the tenth day of the following month. Each of the Parties will use reasonable endeavours to ensure that invoices for each Quarter are issued at least one month prior to end of the immediately preceding Quarter to enable payment by sanofi pasteur against such invoice on or before the first day of each Quarter. Emergent shall provide sanofi pasteur with annual reconciliation statements that specify the actual number of FTEs and the actual Emergent Expenses for the last four (4) Quarters in the aggregate within sixty (60) days of the completion of each Year. If, with respect to a particular Year:

- (a) the actual FTE Cost plus the Emergent Expenses specified in such annual reconciliation statement is less than the amount paid by sanofi pasteur to Emergent with respect to that Year, such excess shall be set against the amounts due to Emergent with respect to forthcoming Emergent Activities until such balance is zero or if no such activities are contemplated, repaid to sanofi pasteur; or
- (b) the actual FTE Cost plus the Emergent Expenses specified in such annual reconciliation statement is more than the amount actually paid by sanofi pasteur to Emergent with respect to that Year, sanofi pasteur shall pay the deficiency within thirty (30) days of the date of such statement.

#### 5.14 Funding Audit Rights

Emergent shall keep complete and accurate books and financial records pertaining to its costs and expenses of conducting the Emergent Activities (including duly completed Activity Forms), which books and financial records shall be retained by Emergent until three (3) years after the end of the Year to which they pertain. sanofi pasteur shall have the right to appoint at its expense an independent certified public accountant reasonably acceptable to Emergent to inspect and audit, during normal business hours and upon reasonable prior written notice, the books and financial records of Emergent relating to its costs and expenses of conducting the Emergent Activities during any Year; provided that sanofi pasteur shall not have the right to inspect or audit any Year more than once and will not go back over records more than three (3) years old unless a discrepancy is found. All books and financial records

made available for inspection or audit shall be deemed to be Emergent Confidential Information.

#### 5.15 Terminated Antigens

If having been evaluated in accordance with the Outline Candidate Evaluation and Selection Plan, the SC determines that a Programme Antigen is not to be selected as a Clinical Candidate, the SC shall consider whether such Programme Antigen can be a back-up Antigen and may or may reasonably be likely at a later point during the Development Programme to be subject to further Development Activities. If the SC determines that such Programme Antigen will not, or may not, be subject to further Development Activities then such Programme Antigen shall be designated a Terminated Antigen.

#### 5.16 Employees, Consultants, Agents and Sub-contractors

Each Party undertakes that any of its employees, consultants, agents or sub-contractors engaged in any Development Activities shall be bound by obligations of confidentiality and non-use consistent with the terms of this Agreement and shall be bound by an agreement pursuant to which he, she or it is obliged to:

- (a) follow such Party's policies and procedures regarding reporting any invention, discovery, process, software programme, information, Know How or Material characterised, conceived, developed, derived, discovered, generated, identified or otherwise made by such person in the course of his or her employment or its retainer with such Party;
- (b) assign to such Party all of his or her right, title and interest in and to any such invention, discovery, process, software program, information, Know How or Material characterised, conceived, developed, derived, discovered, generated, identified or otherwise made by such person in the course of his or her employment or its retainer with such Party, including any intellectual property or proprietary right thereto;
- (c) co-operate in the preparation, filing, prosecution, maintenance, defence and enforcement of any Patent Rights claiming the same; and
- (d) perform all acts and sign, execute, acknowledge and deliver any and all papers, documents and instruments required for effecting the obligations and purposes of that agreement.

### COMMERCIALISATION OF PRODUCT

#### 6.1 Commercialisation Activities

Subject to the terms and conditions of this Agreement, sanofi pasteur shall have sole discretion over, and sole responsibility for, the Commercialisation of Products in the Territory including all decisions with respect to medical affairs, pricing, product launch, marketing, and sales activities. sanofi pasteur shall have sole responsibility for all costs and expenses in connection with such Commercialisation activities. sanofi pasteur shall conduct all Commercialisation activities in compliance in all

material respects with all requirements of Applicable Law.

# 6.2 sanofi pasteur Diligence

sanofi pasteur shall use Commercially Reasonable Efforts:

- (a) to Commercialise a Unitary Product in each Major Market Country; and
- (b) if a Combination Product is Developed, to Commercialise such Combination Product in each Major Market Country.

sanofi pasteur shall Commercialise each Product (whether a Unitary Product or a Combination Product) in accordance with the Commercialisation Plan for such Product.

#### 6.3 Commercialisation Plan

No later than six (6) months prior to the anticipated date of submission to any Regulatory Authority in any Major Market Country of the first application for a Marketing Authorisation for any Product (whether a Unitary Product or a Combination Product), sanofi pasteur shall prepare and provide to Emergent a Commercialisation Plan for such Product. That Commercialisation Plan shall include the matters referred to in the Outline Commercialisation Plan. sanofi pasteur shall consider in good faith any comments made by Emergent. Each Commercialisation Plan shall be updated by sanofi pasteur and submitted to the SC as provided for in this Clause 6.3 not less than annually. Within thirty (30) days of the submission of any Commercialisation Plan or any amendment or update to a Commercialisation Plan, the SC shall, if so requested by Emergent, meet to review and consider that plan or amendment.

#### 6.4 Commercialisation Reports

sanofi pasteur shall keep Emergent reasonably informed of the progress of sanofi pasteur's efforts to Commercialise any Product in the Field in the Territory through semi-annual reports, which reports shall summarise sanofi pasteur's efforts to Commercialise such Product in accordance with the Commercialisation Plan for such Product.

#### 6.5 Development and Use of Trademarks

sanofi pasteur shall have the sole right, in its sole discretion (but in consultation with Emergent) to determine the Trademarks to be used with respect to any Product throughout the Territory (such Trademarks, the "Product Trademarks"); provided however, that sanofi pasteur shall not, and shall not permit its Affiliates, to use in their respective businesses, any Trademark that is confusingly similar to, misleading or deceptive with respect to, or that dilutes any of the Trademarks used by Emergent or its Affiliates in their respective businesses.

#### 6.6 Combination Products

Without prejudice to its obligations under this Agreement, sanofi pasteur shall be entitled to make all strategic decisions relating to the Commercialisation of

Combination Products including in relation to launch and pricing; provided that sanofi pasteur shall promptly inform Emergent of any such decisions and shall provide such further information and explanation of such decision as Emergent may reasonably request.

### 6.7 Emergent Distribution Option

In the event that sanofi pasteur wishes to appoint a Third Party to distribute, co-market or co-promote any Product, or act as its sales representative or commissionaire for any Product, in any country in the Territory or is contemplating any similar arrangement, sanofi pasteur shall notify Emergent accordingly and shall, at Emergent's request, and to the extent that any contractual obligation that sanofi pasteur may have with Third Parties does not prohibit it from doing so, consider Emergent as a potential appointee in such country and in deciding which (if any) person to appoint in such country shall in all respects treat Emergent equally with any Third Party being considered for such appointment.

#### 7. MILESTONE AND ROYALTY PAYMENTS

### 7.1 Upfront Fee

sanofi pasteur shall pay Emergent a non-refundable, non-creditable upfront fee in the amount of Three Million Euros ( $\in$  3,000,000) in immediately available funds on the date of this Agreement provided that such payment shall be made against an invoice issued by Emergent.

#### 7.2 Milestone Payment

7.2.1 **Milestone Events**. sanofi pasteur shall, with respect to the Products, make each of the following non-refundable, non-creditable payments to Emergent in accordance with Clause 7.2.2 on the first occurrence of the corresponding milestone event:

$ \begin{array}{cccccccccccccccccccccccccccccccccccc$		Milestone Event	Payments
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$			
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	1	[**]	€ [**]
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	2	[**]	€ [**]
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	3	[**]	€ [**]
$ \begin{array}{c} \varepsilon \\ [**] \\ 7 \\ [**] \end{array} $	4	[**]	€ [**]
7 [**] € [**]		[**]	€ [**]
, []	6	[**]	€ [**]
8 [**]	7		€[**]
	8	[**]	€ [**]

.2.2	Notice that a Milestone Event has Occurred and Payment. sanofi pasteur or Emergent (as the case may be) shall provide the other Party with prompt written notice upon each	1
1		€ [**]
0	[**]	€ [**]

Milestone

- occurrence of a milestone event set out in Clause 7.2.1. On such occurrence, Emergent (as the case may be) shall provide the other Party with prompt written notice upon each occurrence of a milestone event set out in Clause 7.2.1. On such occurrence, Emergent shall issue an invoice for the amount due and sanofi pasteur shall pay such within ten (10) days of the end of the calendar month in which it received such invoice.
- 7.2.3 **Milestone payments paid only once.** For the avoidance of doubt (a) milestones 1 to 11 (inclusive) set forth in Clause 7.2.1 shall be payable no more than once, irrespective of the number of trigger events associated with any such given milestone and irrespective of whether the milestone is triggered by the activities of sanofi pasteur, its Affiliates or any Sublicensee; and (b) each of milestones 1 to 5 (inclusive) are payable prior to milestones 6 or 8 and if any of milestones 1 to 5 (inclusive) has not been paid when either milestone 6 or 8 becomes payable sanofi pasteur shall immediately pay such unpaid milestone.
- 7.2.4 **Definition.** For the purpose of this Clause 7.2 an "Efficacy and Effectiveness Study" means a study designed and sufficiently powered to show that a vaccine candidate confers a reduction in the infection rate in cases per thousand or the reduction of clinical signs of confirmed serogroup B meningococcal disease in immunized populations ("Efficacy") and demonstrates direct and indirect protection or any clinical benefit obtained in a vaccinated population ("Effectiveness").
- 7.3 Royalties

Milestone Event

In consideration of the licences granted by Emergent to sanofi pasteur under Clause 8.1 and in recognition of Emergent's contribution to the Development Programme and Emergent's joint ownership with sanofi pasteur of the Joint Technology, sanofi pasteur shall, subject to the terms and conditions of this Agreement, pay Emergent on a country-by-country basis royalties in an amount equal to the following:

- (a) [\*\*] percent ([\*\*]%) of, in the case of a Unitary Product, the aggregate Net Sales and, in the case of a Combination Product, the aggregate Adjusted Combination Net Sales, in each case in a country, provided that the Emergent Patent Rights or Joint Patent Rights in such country include at least one Valid Claim covering the Product;
- (b) [\*\*] percent ([\*\*]%) of, in the case of a Unitary Product, the aggregate Net Sales and, in the case of a Combination Product, the aggregate Adjusted Combination Net Sales, in each case in any country in which the Exploitation of such Product would not infringe a Valid Claim of Emergent Patent Rights or Joint Patent Rights (or, for the avoidance of doubt, there are no Emergent Patent Rights or Joint Patent Rights); and

(c) [\*\*] percent ([\*\*]%) of any license fees, upfront payments or milestones received by sanofi pasteur or any of its Affiliates from any Sub-Licensee provided that if a milestone is payable by such Sub-Licensee to sanofi pasteur or one of its Affiliates on the occurrence of one of the events listed in Clause 7.2.1, sanofi pasteur shall only be required to pay a royalty of [\*\*] percent ([\*\*]%) on the amount (if any) by which the milestone payable by the Sub-Licensee on such occurrence exceeds the amount payable by sanofi pasteur to Emergent on such occurrence pursuant to Clause 7.2.1.

## 7.4 Adjustment of Royalty Rate

7.4.1 **Royalty under Clause 7.3(a)**. If a Unitary Product (whether developed and launched as a stand alone product or as a constituent of a Combination Product) contains one or more Additional Antigens, the royalty payable pursuant to Clause 7.3(a) shall be adjusted according to the number of Programme Antigens compared to the total number of Programme Antigens and Additional Antigens in such Unitary Product as follows:

## Number of Programme Antigens and Additional Antigens in a Unitary Product

		[**]	[**]	[**]	[**]	[**]
Number of	[**]	[**]	[**]	[**]	[**]	[**]
Programme	[**]		[**]	[**]	[**]	[**]
Antigens in	[**]			[**]	[**]	[**]
that Unitary	[**]				[**]	[**]
Product	[**]					[**]

provided that, if the aggregate royalties payable by sanofi pasteur to (i) Emergent as set out in the table above; and (ii) any Third Party pursuant to a sanofi pasteur In-Licence on the sale of the Unitary Product (whether sold as a stand alone product or as a constituent of a Combination Product) in the relevant country if and to the extent that such royalty is payable for access to a Third Party Antigen in the Unitary Product or any adjuvant or for access to any technology necessary or reasonably useful for the manufacture of any Programme Antigen or Additional Antigen incorporated in such Unitary Product but, for the avoidance of doubt, excluding any technology relating to delivery of the Product, ((i) and (ii) in aggregate, the "Royalty Burden") are equal to or less than [\*\*] percent ([\*\*]%) of Net Sales of such Unitary Product or, if the Unitary Product is sold as a constituent of a Combination Product, [\*\*] percent ([\*\*]%) of Adjusted Combination Net Sales of such Combination Product, the royalty payable to Emergent pursuant to Clause 7.3(a) shall not be less than [\*\*] percent ([\*\*]%). If on a recalculation of the Royalty Burden to include such increased royalty to Emergent equals [\*\*] percent ([\*\*]%). For the avoidance of doubt, the royalty payable to Emergent pursuant to Clause 7.3(a) shall not in any event be less than the applicable amount provided for in the royalty grid in this Clause 7.4.1. The Royalty Burden shall be calculated at the time of the relevant sale of the Unitary

Product or the Combination Product (as the case may be) and no specific royalty shall be counted more than once.

7.4.2 **Royalty under Clause 7.3(b)**. If a Unitary Product (whether developed and launched as a stand alone product or as a constituent of a Combination Product) contains one or more Additional Antigens the royalty payable pursuant to Clause 7.3(b) shall be adjusted according to the number of Programme Antigens compared to the total number of Programme Antigens and Additional Antigens in that Unitary Product as follows:

### Number of Programme Antigens and Additional Antigens in a Unitary Product

Number of	[**]	[**] [**]	[**] [**]	[**] [**]	[**] [**]	[**] [**]
Programme Antigens in that Unitary Product	[**] [**] [**]	. ,	[**]	[**] [**]	[**] [**] [**]	[**] [**] [**]

provided that, if the Royalty Burden is equal to or less than [\*\*] percent ([\*\*]%) of Net Sales of such Unitary Product, or, if such Unitary Product is sold as a constituent of a Combination Product, [\*\*] percent ([\*\*]%) of Adjusted Combination Net Sales of such Combination Product, the royalty payable to Emergent pursuant to Clause 7.3(b) shall not be less than [\*\*] percent ([\*\*]%). If on a recalculation of the Royalty Burden to include such increased royalty to Emergent the Royalty Burden would be more than [\*\*] percent ([\*\*]%), such royalty shall be reduced so that the Royalty Burden calculated to include the revised royalty payable to Emergent equals [\*\*] percent ([\*\*]%). For the avoidance of doubt, the royalty payable to Emergent pursuant to Clause 7.3(b) shall not in any event be less than the applicable amount provided for in the royalty grid in this Clause 7.4.2.

- 7.4.3 **Minimum Royalties for Combination Products**. If the Product is sold as a Combination Product, the royalty payable to Emergent pursuant to Clause 7.3 (as adjusted pursuant to Clause 7.4.1 or Clause 7.4.2, if applicable) shall be subject to a minimum as set out in the definition of Net Sales.
- 7.4.4 **Verification of Royalty Burden**. If at any time during the Term, either or both Clauses 7.4.1 or 7.4.2 apply to reduce the royalty payable pursuant to Clause 7.3, Emergent shall be entitled to appoint an independent Third Party to verify the applicable Royalty Burden. sanofi pasteur shall provide such Third Party with all information necessary for him to verify the applicable Royalty Burden including access to any agreements pursuant to which a royalty included in the Royalty Burden is payable and any other information necessary to explain or verify the amount of such royalty with respect to any country at the relevant time. All agreements and information made available for inspection shall be deemed to be sanofi pasteur Confidential Information. For the avoidance of doubt, any such Third Party shall prior to such inspection enter into a non-disclosure agreement in a form reasonably

acceptable to sanofi pasteur. The Third Party shall disclose to the Parties the correct Royalty Burden for the relevant country at the relevant time and the specific details concerning any discrepancy with sanofi pasteur's calculation of the Royalty Burden but no other information shall be provided to Emergent.

7.4.5 **Worked Examples.** The Parties have set forth in Schedule 10 illustrative examples of the calculation of royalties that would be payable on Unitary Products and Combination Products in certain circumstances pursuant to Clauses 7.3 and 7.4.

#### 7.5 Royalty Term

sanofi pasteur's obligation to pay royalties to Emergent under Clause 7.3 on Net Sales shall terminate, on a country-by-country basis, with respect to any Product on the later to occur of (i) the [\*\*] anniversary of the First Commercial Sale in such country; and (ii) the expiration date in such country of the last to expire of any Emergent Patent Rights or Joint Patent Rights that include at least one Valid Claim covering such Product in such country. Upon termination of the royalty obligations of sanofi pasteur under this Clause 7.5 in a country, the licence grants to sanofi pasteur in Clause 8.1 shall become non-exclusive, irrevocable and fully paid-up with respect to such country and Net Sales of such Product in such country shall be excluded from the royalty calculations set out in Clause 7.3.

### 7.6 Royalty Statements

- 7.6.1 Written Reports. During the Term, following the First Commercial Sale, sanofi pasteur shall on or before the thirtieth (30th) day following the end of each Quarter deliver to Emergent a written report for that Quarter showing, in each case on a country-by-country basis:
  - (a) invoiced sales, Net Sales and, if applicable, Adjusted Combination Net Sales (including the calculation of Adjusted Combination Net Sales);
  - (b) the number of units of Product sold;
  - (c) if there has been any adjustment to the royalty rate pursuant to Clause 7.4, the basis and calculation of such adjustment and a breakdown of the Royalty Burden;
  - (d) the amount of royalties due on such Net Sales or Adjusted Combination Net Sales (calculated in accordance with GAAP and Clauses 7.3 and 7.4); and
  - (e) all license fees, upfront payments or milestones received by sanofi pasteur or any of its Affiliates from any Sub-Licensee and the amount payable pursuant to Clause 7.3(c).
- 7.6.2 **Invoices**. sanofi pasteur shall, at the same time as it delivers each written report required by Clause 7.6.1, submit to Emergent a model form invoice for the amount of royalties shown in each such written report to be due. Emergent shall issue an invoice for the royalties payable according to such written report and such model form invoice. sanofi pasteur acknowledges and agrees that all such invoices shall be issued by Emergent in reliance on the information provided by sanofi pasteur. Neither the

issue of any such invoice nor receipt of payment, shall be, nor shall either be deemed to be, acceptance by Emergent of the accuracy of any written report and shall in each case be without prejudice to Emergent's rights to audit or dispute the amount of royalties payable.

- 7.6.3 **Payments.** sanofi pasteur shall, within ten (10) days of the end of the month in which it receives the relevant invoice in accordance with Clause 7.6.2, pay to Emergent or, if not prohibited by law, to whomsoever Emergent shall direct in writing (provided that, for the avoidance of doubt, the provisions of Clause 7.9.1 shall continue to apply to any payment to any such designee and sanofi pasteur shall not be required to incur any additional cost as a result of a payment to any such designated, in Euros to a bank designated in writing by Emergent (such designation to include relevant wiring instructions), or in such other manner as may be agreed between the Parties from time to time, the amount stated in such invoice.
- 7.6.4 **Currency Conversions.** Where the Product is sold in a currency other than Euros all amounts payable will first be calculated in the currency of sale and then converted by sanofi pasteur into Euros at the mid-market exchange rate(s) quoted by Barclays Bank plc in London (or such other bank as the Parties may agree from time to time) for Euros in exchange for that other currency on the final day of the period to which the payment relates.

### 7.7 Records and Audits

- 7.7.1 **Records.** sanofi pasteur shall keep, and shall cause its Affiliates and Sub-Licensees to keep, complete and accurate books and financial records containing all data necessary for the calculation of the amounts payable by sanofi pasteur pursuant to this Agreement including with respect to the calculation and actual payment of the Royalty Burden, which books and financial records shall be kept in accordance with GAAP and shall be retained by sanofi pasteur, and its Affiliates and Sub-Licensees as appropriate, until three (3) years after the end of the Year to which they relate.
- 7.7.2 Audit Procedure. Upon the written request of Emergent, sanofi pasteur shall permit an independent certified public accounting firm of internationally recognised standing selected by Emergent, and reasonably acceptable to sanofi pasteur, to inspect and audit, during normal business hours and upon reasonable prior written notice, such of the records of sanofi pasteur as may be reasonably necessary to verify the accuracy of the reports provided in accordance with Clause 7.6; provided that Emergent shall not have the right to inspect or audit records for any Year more than once or records more than three (3) years old unless a discrepancy is found. If such accounting firm concludes that sanofi pasteur owed additional amounts to Emergent during such period, sanofi pasteur shall pay Emergent the difference between the amount actually owed, as determined by the accounting firm, and the amount actually paid by sanofi pasteur, with interest calculated in accordance with Clause 7.8 from the date originally due to the date of payment, within thirty (30) days after the date on which such accounting firm's written report is delivered to sanofi pasteur. If the accounting firm determines that there has been an underpayment, sanofi pasteur shall bear all costs related to such audit otherwise Emergent shall bear the cost of such audit. All books and financial records made available for inspection or audit shall be deemed to be sanofi pasteur Confidential Information. For the avoidance of doubt, any such independent accounting firm shall, prior to such inspection, enter into a non-

disclosure agreement in a form reasonably acceptable to sanofi pasteur. The accounting firm shall disclose to the Parties whether nor not the payment in question was accurately calculated by sanofi pasteur and the specific details concerning any discrepancies but no other information shall be provided to Emergent.

7.7.3 Access to Sub-Licensees. sanofi pasteur shall include in each sub-licence granted by it pursuant to this Agreement a provision requiring the Sub-Licensee to make reports to sanofi pasteur, to keep and maintain records of sales made pursuant to such sub-licence and to grant access to such records by Emergent's independent accountant to the same extent required of sanofi pasteur under this Agreement.

#### 7.8 Interest

All amounts due from sanofi pasteur to Emergent under this Agreement shall be paid by wire transfer in immediately available funds to an account designated by Emergent. Any payment that is not paid on the date such payment is due under this Agreement shall bear interest at a rate equal to the lesser LIBOR plus two (2) percentage points and the maximum rate permitted by law, calculated on the number of days such payment is delinquent, compounded monthly. For the purposes of this Agreement LIBOR shall mean the London Interbank Offered Rate as calculated by the British Bankers' Association or, if LIBOR ceases to be available, the base rate of a London bank selected by Emergent.

### 7.9 Withholding

- 7.9.1 **Payments.** Any consideration payable by either Party shall be paid free and clear of any deduction or withholding for or on account of tax, setoffs or counterclaims whatsoever, save for any deduction or withholding required by Applicable Law. Where such a deduction or withholding is required to be made, the Party making the deduction or withholding shall give the other Party such assistance as may be necessary or expedient to enable that other Party to claim exemption therefrom or a reduction thereof and upon request of such other Party shall provide documentation in a form sufficient to evidence the payment of the tax. Such assistance shall include the provision by sanofi pasteur to Emergent of such forms as the relevant tax authority may require Emergent to complete.
- 7.9.2 Information to be provided by Emergent. Emergent shall complete and return to sanofi pasteur any form provided by sanofi pasteur that is required by the relevant tax authorities from time to time (including, if required, prior to the first payment in any calendar year) to (i) attest Emergent's fiscal residence and (ii) obtain the application of the reduced withholding tax rate or the exemption of withholding tax rate, according to the relevant bilateral convention for the prevention of double taxation. In the event that Emergent fails to return to sanofi pasteur such forms duly completed and signed before the due date for the relevant payment, sanofi pasteur will, if and to the extent required by Applicable Law, declare and pay withholding tax at the rate prescribed by Applicable Law, and such tax will be deducted from the amount payable by sanofi pasteur to Emergent. sanofi pasteur shall remit the withholding tax to the proper tax authority and proof of payment of such tax shall be secured and sent to Emergent as evidence of such payment; provided, however, that Emergent may, at any time prior to a payment due date, specify a later due date for payment, and sanofi pasteur shall delay making such payment to such later due date (without incurring any liability

pursuant to Clause 7.8), in order to provide Emergent with additional time in which to obtain the required information or otherwise secure approval for exemption of withholding tax or reduction of the withholding tax rate.

#### 7.10 VAT

If VAT is payable on any supply by either Party under this agreement, the Party receiving the supply shall, in addition to any consideration due hereunder with respect to such supply, promptly pay to the Party making the supply the amount of such VAT upon receipt of a valid VAT invoice in the prescribed form with respect to such supply.

#### 7.11 Changing Standards

Each Party shall consider in good faith, and not unreasonably refuse, any request by the other Party to modify any reporting requirements or provisions relating to records as set out in this Agreement in a manner necessary to permit the requesting Party to comply with any reporting or financial standards applicable to it or its Affiliates from time to time.

### 8. LICENCE GRANTS

#### 8.1 Emergent Licence Grants

- 8.1.1 **Licence under Emergent Technology**. Subject to the terms of this Clause 8.1.1 and the other terms of this Agreement, Emergent hereby grants to sanofi pasteur an exclusive (even as to Emergent) worldwide licence during the term of this Agreement in the Territory in the Field, with the right, subject to Clause 8.1.3, to grant sub-licences, under the Emergent Technology and Emergent's right and interest in Joint Technology:
  - (a) to research and Develop any Programme Antigen; and
  - (b) to Exploit any Product;

provided that (i) no Product shall include, and Emergent grants no rights to Exploit, any Terminated Antigen or Repatriated Antigen; and (ii) Emergent expressly reserves for itself such rights as may be necessary or reasonably useful to (A) perform the tasks assigned to it in the Development Plan and any Annual Development Plan and to conduct the Emergent Activities in accordance with this Agreement; (B) Exploit any Terminated Antigen outside the Field; (C) Exploit any Repatriated Antigen in or outside the Field; and (D) Exploit any Co-Exclusive Antigen in or outside the Field provided that such rights shall, in the Field, be co-exclusive with sanofi pasteur. For the avoidance of doubt, sanofi pasteur shall have no right to research, Develop or otherwise Exploit any Terminated Antigen in the Field.

8.1.2 **Regulatory Documentation.** Subject to the other terms of this Agreement, Emergent and its Affiliates hereby grant to sanofi pasteur and its Affiliates a co-exclusive (with Emergent and its Affiliates) licence and right of reference in the Territory during the

term of this Agreement, with the right to grant sub-licences subject to Clause 8.1.3, under Emergent's rights and interests in the Regulatory Documentation for or relating to any Clinical Candidate or Product to the extent not otherwise assigned pursuant to Clause 5.5.2 so as to enable sanofi pasteur to exercise its rights under the grants set out in Clause 8.1.1. Emergent shall, as soon as reasonably practicable following sanofi pasteur's written request, provide sanofi pasteur with access to all such Regulatory Documentation and all information contained therein

8.1.3 **Right to Sublicense**. sanofi pasteur shall be entitled to grant sublicences under the rights granted pursuant to Clause 8.1.1 and 8.1.2 subject to Emergent's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed. In the event that sanofi pasteur wishes to obtain Emergent's consent to a proposed sublicence pursuant to Clause 8.1.1 or Clause 8.1.2, sanofi pasteur shall provide written notice to Emergent of the proposed sublicence at least thirty (30) days prior to its execution and provide copies to Emergent of each such sublicence with the financial terms redacted but otherwise substantially in the form to be executed at least ten (10) Business Days prior to such execution. Within ten (10) Business Days of execution of such sublicence, sanofi pasteur shall provide a copy of the sublicence in the form executed. For the avoidance of doubt, any such sublicence shall be consistent with the terms of this Agreement (including with regard to audit rights and confidentiality) and shall not relieve sanofi pasteur of its obligations pursuant to this Agreement. Sub-Licensees shall not be entitled to grant further sublicenses under the Emergent Technology or Joint Technology.

### 8.2 Materials

Emergent hereby grants to sanofi pasteur the right to use Materials provided by Emergent to sanofi pasteur pursuant to this Agreement provided that any such Materials including any replication, copy, progeny or derivative thereof and any Materials derived from such Materials (the "Emergent Materials"), shall be used solely for the Development Activities as provided in the Development Plan or any Annual Development Plan and in compliance with Applicable Law. sanofi pasteur shall not make any Emergent Materials available to any Third Party without Emergent's prior written consent. Any Emergent Materials are provided subject to Clause 12.2 and all right, title and interest in and to any such Emergent Materials shall be, and remain, vested in Emergent.

#### 8.3 sanofi pasteur Licence Grants

- 8.3.1 **Development.** Subject to the other terms of this Agreement, sanofi pasteur and its Affiliates hereby grant to Emergent and its Affiliates a non-exclusive (with sanofi pasteur), royalty-free, worldwide licence, without the right to grant sub-licences (except as necessary or reasonably useful in connection with any engagement by Emergent of a Third Party to conduct any Emergent Activity as provided for in any Annual Development Plan), under the sanofi pasteur Technology and sanofi pasteur's right and interest in the Joint Technology solely to conduct Emergent Activities.
- 8.3.2 **Repatriated Antigens and Co-Exclusive Antigens.** Subject to the other terms of this Agreement, sanofi pasteur and its Affiliates hereby grant to Emergent and its Affiliates (a) an exclusive, royalty-free, worldwide licence, with the right to grant sub-licences under sanofi pasteur's right and interest in the Joint Technology to

Exploit Repatriated Antigens in and outside the Field; and (b) a co-exclusive (with sanofi pasteur), royalty-free, worldwide licence, with the right to grant a Third Party a sub-licence under sanofi pasteur's right and interest in the Joint Technology to Exploit Co-Exclusive Antigens in and outside the Field. For the purpose of this Agreement, Emergent's co-exclusive right to Exploit the Co-Exclusive Antigens shall mean that Emergent is entitled to Exploit the Co-Exclusive Antigens itself or license or sub-license one Third Party to Exploit the Co-Exclusive Antigens, in or outside the Field.

#### 8.4 No Other Rights

For avoidance of doubt, no Party or any of its Affiliates shall have any right, express or implied, to the Know How, Patent Rights or other intellectual property of the other Party, except as expressly provided in Clauses 8.1, 8.2, 14.1 and 14.3.

### 9. INTELLECTUAL PROPERTY

- 9.1 Ownership of Intellectual Property
- 9.1.1 **Emergent Intellectual Property**. Subject to the licence granted by Emergent to sanofi pasteur in Clause 8.1, as between the Parties, Emergent shall own and retain all right, title and interest in and to the Emergent Technology.
- 9.1.2 **sanofi pasteur Intellectual Property**. Subject to the licence granted by sanofi pasteur to Emergent in Clause 8.3, as between the Parties, sanofi pasteur shall own and retain all right, title and interest in and to the sanofi pasteur Technology.
- 9.1.3 **Joint Intellectual Property**. As between the Parties, each Party shall own an undivided one-half interest in and to the Joint Technology. Except as expressly provided for in this Agreement, neither Party shall use, or permit any Third Party to use, any Joint Technology for any purpose, other than the Development or Commercialisation of a Programme Antigen or Product in accordance with this Agreement, without the prior written consent of the other Party.
- 9.1.4 **Determination of Ownership.** The determination of whether any Technology is made, developed or conceived by or on behalf of a Party in the conduct of the Development Programme, and consequently the ownership of such Technology, shall be determined in good faith by both Parties in accordance with Applicable Law of the United States. All such determinations shall be documented to ensure that any applications for Patent Rights reflect appropriate inventorship and that inventions and Patent Rights are assigned to or held by the appropriate Party. In the event of a disagreement, the Parties agree to jointly select and appoint an independent outside patent counsel (who is not the usual patent counsel of either party), or failing agreement as to the identity of such patent counsel within ten (10) days of either Party notifying the other that it requires such appointment, independent patent counsel appointment, each of the Parties shall furnish to the expert (subject to such obligations of confidentiality and non-use as may be reasonably required by them), with a copy to the other Party, a written summary of such Party's position and any relevant evidence supporting such position including all information necessary for the expert to make such determination. Any such written summary and evidence shall not, unless the

Parties otherwise agree, exceed 15,000 words. Within fifteen (15) days of receipt of the other Party's summary (or such longer period as may be required to ensure the presence of the expert) there shall be a one-day oral hearing before the expert at which each Party shall be given an equal opportunity to present its own position and hear and respond to the oral presentation given by the other Party. Within fifteen (15) days of such oral hearing, each Party may submit a written rebuttal of the other Party's summary providing that any rebuttal shall not exceed 5,000 words. The expert shall determine inventorship and ownership of such Technology in accordance with this Agreement. The decision of such outside patent counsel shall be final and binding on the Parties. In the event the independent outside patent counsel rules in favour of sanofi pasteur's position then Emergent shall pay the fees and expenses of the expert, and in the event that the independent outside patent counsel rules in favour of Emergent's position then sanofi pasteur shall pay the fees and expenses of the expert.

- 9.1.5 **Disclosure.** During the Development Programme, each Party shall promptly disclose, and shall cause its Affiliates and sub-licensees to disclose, to the other Party in writing the characterisation, conception, development, derivation, discovery, generation, identification or making of any Technology in the course of work conducted under or in connection with this Agreement.
- 9.1.6 **Assignment**. Each Party shall, and does hereby, assign, and shall cause its Affiliates, sub-contractors and sub-licensees to so assign, to it or to the other Party, as applicable, without additional compensation, such right, title and interest in and to any Know How, Patent Rights or other intellectual property, as is necessary to fully effect the ownership provisions set out in this Clause 9.1.
- 9.1.7 **Registration and Protection of Trademarks**. sanofi pasteur shall have the sole right, at its sole cost and expense, to obtain, maintain, register, extend, enforce and defend trademark protection for all Product Trademarks.
- 9.2 Filing, Prosecution and Maintenance of Patent Rights
- 9.2.1 **Emergent Patent Rights**. Emergent shall have the first right (but not the obligation) to prepare, file, prosecute and maintain the Emergent Patent Rights. Emergent shall diligently file and prosecute claims relating to Clinical Candidates in the countries specified in Schedule 9. Emergent shall provide sanofi pasteur at least once per Year with an updated list of the patents and patent applications comprising the Emergent Patent Rights. Emergent shall also notify sanofi pasteur of the lapse, revocation, surrender or abandonment of any patent or patent application included among the Emergent Patent Rights.
- 9.2.2 **sanofi pasteur Patent Rights**. sanofi pasteur shall have the first right (but not the obligation) to prepare, file, prosecute and maintain the sanofi pasteur Patent Rights throughout the Territory, in its sole discretion. In the event that sanofi pasteur shall grant Emergent a license to sanofi pasteur Patent Rights pursuant to Clauses 14.3.1 or 14.3.2 then sanofi pasteur shall provide Emergent with a list of all patents and patent applications comprising sanofi pasteur Patent Rights.
- 9.2.3 **Joint Patent Rights**. Decisions regarding the preparation, filing, prosecution and maintenance of the Joint Patent Rights shall be made by the SC. Upon the identification of Joint Technology the SC shall: (i) promptly discuss such Joint

Technology; (ii) promptly discuss the desirability of filing patent application(s) covering such Joint Technology, and the relevant countries for filing which shall in any event include those countries listed in Schedule 9; and (iii) make the final decision with respect to any such filings as soon as practicable. Thereafter, sanofi pasteur, at its expense and through patent attorneys or agents of its choice and reasonably acceptable to Emergent, shall prepare, file, prosecute and maintain the Joint Patent Rights provided that Emergent shall at sanofi pasteur's request and expense make such filings and take such other actions in relation to the prosecution and maintenance of the Joint Patent Rights as the SC considers appropriate from time to time. Such applications shall be filed expeditiously at the appropriate time in all countries listed in Schedule 9 and all other countries in which the SC determines patent protection is necessary or desirable. sanofi pasteur shall not abandon any such application for patent or permit any patent issuing therefrom to lapse in a country listed in Schedule 9 without Emergent's prior written consent.

- 9.2.4 Consultation. Each Party (in this paragraph, the "Controlling Party") shall regularly provide the other Party with copies of all patent applications to be filed by it under Clause 9.2 and other material submissions and correspondence with any patent authorities, as applicable, in sufficient time to allow for review and comment by the other Party. In addition, to the extent practicable, the Controlling Party shall provide the other Party and its counsel with an opportunity to consult with the Controlling Party and its counsel regarding the filing and contents of any application, amendment, registration, submission, response or correspondence with any patent authorities with respect to, and the Controlling Party shall consider in good faith the reasonable requests of the other Party regarding the filing and prosecution of such Patent Rights.
- 9.2.5 **Election not to File, Prosecute or Maintain.** If a Party elects not (i) to pursue in any country in the Territory the filing, prosecution or maintenance of Patent Rights in respect of which it has the first right or obligation to file, prosecute or maintain pursuant to Clauses 9.2.1, 9.2.2, 9.2.3 or 9.2.4, or (ii) to take any other action with respect to such Patent Rights in a country in the Territory that is necessary or useful to establish or preserve rights thereto, then such Party shall so notify the other Party promptly in writing to enable the other Party to meet any deadlines by which an action must be taken to establish or preserve a right in such Patent Rights, as applicable, in such country. The Party receiving such notice shall have the right, but not the obligation, to pursue the filing or registration, or support the continued prosecution or maintenance, of such Patent Rights in such country through patent attorneys or agents of its choice and reasonably acceptable to the other Party. If the Party receiving such notice elects to pursue such filing or registration, as the case may be, or to continue such support, then such Party shall notify the other Party of such election and the other Party shall, and shall cause its Affiliates to, reasonably cooperate with such Party in this regard. If Emergent elects to pursue the filing or registration, or support the continued prosecution or maintenance of Joint Patent Rights in a country other than a Major Market Country and sanofi pasteur subsequently Commercialises a Product in such country, sanofi pasteur shall reimburse Emergent for all out-of-pocket costs and expenses incurred in filing, prosecuting or maintaining such Patent Rights in such country. For clarity, sanofi pasteur shall not be entitled to make an election pursuant to this Clause 9.2.5 with respect to Joint Patent Rights in any Major Market Country.

#### 9.3 Enforcement of Patent Rights

9.3.1 **Notification of Infringement**. If either Party learns of any infringement or threatened infringement by a Third Party of the sanofi pasteur Patent Rights, the Emergent Patent Rights or the Joint Patent Rights, such Party shall promptly notify the other Party and shall provide such other Party with any available evidence of such infringement.

#### 9.3.2 Enforcement

- (a) In the event of any infringement of an Emergent Patent Right, a sanofi pasteur Patent Right or a Joint Patent Right in the Territory, sanofi pasteur shall have the first right, but not the obligation, to attempt to remove such infringement by commercially appropriate steps, including filing an infringement suit or taking other similar action. If required by Applicable Law in order for sanofi pasteur to prosecute such suit, Emergent shall join such suit as a party, and sanofi pasteur shall reimburse Emergent on a Quarterly basis for reasonable out-of-pocket costs and expenses incurred by Emergent with respect to such joinder.
- (b) If sanofi pasteur fails within three (3) months following notice of infringement to take commercially appropriate steps to remove such infringement in accordance with paragraph (a) above, then Emergent shall have the right to attempt to remove such infringement; provided, however, that if sanofi pasteur has commenced negotiations with an alleged infringer for discontinuance of such infringement within such three-month period, sanofi pasteur shall have an additional period of three (3) months to conclude its negotiations before Emergent may bring suit for such infringement.
- (c) The Party not enforcing the applicable Patent Rights shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence and making its employees available at reasonable business hours, subject, if the enforcing Party is sanofi pasteur, to reimbursement to Emergent on a Quarterly basis of any reasonable out-of-pocket costs and expenses incurred by Emergent. Any damages or other monetary awards recovered pursuant to this Clause 9.3.2 shall be allocated first to the costs and expenses of the Parties. Any amounts remaining shall be deemed to be [\*\*].
- 9.3.3 **Settlement with a Third Party**. The Party that controls the prosecution of a claim with respect to any Patent Right shall also have the right to control settlement of such claim; provided, however, that no settlement shall be entered into without the written consent of the other Party if such settlement would materially adversely affect the interests of such other Party. Any amount paid by a Third Party pursuant to this Clause 9.3.3 shall be allocated first to the costs and expenses of the Parties. Any amounts remaining shall be deemed to be [\*\*].

#### 9.4 Infringement of Third Party Rights

9.4.1 **Third Party Infringement Suit.** In the event that a Third Party institutes a Patent Right infringement suit against sanofi pasteur or Emergent during the term of this Agreement, alleging that the Exploitation of a Programme Antigen or Product in

accordance with this Agreement infringes the intellectual property rights of such Third Party, then sanofi pasteur shall have the first right, but not the obligation, at its sole cost and expense, to assume direction and control of the defence of claims arising therefrom (including the right to settle such claims at its sole discretion, provided that sanofi pasteur shall not settle or otherwise compromise any such claims in any way that would materially adversely affect the Emergent Patent Rights). Emergent shall assist and cooperate in connection with the defence of such suit upon the reasonable request of sanofi pasteur, subject to sanofi pasteur's reimbursement on a Quarterly basis of any reasonable out-of-pocket costs and expenses incurred by Emergent.

#### 9.5 Patent Extensions

The SC shall make determinations as to whether to seek patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future regarding the Emergent Patent Rights, the sanofi pasteur Patent Rights or the Joint Patent Rights with respect to any Product in each country in the Territory so as to secure optimal protection for such Product under Applicable Law; provided that no such extensions shall be sought without the consent of both Parties. Emergent shall be responsible for seeking any such extensions for the Emergent Patent Rights and sanofi pasteur shall be responsible for seeking any such extensions for the sanofi pasteur Patent Rights and the Joint Patent Rights. Each Party shall reasonably cooperate, as requested by the other Party, to implement such decisions of the SC.

#### 9.6 Patent Costs

Except as expressly provided for in this Clause 9, sanofi pasteur shall be responsible for all costs incurred after the Effective Date in connection with the filing, prosecution, maintenance (including in connection with oppositions, re-examinations, interferences and re-issues), defence (including in connection with proceedings for declaratory judgment) and enforcement of the Emergent Patent Rights, the Joint Patent Rights and the sanofi pasteur Patent Rights. Within thirty (30) days of the end of each Quarter, Emergent shall provide sanofi pasteur with an invoice that specifies the reasonable and verifiable out-of-pocket costs (including the expenses paid to outside legal counsel and experts, filing and maintenance expenses) incurred by Emergent in connection with (a) the preparation, filing, prosecution and maintenance of Emergent Patent Rights and Joint Patent Rights (including in connection with seeking patent term extensions); (b) any infringement action relating to the Emergent Patent Rights or Joint Patent Rights, or otherwise for sanofi pasteur's account pursuant to this Clause 9, in such Quarter and sanofi pasteur shall pay such amount to Emergent within thirty (30) days of receiving such invoice.

#### 10. CONFIDENTIALITY

## 10.1 Confidentiality Requirements

Each Party (the "Receiving Party") shall treat any and all Confidential Information that it receives from the other Party (the "Disclosing Party") under this Agreement as strictly confidential and shall not disclose the same to any Third Party or use it except in connection with the Development and Commercialisation of a Product in

accordance with this Agreement without the prior written consent of the Disclosing Party, except for any part of the Confidential Information which:

- (a) is known to the Receiving Party prior to the date of first disclosure by the Disclosing Party as evidenced by written record or other proof;
- (b) is or shall become in the public domain through no breach of this Agreement;
- (c) is acquired lawfully by the Receiving Party from a Third Party that has no confidentiality obligation to the Disclosing Party; or
- (d) has been independently discovered or developed (as demonstrated by contemporaneous written or electronic evidence maintained in the ordinary course of business of the Receiving Party) by employees or agents of the Receiving Party without access to, or use of, Confidential Information disclosed by the Disclosing Party to the Receiving Party.

Specific aspects or details of Confidential Information shall not be deemed to be in the public domain or in the possession of a Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of such Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of a Party merely because individual elements of such Confidential Information are in the public domain or in the possession of such Party unless the combination and its principles are in the public domain or in the possession of such Party.

#### 10.2 Confidentiality of Unpatented Joint Technology

Each Party shall treat all unpatented Joint Technology as strictly confidential and shall not disclose the same to any Third Party except to the extent that it is or shall become public knowledge through no fault on its part and neither Party shall use such Joint Technology except in connection with the Development and Commercialisation of a Product in accordance with this Agreement.

#### 10.3 Exceptions

Notwithstanding the terms of Clauses 10.1 and 10.2 each Party may disclose any information and data in respect of which it is restricted pursuant to either Clause:

- (a) to its employees but only on a "need to know" basis provided each such employee enters into a confidentiality agreement at least as restrictive with respect to the Confidential Information as this Clause 10; or
- (b) to Affiliates, permitted sub-licensees and sub-contractors and their respective employees (but only on a "need to know" basis) and Third Party consultants, scientific and clinical investigators and others (in each case, subject to such persons entering into a confidentiality agreement at least as restrictive with respect to the Confidential Information as this Clause 10) where reasonably necessary for carrying out the purposes of this Agreement or, in the case of Affiliates and such Affiliates employees, for the conduct of its, or such Affiliates', business:

- (c) on a "need to know" and confidential basis to its, or its Affiliates', legal and financial advisors to the extent such disclosure is reasonably necessary in connection with such Party's activities as expressly permitted by this Agreement or for the conduct of its, or such Affiliates', business;
- (d) to a prospective assignee pursuant to Clause 19.1 and such Third Party's employees, advisors, representatives, Affiliates, partners, members, shareholders and financing sources in each case on a "need to know" basis and subject to such persons entering into a confidentiality agreement at least as restrictive with respect to the Confidential Information as this Clause 10 (except that the obligations under such confidentiality agreement shall terminate five (5) years after disclosure of the relevant Confidential Information to such assignee or other Third Party);
- (e) to any Regulatory Authority or government agency or authority to the extent such disclosure is useful or reasonably necessary to achieve the purposes of this Agreement or to any taxing or other authority competent to impose, administer or collect taxation to the extent such disclosure is useful or reasonably necessary; and
- (f) as required by Applicable Law, the rules or regulations of a relevant stock exchange or similar governing body (including the U.S. Securities and Exchange Commission) or an order of any government agency, department or court; provided that:
  - (i) to the extent permitted prompt written notice of the disclosure shall be given to the Disclosing Party;
  - (ii) such disclosure shall be only to the extent so required;
  - (iii) if permitted, and to the extent reasonably practicable, written notice of the requirement shall be given to Disclosing Party and the Parties shall discuss the timing and content of such disclosure with a view to preventing or minimising loss of confidentiality for the material; and
  - (iv) insofar as material so required to be disclosed is not made public, the obligation of confidentiality hereunder shall continue to apply to it.

#### 10.4 Survival of Confidentiality Requirements

The obligations of the Parties under Clauses 10.1 to 10.3 shall survive the expiration or termination of this Agreement for whatever reason for a period of five (5) years to the extent the Confidential Information or the unpatented Joint Technology remains confidential; provided that in the event that either Party remains entitled to use the unpatented Joint Technology after the expiration or termination of this Agreement, that Party shall be entitled to disclose the unpatented Joint Technology to a Third Party to the extent that such disclosure is necessary to that Party's effective exercise of such entitlement.

#### 10.5 Injunctive Relief

The Parties understand and agree that remedies in damages may be inadequate to protect against any breach of any of the provisions of this Clause 10 by either Party or their employees, officers and any other person acting in concert with it or on its behalf. Accordingly, each Party shall be entitled to the granting of interim and final injunctive relief by a court of competent jurisdiction in the discretion of that court against any action that constitutes any breach of this Clause 10.

#### 10.6 Use of Name

Neither Party shall mention or otherwise use the name, symbol, trademark, trade name or logotype of the other Party (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Clause shall not prohibit either Party from making any disclosure identifying the other Party that is required by Applicable Law.

#### 10.7 Publications and Presentations

During the term of this Agreement, each Party shall submit to the other Party (the "Non-Publishing Party") for review and approval all proposed academic, scientific and medical publications and public presentations relating to any aspect of the Development Programme or to any Programme Antigen or any Product. Such review and approval shall be conducted for the purposes of preserving intellectual property protection and determining whether any portion of the proposed publication or presentation containing the Confidential Information of the Non-Publishing Party or the unpatented Joint Technology should be modified or deleted. Written copies of such proposed publications and presentations shall be submitted to the Non-Publishing Party no later than sixty (60) days before submission for publication or presentation. The Non-Publishing Party shall provide its comments, if any, and (if it so chooses) its approval within thirty (30) days of its receipt of such written copy. The review period may be extended for an additional sixty (60) days upon request of the Non-Publishing Party in the event the Non-Publishing Party can demonstrate reasonable need for such extension, including the preparation and filing of patent applications. By mutual written agreement of the parties, this period may be further extended. Each Party shall comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of the other Party in any publications and presentations. For the avoidance of doubt, nothing in this Clause 10.7 shall require either Party to allow disclosure of its Confidential Information.

#### 11. REGULATORY MATTERS

#### 11.1 Regulatory Approvals

Except with respect to Regulatory Approvals and Clinical Study Applications required to commence any Phase I Study undertaken by Emergent in accordance with the Development Plan, which approvals shall be obtained by Emergent, sanofi pasteur shall be responsible for the preparation and submission, at its own expense, but generally in consultation with Emergent, of all applications for any Regulatory Approvals required for the Exploitation of the Programme Antigens or any Product in any country in the Territory and Emergent shall, at sanofi pasteur's cost, provide such

assistance as sanofi pasteur may reasonably require in connection with such applications. Within a reasonable time prior to filing, Emergent or sanofi pasteur, as the case may be, shall provide to the SC for its consideration and comment (a) summaries of significant documents or reports relating to any Clinical Candidate or Product to be filed with any Regulatory Authority; and (b) copies or details of all significant communications and interactions with Regulatory Authorities relating to any Clinical Candidate or Product. For the avoidance of doubt, sanofi pasteur will not be required to share with Emergent any sanofi pasteur Confidential Information or Know How relating to sanofi pasteur Antigens or Third Party Antigens.

#### 11.2 Adverse Event Reporting

The Parties shall develop, maintain and implement standard operating procedures for the investigation and reporting of Adverse Events concerning the Programme Antigens and any Product. The Parties shall immediately implement such agreed upon procedures and shall provide each other on a regular basis with any information which has become available to them and which is relevant to the safe use of the Programme Antigens or any Product or which is required by Applicable Law in all countries where any Programme Antigen or Product is marketed or is in a Clinical Study. Emergent shall be responsible for reporting Serious Adverse Events arising in connection with Emergent sponsored studies to the appropriate Regulatory Authorities in accordance with Applicable Law. sanofi pasteur shall be responsible for making all other such reports. Each Party shall forward to the other any information it receives relating to a Serious Adverse Event for a Product or Programme Antigen within twenty-four (24) hours of coming into possession or control of such information, by transmitting it in accordance with such procedures as the Parties may agree in writing from time to time. The Parties shall transmit to each other a copy of any report relating to a Serious Adverse Event for a Product or Programme Antigen made to any Regulatory Authority or ethics committee within two (2) Business Days following its submission to the Regulatory Authority by transmitting it in accordance with such procedures as the Parties may agree in writing from time to time.

#### 12. WARRANTIES

#### 12.1 Mutual Warranties

Each Party hereby warrants to the other Party that:

- (a) it is duly organised, validly existing and in good standing under the laws of the state or country, as applicable, in which it is organised;
- (b) it has the requisite power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder;
- (c) it has taken all requisite action on its part to authorise the execution and delivery of this Agreement and the performance of its obligations hereunder;
- (d) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation enforceable against such Party in accordance with its terms except as enforcement may be limited by (i)

- applicable bankruptcy, insolvency, reorganisation, moratorium, and other laws of general application affecting enforcement of creditors' rights generally and (ii) by laws relating to the availability of specific performance, injunctive relief or other equitable remedies;
- (e) all necessary consents, approvals and authorisations of all governmental authorities and other persons required to be obtained by it in connection with this Agreement have been obtained; and
- (f) the execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of Applicable Law or any orders of governmental bodies; and (ii) do not conflict with, or constitute a default under, any contractual obligation of it.

#### 12.2 Disclaimer

EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND REGARDING TECHNOLOGY AND INFORMATION, MATERIALS, PRODUCTS OR INTELLECTUAL PROPERTY, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, ENFORCEABILITY OR VALIDITY.

#### 12.3 Limitation on Liability

Except in circumstances of gross negligence or wilful misconduct by a Party or any of its Affiliates, directors, officers, employees or agents, neither Party shall be liable to the other with respect to the subject matter of this Agreement for special (including punitive and exemplary), indirect, incidental or consequential damages or lost profits, whether in contract, warranty, negligence, tort, strict liability or otherwise. This Clause 12.3 shall not limit either Party's liability pursuant to Clause 13.

#### 13. INDEMNIFICATION

#### 13.1 Emergent Indemnity

Emergent shall indemnify, protect and hold harmless sanofi pasteur and its Affiliates, directors, officers, employees and agents (the "sanofi pasteur Indemnitees") against any and all losses, damages, fines, costs, expenses (including reasonable attorneys' fees) and liabilities ("Liabilities") incurred or imposed upon the sanofi pasteur Indemnitees, or any of them, in connection with any claims, suits, actions, demands or judgments of Third Parties ("Third Party Claim") arising from or occurring as a result of:

(a) the breach by Emergent of any terms of this Agreement or the negligence of Emergent or any of the Emergent Indemnitees; and

(b) Emergent's activities under the Development Plan or any Annual Development Plan (including the use of any Programme Antigen or Product in any Phase I Study conducted by or for Emergent); except for those Liabilities for Third Party Claims in respect of which sanofi pasteur is responsible pursuant to Clause 9.6, which liabilities shall be borne by sanofi pasteur in accordance with that Clause, or for which sanofi pasteur has an obligation to indemnify Emergent and its Affiliates, directors, officers, employees and agents under Clause 13.2, as to which Liabilities each Party shall indemnify the other to the extent of their respective liability for such Liabilities. For the avoidance of doubt, Emergent shall have no liability to sanofi pasteur for any Third Party Claim alleging that any Emergent Activities infringe the intellectual property rights of any Third Party.

#### 13.2 sanofi pasteur Indemnit

sanofi pasteur shall indemnify, protect and hold harmless Emergent and its Affiliates, directors, officers, employees and agents (the "Emergent Indemnitees") against any and all Liabilities incurred or imposed upon the Emergent Indemnitees, or any of them, in connection with any Third Party Claim arising from or occurring as a result of:

- (a) the breach by sanofi pasteur of any terms of this Agreement or the negligence of sanofi pasteur or any of the sanofi pasteur Indemnitees;
- (b) sanofi pasteur's activities under the Development Plan or any Annual Development Plan (including the use of any Programme Antigen or Product in any Clinical Study other than any Phase I Study conducted by or for Emergent);
- (c) the Exploitation of any Programme Antigen or Product; and
- (d) any allegation that the activities of either Party in accordance with this Agreement infringe the intellectual property rights of a Third Party.

except for those Liabilities for Third Party Claims for which Emergent has an obligation to indemnify sanofi pasteur Indemnitees under Clause 13.1, as to which Liabilities each Party shall indemnify the other to the extent of their respective liability for such Liabilities.

#### 13.3 Indemnification Procedure

In the event that either Party receives notice of a Third Party Claim such Party shall inform the other Party as soon as reasonably practicable. Subject to Clause 9, the Parties shall confer on how to respond to the Third Party Claim and how to handle the Third Party Claim in an efficient manner. In the event that a Party is seeking indemnification under this Clause 13 it shall permit the indemnifying Party (at the indemnifying Party's option) to assume direction and control of the defence of the Third Party Claim (including the right to settle the claim solely for monetary consideration), shall co-operate as requested (at the expense of the indemnifying Party) in the defence of the Third Party Claim, and shall not settle or compromise the Third Party Claim without the express written consent of the indemnifying Party, such

consent not to be unreasonably withheld, conditioned or delayed.

#### 14. TERM AND TERMINATION

#### 14.1 Expiry by country

Unless terminated earlier pursuant to Clause 14.2, this Agreement shall expire on a country-by-country basis on the expiration of the obligation of sanofi pasteur to make royalty payments under Clause 7.3 with respect to that particular country and thereafter sanofi pasteur shall have, with respect to that country, a fully paid-up, non-exclusive, royalty free, perpetual licence under the Emergent Technology and Emergent's right and interest to the Joint Technology to Exploit Products in the Field.

#### 14.2 Termination

14.2.1 **Termination by either Party**. Either Party will be entitled to terminate this Agreement with immediate effect by notice in writing if the other Party files for protection under bankruptcy or insolvency laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver, administrator, manager, trustee or like official over its property that is not discharged within ninety (90) days, proposes a written agreement of composition or extension of its debts, proposes or is a party to any dissolution, winding-up or liquidation, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which involuntary petition is not discharged within sixty (60) days of the filing thereof or undergoes or suffers any analogous event or process in any jurisdiction.

#### 14.2.2 **Termination by sanofi pasteur**. sanofi pasteur may terminate this Agreement:

- (a) for any reason or no reason, upon not less than six (6) months' prior written notice to Emergent, provided that such notice may not be served prior to the first anniversary of the Effective Date; and
- (b) with immediate effect on a Change of Control of Emergent upon written notice to Emergent provided that such notice is served within thirty (30) days of the earlier of the date on which Emergent notifies sanofi pasteur of such Change of Control or the date on which sanofi pasteur becomes aware of such Change of Control.

#### 14.2.3 **Termination by Emergent**. Emergent shall be entitled to terminate this Agreement:

- (a) with immediate effect if sanofi pasteur challenges the validity or enforceability of any Emergent Patent Rights or Joint Patent Rights;
- (b) if sanofi pasteur is in material breach of its obligation to use Commercially Reasonable Efforts pursuant to Clause 5.12 and does not remedy such breach within ninety (90) days of its receipt of written notice from Emergent requiring such breach to be remedied and without prejudice to the generality of the foregoing, sanofi pasteur shall be deemed to be in breach of such obligation if:
  - (i) there has been a material failure by sanofi pasteur to execute, resource or deliver the Development Plan;

- (ii) at any time prior to the grant of a Marketing Authorisation for a Product in a Major Market Country, sanofi pasteur does not have at least one Programme Antigen in active clinical Development provided that at least one Programme Antigen has met the Selection Criteria;
- (iii) sanofi pasteur fails to select and progress into clinical Development a Programme Antigen that has met the Selection Criteria unless there is already a Programme Antigen in a Phase I Study or a later stage of active clinical Development or a Product is being marketed in a Major Market Country;
- (iv) there is a material failure by sanofi pasteur to maintain, augment, exploit or defend the Emergent Technology or the Joint Technology in a commercially reasonable manner.
- (v) sanofi pasteur fails to conduct any substantial Development activities during any twelve (12) month period;
- (vi) there is a material failure by sanofi pasteur, other than for technical reasons, to use Commercially Reasonable Efforts to Develop the Product for all target vaccine populations agreed in the target product profile (e.g., new-borns, children to age two (2) and Adolescents);
- (vii) sanofi pasteur or one of its Affiliates or any Sub-Licensee undertakes a Phase II study with a Competitive Product and sanofi pasteur is not actively continuing to Develop or Commercialise a Product;
- (viii) sanofi pasteur or one of its Affiliates or any Sub-Licensee commences a Phase III Study with a Competitive Product, before sanofi pasteur commences a Phase III Study with a Product and sanofi pasteur is not actively continuing to Develop or Commercialise a Product;
- (ix) there is a material failure by sanofi pasteur to provide Emergent with adequate and sufficiently detailed information to enable Emergent to assess whether sanofi pasteur is in breach of its diligence obligations pursuant to Clause 5.12, particularly after the Transition Date; or
- (x) there is a registering/filing by sanofi pasteur or any Affiliate of sanofi pasteur or any Sub-Licensee for a Marketing Authorisation for a Competitive Product, if sanofi pasteur is not actively Developing or Commercialising a Product.
- (c) if sanofi pasteur is in material breach of its obligation to use Commercially Reasonable Efforts pursuant to Clause 6.2 and does not remedy such breach within ninety (90) days of its receipt of written notice from Emergent requiring such breach to be remedied and without prejudice to the generality of the foregoing, sanofi pasteur shall be deemed to be in breach of such obligation if:

- (i) there is a material failure by sanofi pasteur to apply Commercially Reasonable Efforts to execute, resource and deliver the agreed Commercialisation Plan;
- (ii) there is a material failure by sanofi pasteur to apply Commercially Reasonable Efforts as assessed by time, resource and performance criteria that would be applied by a commercial organisation to launch, commercialise, exploit and maximise the value of a paediatric vaccine product in a competitive global marketplace;
- (iii) sanofi pasteur (or one of its Affiliates or a Sub-Licensee) launches, Commercialises or Exploits a Competitive Product, and sanofi pasteur is not actively Developing or Commercialising a Product;
- (iv) there is a material failure by sanofi pasteur to provide Emergent with adequate and sufficiently detailed information to be able to assess whether sanofi pasteur is in breach of its diligence obligations pursuant to Clause 6.2; or
- (v) there is a material failure by sanofi pasteur to provide sufficient information or access to an independent representative to enable assessment of royalties payable by sanofi pasteur to Third Parties as required pursuant to Clause 7.4.4, particularly in relation to the calculation of the Royalty Burden.

For the avoidance of doubt, the Parties acknowledge that whether or not it is commercially reasonable to launch a Unitary Product before a Combination Product in any market will depend on market conditions at the relevant time and that consequently a failure by sanofi pasteur to launch a Unitary Product prior to a Combination Product in any country is not in itself sufficient to demonstrate that sanofi pasteur has failed to use Commercially Reasonable Efforts in accordance with Clause 6.2.

- (d) if sanofi pasteur commits a material breach of its obligations under this Agreement (including any failure to pay when due an amount or amounts in aggregate exceeding Euros [\*\*]) which (if capable of remedy) is not remedied within ninety (90) days of written notice requiring it to be remedied being received by sanofi pasteur. If there is a dispute relating to any payment to be made by sanofi pasteur, sanofi Pasteur shall pay the undisputed portion of such amount and the dispute relating to the disputed portion shall be resolved by the Senior Officers in accordance with Clause 25.2 or, failing that, in accordance with Clause 25.3. To the extent applicable, the decision of the Senior Officers or courts shall be applied to the future calculation of amounts properly due from sanofi pasteur in connection with this Agreement.
- (e) with immediate effect upon written notice by Emergent, if (i) all Programme Antigens have been tested in preclinical Development and none have met the Selection Criteria, or (ii) all Programme Antigens that have met the Selection Criteria have been tested in a Phase I Study, and none of the Programme Antigens that have met the Selection Criteria have been found to meet the

Primary Inclusion Criteria, and in either case there has been no active Clinical Study involving a Programme Antigen for a period of twelve (12) months.

#### 14.3 Consequences of Termination

- 14.3.1 Termination by Emergent other than pursuant to Clause 14.2.3(e). In the event that this Agreement is terminated by Emergent pursuant to Clause 14.2.1 or Clause 14.2.3(a) to (d) then:
  - (a) sanofi pasteur shall reimburse Emergent for all FTE Costs (including in respect of FTEs that would have been devoted to or supported Emergent Activities in the absence of such termination) and Emergent Expenses in each case incurred or suffered in, or relating to, the period ending on the later of (i) six (6) months from the date of the notice of termination; (ii) eighteen (18) months from the Effective Date and (iii) the date of termination, together with any non-cancellable Emergent Expenses committed to prior to the date of notice of termination whenever incurred;
  - (b) Emergent shall have a non-exclusive, fully paid-up, royalty free licence under the sanofi pasteur Programme Technology in the Field and, without prejudice to Emergent's rights pursuant to Clause 14.3.7, sanofi pasteur's interest in the Joint Technology, to Exploit any Programme Antigens, Terminated Antigens, Repatriated Antigens or Product anywhere in the world with the right to grant sub-licences; provided that with respect to any Technology Controlled by sanofi pasteur pursuant to a sanofi pasteur In-Licence, the sub-licence granted by sanofi pasteur under such sanofi pasteur In-Licence shall be limited to such rights (if any) as sanofi pasteur is permitted to grant Emergent pursuant to the relevant sanofi pasteur In-Licence and provided further that Emergent shall be responsible for any payments under any such sanofi pasteur In-Licence attributable to the Exploitation of any Products by Emergent after the date of such termination.
  - (c) sanofi pasteur and Emergent shall, if requested by Emergent, discuss in good faith the terms, which terms shall be commercially reasonable, for the grant by sanofi pasteur to Emergent of a non-exclusive licence under the sanofi pasteur Independent Technology in the Field to Exploit Programme Antigens, Terminated Antigens, Repatriated Antigens and Products anywhere in the world; provided that in relation to any Technology Controlled by sanofi pasteur pursuant to a sanofi pasteur In-Licence, the Parties acknowledge that any sub-licence granted by sanofi pasteur under such sanofi pasteur In-Licence would be limited to such rights (if any) as sanofi is permitted to grant Emergent pursuant to the relevant sanofi pasteur In-Licence; and provided further that if requested by Emergent, sanofi pasteur shall use reasonable efforts to facilitate discussions between Emergent and any Third Party and shall not unreasonably restrict or impede the grant by any Third Party of rights to any Technology Controlled by such Third Party and necessary or reasonably useful for the Exploitation of Programme Antigens, Terminated Antigens, Repatriated Antigens or Products in the Field;

- (d) sanofi pasteur shall cease to use the Emergent Technology for any purpose and shall cease to Exploit any Programme Antigen or Product anywhere in the world;
- (e) unless otherwise agreed pursuant to paragraph (c) above, Emergent shall cease to use the sanofi pasteur Independent Technology for any purpose;
- (f) sanofi pasteur shall at Emergent's request transfer to Emergent:
  - (i) all of its right, title and interest in all Regulatory Documentation and Regulatory Approvals then in its name applicable to any Programme Antigens or Product, and all material aspects of Confidential Information and correspondence Controlled by it as of the date of termination relating to such Regulatory Documentation and Regulatory Approvals; and
  - (ii) all relevant Know How, information, files or data relating to any Programme Antigens or Product, including copies of all reports and data generated or obtained by sanofi pasteur or its Affiliates pursuant to this Agreement that have not previously been provided to Emergent;
- (g) sanofi pasteur shall, at its cost, take such actions as Emergent may reasonably require (including notifications to Regulatory Authorities) to ensure a smooth, orderly and cost-effective transfer of the conduct of Development and Commercialisation (to the extent then conducted by sanofi pasteur) of any Programme Antigens and Product (in the form of such Product as at the date of such termination) from sanofi pasteur to Emergent including in connection with:
  - (i) securing supplies of such Product, including, if appropriate, the assignment of relevant agreements for the manufacture of such Product to Emergent (unless if and to the extent any such agreement precludes sanofi pasteur, having taken, at Emergent's request and expense, such action as Emergent may reasonably require, from making such assignment), the transfer by sanofi pasteur to Emergent or its designee, at Emergent's request, of all stocks of Product or constituent materials available to sanofi pasteur at the time of termination at a transfer price equal to sanofi pasteur's cost of goods for the supply of such Product or constituent plus [\*\*] percent ([\*\*]%) and the transfer to Emergent of all information in its possession with respect to the manufacture of such Product or any constituent; and
  - (ii) the transfer to Emergent of control of all Clinical Studies of Clinical Candidates being conducted as of the effective date of termination.

For the avoidance of doubt, nothing in this Clause 14.3.1 is intended nor shall it operate to (i) grant any rights to Emergent under the sanofi pasteur Independent Technology; (ii) grant any rights to sanofi pasteur under the Emergent Technology; (iii) restrict sanofi pasteur's rights with respect to the sanofi pasteur Technology or the Joint Technology; or (iv) restrict Emergent's rights with respect to the Emergent Technology or the Joint Technology.

- 14.3.2 **Termination at Will by sanofi pasteur**. In the event that this Agreement is terminated by sanofi pasteur pursuant to Clause 14.2.2(a) then:
  - (a) Clause 14.3.1 other than sub-clause 14.3.1(b) shall apply;
  - (b) without prejudice to Emergent's rights pursuant to Clause 14.3.7, Emergent shall have a non-exclusive, fully paid-up, royalty free licence under sanofi pasteur's interest in the Joint Technology to Exploit any Programme Antigens, Terminated Antigens, Repatriated Antigens or Product anywhere in the world with the right to grant sub-licences for the Exploitation of such Programme Antigens, Terminated Antigens and Repatriated Antigens;
  - (c) sanofi pasteur and Emergent shall, if requested by Emergent, discuss in good faith the terms, which terms shall be commercially reasonable, for the grant by sanofi pasteur to Emergent of a non-exclusive licence under the sanofi pasteur Programme Technology in the Field to Exploit Programme Antigens, Terminated Antigens, Repatriated Antigens and Products anywhere in the world; provided that in relation to any Technology Controlled by sanofi pasteur pursuant to a sanofi pasteur In-Licence, the Parties acknowledge that any sub-licence granted by sanofi pasteur under such sanofi pasteur In-Licence would be limited to such rights (if any) as sanofi is permitted to grant Emergent pursuant to the relevant sanofi pasteur In-Licence; and
  - (d) sanofi pasteur and Emergent shall, if requested by sanofi pasteur, discuss in good faith the terms, which terms shall be commercially reasonable, for the grant by Emergent to sanofi pasteur of a non-exclusive licence under the Emergent Programme Technology in the Field.
- 14.3.3 **Termination by Emergent pursuant to Clause 14.2.3(e)**. In the event that this Agreement is terminated by Emergent pursuant to Clause 14.2.3(e) then:
  - (a) Clause 14.3.1 other than sub-clauses 14.3.1(a), (b) and (c) shall apply; and
  - (b) without prejudice to Emergent's rights pursuant to Clause 14.3.7, Emergent shall have a non-exclusive, fully paid-up, royalty free licence under sanofi pasteur's interest in the Joint Technology to Exploit any Programme Antigens, Terminated Antigens, Repatriated Antigens or Product anywhere in the world with the right to grant sub-licences for the Exploitation of such Programme Antigens, Terminated Antigens and Repatriated Antigens.
- 14.3.4 **Termination of Collaboration for a Change of Control of Emergent or Emergent's Insolvency.** In the event that sanofi pasteur terminates this Agreement pursuant to Clause 14.2.1 (an insolvency event) or Clause 14.2.2(b) (a Change of Control) such termination shall be treated as a termination at will pursuant to Clause 14.2.2(a), and Clause 14.3.2 shall apply. If sanofi pasteur elects not to terminate this Agreement in such circumstances it may, by serving notice on Emergent within thirty (30) days of the date on which sanofi pasteur's right to terminate this Agreement arose under Clause 14.2.1 or within the period specified in Clause 14.2.2(b) (as the case may be), elect to continue to Exploit Programme Antigens and Products on the terms of this Agreement subject to the following modifications:

- (a) the JPT and the SC shall be disbanded and cease to have any responsibilities and, subject to Clause 3.5.2, which shall continue to apply to any decisions made by sanofi pasteur, sanofi pasteur shall be entitled to make all strategic decisions relating to the Development of Programme Antigens and Products, provided that in reaching any such decision sanofi pasteur shall act in good faith and in the best interests of the Development and Commercialisation of the Product;
- (b) Emergent shall cease to have any obligations under the Development Plan or Annual Development Plan; provided that if the Change of Control or insolvency occurs prior to the Transition Date, sanofi pasteur shall continue to reimburse Emergent for all FTE Costs and Emergent Expenses, in each case incurred or suffered in, or relating to, the period ending six (6) months from the date of such notice together with any non-cancellable Emergent Expenses committed to prior to such date, provided that during such period Emergent shall follow sanofi pasteur's reasonable instructions for the smooth, orderly and cost-effective transfer of Emergent Activities to sanofi pasteur;
- (c) sanofi pasteur shall prepare each Development Plan, Annual Development Plan and Commercialisation Plan and submit each such plan to Emergent. If and to the extent sanofi pasteur is not prepared to disclose information contained in any such plan to Emergent such information shall be disclosed to an independent expert appointed pursuant to paragraph (e) below;
- (d) sanofi pasteur shall prepare reports of its Development Activities in accordance with Clause 5.10 and submit the same to Emergent. If and to the extent the Parties are unable to agree the form of the report or sanofi pasteur is not prepared to disclose information contained in the report to Emergent such information shall be disclosed to an independent expert appointed pursuant to paragraph (e) below;
- (e) in the event that sanofi pasteur refuses to disclose any plans or reports to Emergent pursuant to paragraphs (c) or (d) above, or at Emergent's request at any other time but not more frequently than once in any Year, the Parties shall upon Emergent's request appoint an independent expert with suitable experience reasonably acceptable to both Parties to review and verify the activities being conducted by sanofi pasteur in connection with the Development and Commercialisation of any Programme Antigen or Product. If the Parties are unable to agree on the identity of the independent expert within ten (10) days of Emergent notifying sanofi pasteur that it desires the appointment of such expert, the independent expert shall be appointed by Emergent and approved by sanofi pasteur, which approval shall not be unreasonably withheld, conditioned or delayed. Upon such appointment, sanofi pasteur shall promptly furnish to the expert (subject to such obligations of confidentiality and non-use as may be reasonably required by sanofi pasteur) all information necessary for the expert to determine whether sanofi pasteur is using Commercially Reasonable Efforts to Develop and Commercialise Products in accordance with this Agreement but for the avoidance of doubt such determination shall not be binding on Emergent. The expert shall be required by the Parties to use all reasonable efforts to render his

- decision within thirty (30) days following his receipt of all such information. The Parties shall share equally the fees and expenses of such expert;
- (f) for the purposes of Clause 5.15, sanofi pasteur shall assume the responsibilities of the SC and shall consider whether Programme Antigens should be designated Terminated Antigens;
- (g) all other provisions of this Agreement shall continue in full force and effect without modification.

For the avoidance of doubt, if sanofi pasteur does not elect either to terminate this Agreement or terminate the collaborative aspects of this Agreement by serving notice on Emergent in accordance with Clause 14.2.1, Clause 14.2.2(b) or this Clause 14.3.4 (as the case may be) within thirty (30) days of the date on which sanofi pasteur's right to terminate this Agreement arose under Clause 14.2.1 or within the period specified in Clause 14.2.2(b) (as the case may be), this Agreement shall continue in full force and effect without any modification.

- 14.3.5 **Termination of Emergent Activities.** If Emergent commits a material breach of its obligations under this Agreement with respect to the performance by Emergent of the Emergent Activities which (if capable of remedy) is not remedied within ninety (90) days of written notice requiring it to be remedied being received by Emergent, sanofi pasteur may on written notice terminate all Emergent Activities and on such termination Emergent shall cease to have any right or obligation to undertake activities under the Development Plan or Annual Development Plan and the Joint Project Team shall be disbanded.
- 14.3.6 **Termination of Collaboration for Emergent's Breach**. In the event that Emergent commits a material breach of its obligations under (i) Clauses 2.4 or 9.2.5; (ii) Clause 10 and the prohibited disclosure constitutes a statutory bar to obtaining patent protection in a Major Market Country that would otherwise have been available for an invention within the Emergent Technology or Joint Technology; (iii) Clause 10 and the prohibited disclosure results in the loss of trade secret status for any trade secret previously identified as such by sanofi pasteur in writing to Emergent provided that Emergent has agreed that the information so identified is a trade secret (provided further that such agreement shall not be unreasonably withheld, conditioned or delayed), and the prohibited disclosure is a direct result of Emergent's gross negligence or wilful misconduct and such prohibited disclosure has a material and irreparable adverse effect on the value or commercial potential of the Emergent Technology or Joint Technology (taken as a whole) in at least one Major Market Country; or (iv) this Agreement with respect to the performance of the Emergent Activities and such material breach is a direct result of Emergent's gross negligence or wilful misconduct and has a material and irreparable adverse effect on the value or commercial potential of the Emergent Technology or Joint Technology (taken as a whole) in at least one Major Market Country, in each case where such material breach (if capable of remedy) is not remedied within ninety (90) days of written notice requiring it to be remedied being received by Emergent, sanofi pasteur may serve further notice on Emergent terminating the collaborative aspects of this Agreement and on receipt of such notice by Emergent Clause 14.3.4 (a) and (c) to (g) shall apply except that:

- (a) sanofi pasteur shall cease to have any obligation to pay any milestone payment pursuant to Clause 7.2.1 if the relevant milestone event occurred after receipt of such notice;
- (b) sanofi pasteur shall not have any obligation to reimburse Emergent for any FTE costs or Emergent Expenses relating to the period after such notice unless if and to the extent that sanofi pasteur requires Emergent to provide assistance with the transfer of any Emergent Activities to sanofi pasteur; and
- (c) Emergent shall cease to have any obligations under the Development Plan or Annual Development Plan.
- 14.3.7 **Joint Technology**. In relation to the Joint Technology after termination:
  - (a) Ownership and Rights. As between the Parties, each Party shall own an undivided one-half interest in and to the Joint Technology with full ownership rights in and to any field and each Party shall have the right, subject to the rights and licences granted under, and the other provisions of, this Agreement, to freely Exploit, transfer, license or encumber its rights in any such jointly owned subject matter without the consent of, or payment or accounting to, the other Party, and each Party waives any right it may have under Applicable Law to require such payment, accounting or consent.
  - (b) Filing, Prosecution and Maintenance. The Parties shall agree which Party (in this Clause 14.3.7, the "Controlling Party") shall be responsible, using counsel reasonably acceptable to both Parties, for the preparation, filing, prosecution and maintenance of the Joint Patent Rights as agreed by the Parties. All out-of-pocket costs incurred by the Parties in connection with the preparation, filing, prosecution and maintenance of Joint Patent Rights shall be shared equally between the Parties. To the extent practicable, the Controlling Party shall provide the other Party and its counsel with an opportunity to consult with the Controlling Party and its counsel regarding the filing and contents of any application, amendment, registration, submission, response or correspondence with any patent authorities with respect to, and the Controlling Party shall consider in good faith the reasonable requests of the other Party regarding the filing and prosecution of such Patent Rights and shall not, without the prior written consent of the other Party (which approval shall not be unreasonably withheld, conditioned or delayed), cease the prosecution or maintenance of, or modify the claims of, or elect not to file a patent application in respect of any Joint Patent Rights.
  - (c) Election not to File, Prosecute or Maintain. If one Party does not wish to bear the expenses in connection with the preparation, filing, prosecution or maintenance of any Joint Patent Rights in any country it shall notify the other Party who shall have the right to prepare, file, prosecute and maintain such Joint Patent Rights at its own expense, through counsel of its choosing, without the consent of such first Party, whereupon the first Party shall, and shall cause its Affiliates to, (i) reasonably cooperate with the other Party in this regard, and (ii) promptly release or assign to the other Party, without consideration, all right, title and interest in and to such Joint Patent Rights in such country. If the other Party fails to notify the first Party within ninety (90) days

that it wishes to assume such responsibility at its own cost, and the first Party is the Controlling Party, the Controlling Party shall be free to allow such Joint Patent Rights to lapse.

- 14.3.8 Confidential Information and Materials. On expiration or termination of this Agreement for any reason, (i) each Party shall promptly return all Confidential Information of the other Party that is not subject to a licence grant hereunder that survives such expiration or termination; provided that each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations under this Agreement and (ii) sanofi pasteur shall either return or, at Emergent's request, destroy all Emergent Materials provided that sanofi pasteur may retain Materials that are subject to a continuing licence grant hereunder.
- 14.3.9 Other Consequences. The expiration or termination of this Agreement for any reason shall be without prejudice to:
  - (a) the obligation of either Party to pay to the other Party any amount due to the other Party with respect to the period prior to the effective date of such expiration or termination, by way of royalty or otherwise, under this Agreement;
  - (b) any right of, or remedy available to, either Party against the other Party in respect of anything done or omitted under this Agreement prior to such expiration or termination; and
  - (c) those rights, and shall not release either Party from those of its obligations, which expressly survive termination in accordance with this Agreement and Clauses 8.3.2, 9.1.4, 9.1.6, 10, 11.2, 12.3, 13, 14.3, 16, 17, 18, 21, 22, 23, 25, and 28 and all payment, reporting and audit terms to the extent applicable to activities occurring before or surviving termination and any other provisions which are expressed to survive expiration or termination or which are required to give effect to such expiration or termination shall continue in full force and effect.

#### 14.4 No Further Grant

Except as specified in Clauses 14.1 and 14.3 neither Party shall be under any obligation to grant the other Party any licence under any Emergent Technology or sanofi pasteur Technology with respect to the period after the expiration or termination of this Agreement.

#### 15. FORCE MAJEURE

#### 15.1 Force Majeure

A Party shall not be liable for a failure to perform any of its obligations under this Agreement during the period and to the extent that that Party is prevented or hindered from complying with them by any cause beyond its reasonable control including (insofar as beyond such control but without prejudice to the generality of the foregoing expression) strikes, lock-outs, labour disputes, act of God, war, riot, civil

commotion, terrorism, epidemic disease, malicious damage, compliance with any law or governmental order, rule, regulation or direction, accident, breakdown of plant or machinery, fire, flood, storm, earthquake (each an "event of Force Majeure"). The affected Party shall give notice to the other Party of the event of Force Majeure and its effect on its ability to perform its obligations. If the notice is not given by the affected Party within a reasonable period after that Party knew or ought to have known of the event of Force Majeure, it shall remain liable to the other Party for the consequences of its failure to perform.

#### 15.2 Obligation to Consult

The exemption provided by Clause 15.2 shall be granted to the relevant Party for as long as the event of Force Majeure persists; provided that if it shall persist for a continuous period of more than six (6) months the Party not affected by the event of Force Majeure may terminate this agreement on thirty (30) days notice.

#### 16. PUBLICITY

#### 16.1 Press Announcement.

The Parties shall release the press announcement set out in Schedule 6 on the date of this Agreement or on such later date as may be agreed by the Parties.

#### 16.2 No Publicity Without Consent

Subject to Clauses 16.1 and 16.3 neither Party shall make any public announcement or statement or issue any press release or other publicity materials or make any other disclosure with respect to the existence of this Agreement, its terms, conditions or subject matter, or the status or content or conduct of the Development Programme without the prior written consent of the other Party except if and to the extent (i) required by Applicable Law, the rules or regulations of a relevant stock exchange or similar governing body (including the U.S. Securities and Exchange Commission) or an order of any government agency, department or court, provided that in each such case the disclosing Party shall to the extent permitted promptly notify the other of such disclosure; or (ii) the proposed public announcement does not contain information beyond that included in an earlier press release issued in accordance with this Clause 16.

#### 16.3 Permitted Disclosure

Either Party may disclose the terms or conditions of this Agreement and, subject to Clause 10, information relating to the status, content or conduct of the Development Programme:

- (a) on a "need to know" basis to its, and its Affiliates, legal and financial advisors to the extent such disclosure is reasonably necessary in connection with such Party's activities as expressly permitted by this Agreement or for the conduct of its business;
- (b) to a Third Party in connection with:

- (i) an equity investment or other form of financing in such Party, or one of its Affiliates, by such Third Party;
- (ii) a merger, consolidation or similar transaction entered into by such Party, or one of its Affiliates; or
- (iii) the sale of all or substantially all of the assets of such Party, or one of its Affiliates;
- (c) as may be required in connection with an offer of shares or other securities by that Party or one of its Affiliates to the public;
- (d) on a "need to know" basis, to a prospective assignee pursuant to Clause 19.1 and such Third Party's employees, advisors, representatives, Affiliates, partners, members, shareholders and financing sources; or
- (e) to any government agency or authority, at its request or as may be required by Applicable Law, regulation, rule or order.

#### 17. NOTICES

#### 17.1 Notices

Any notice in connection with this Agreement (a "Notice") will be in writing, in the English language, signed by or on behalf of the Party giving it and will be delivered by hand (including by internationally recognised courier), or prepaid airmail, facsimile transmission, but not e-mail, either to the recipient at the address or facsimile number set out for that Party in Clause 17.3 or such other address or facsimile number within the same country as set out below for that Party as the recipient has previously notified to the sender in accordance with this clause.

#### 17.2 Deemed service of Notices

A Notice shall be deemed to have been duly served:

- (a) if delivered by hand, at the time of delivery;
- (b) if sent by prepaid airmail at 10.00 a.m. (local time at the place of destination) on the fifth Business Day after the date on which it was mailed; and
- (c) if sent by facsimile, at the time of transmission; provided that a confirming copy is sent by first class post or prepaid airmail if the sender and recipient are in different countries within twenty-four (24) hours after transmission and that no notification informing the sender that the facsimile has not been delivered has been received by the sender;

provided that if the Notice is delivered by hand or transmitted by facsimile and such delivery or transmission occurs after 4.00 pm on a Business Day or on a day other than a Business Day, service will be deemed to occur at 9.00 am on the next following Business Day (such times and dates being local time at the address of the recipient).

#### 17.3 Addresses for Notices

The addresses and facsimile numbers for the parties are as follows:

#### If to Emergent:

Emergent Europe Limited 545 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire, RG41 5TU England

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Fax no. 44 (0) 118 9443301

Attention: President, Emergent Europe Limited

With copy to:

Emergent Biosolutions, Inc 300 Professional Drive Gaithersburg, MD 20879

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Fax no: 1 301 944 0173 Attention: General Counsel

If to sanofi pasteur:

Sanofi Pasteur S.A. 2, avenue pont pasteur Lyon 69007 France

Fax no. 33 4 3737 7061 Attention: General Counsel

With copy to: Vice President, Corporate Development

Sanofi Pasteur SA 1541 avenue Marcel Mérieux Marcy l'Etoile, 69280 France

## 17.4 Notices Served In Court Proceedings

For the avoidance of doubt, where proceedings have been commenced in any court of competent jurisdiction, any documents issued in the course of those proceedings will be served in accordance with the procedural rules governing the service of documents in those proceedings.

#### 17.5 Other Communications

For the avoidance of doubt, this Clause 17 shall not apply to routine communications between members of the SC, JPT or the Project Leaders. Any such communications shall be in English and may be via e-mail. The SC shall establish, and the Parties shall comply, and shall each cause its respective employees, representatives and agents to comply, with, such procedures as the SC considers appropriate to ensure the security and confidentiality of any such communications.

#### 18. RELATIONSHIP OF PARTIES

#### 8.1 No Partnership nor Agency

Nothing in this Agreement shall be deemed to constitute the relationship of partners nor of principal and agent between the Parties.

#### 18.2 No Responsibility for Other Party

Neither Party nor its Affiliates shall be responsible for the acts or defaults of the other Party or its Affiliates or the employees or representatives of the other Party or its Affiliates.

#### 19. ASSIGNMENT AND DELEGATION

#### 19.1 Permitted Assignments

19.1.1 Assignment by either Party. Either Party may on written notice to the other Party but without that other Party's consent, assign any or all of its rights and delegate any or all of its obligations under this Agreement to any of its Affiliates or to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of the business to which this Agreement relates.

#### 19.1.2 Assignments by Emergent. Emergent may:

- (a) on written notice to sanofi pasteur but without sanofi pasteur's consent, assign to any Third Party any or all of Emergent's rights under Clause 7.2 and Clause 7.3, and in connection with such an assignment, any or all of its rights under Clause 7.4, Clause 7.6 through 7.9 and/or Clause 7.11; and
- (b) assign, and grant a security interest in, without the consent of sanofi pasteur, any or all of its rights under this Agreement to any Third Party providing financing to Emergent, and its successors and assigns, or any agent or trustee acting on its behalf, sanofi pasteur hereby acknowledges that any such assignment and granting of a security interest are made only for the purpose of securing Emergent's obligations to such Third Party under the applicable financing documents, and shall not subject such Third Party, and its respective successors and assigns, or any agent or trustee acting on its behalf, to, or transfer or in any way affect or modify, any obligation or liability that Emergent may have to sanofi pasteur hereunder. Further, notwithstanding Clause 20, any such Third Party shall be considered a third-party beneficiary of this Agreement with a right of enforcement as if it were a Party hereto

#### 19.2 Other Assignments

Subject to the foregoing provisions of Clause 19.1 neither Party shall assign, sub-contract, sub-license, charge or part with or otherwise dispose of this Agreement or the benefit thereof or any right or obligation hereunder to a Third Party without the express prior written consent of the other Party such consent not to be unreasonably withheld, conditioned, or delayed.

#### 19.3 Performance by Affiliates

Each Party may perform any and all of its obligations and exercise any and all of its rights under this Agreement through any Affiliate; provided that such Party shall remain responsible to the other Party for the compliance by any such Affiliate of its performance of this Agreement.

#### 20. THIRD PARTY RIGHTS

This Agreement does not create any right enforceable by any person who is not a Party except that a person who is the permitted successor to or assignee of the rights of a Party shall, subject to and upon any succession or assignment permitted by this Agreement, be deemed to be a party to this Agreement and the rights of such successor or assignee shall be regulated by the terms of this Agreement.

#### 21. WAIVER

The failure on the part of either Party to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right or operate to bar the enforcement thereof at any time or times thereafter.

#### 22. SEVERABILITY

#### 22.1 Severability

If the whole or any part of this Agreement is or becomes or is declared illegal, invalid or unenforceable in any jurisdiction for any reason (including both by reason of the provisions of any legislation and also by reason of any decision of any court or Regulatory Authority which either has jurisdiction over this Agreement or has jurisdiction over any of the Parties):

- (a) in the case of the illegality, invalidity or unenforceability of the whole of this Agreement, it shall terminate in relation to the jurisdiction in question; or
- (b) in the case of the illegality, invalidity or unenforceability of part of this Agreement, that part shall be severed from this Agreement in the jurisdiction in question and that illegality, invalidity or unenforceability shall not in any way whatsoever prejudice or affect the remaining parts of this Agreement which shall continue in full force and effect.

#### 22.2 Good Faith Negotiation

If any such circumstances arise and the commercial relationship between the Parties contemplated hereby is as a result significantly altered the Parties shall negotiate in good faith an appropriate amendment to this Agreement.

#### 23. ENTIRE AGREEMENT

#### 23.1 Entire Agreement

This Agreement (including the Schedules) constitute the entire agreement between the parties relating to their subject matter, and supersede all prior written or oral agreements, representations or understandings between the parties relating to that subject matter.

#### 23.2 No Reliance on Other Provisions

Each Party confirms that, in agreeing to enter into this Agreement, it has not relied on any representation, warranty, collateral contract or other assurance except those set out in this Agreement and to the extent any previous representation, warranty, collateral contract or assurance was made to a Party, such Party waives all rights and remedies with respect thereto.

#### 23.3 Implied Terms

ALL CONDITIONS, WARRANTIES AND OTHER TERMS IMPLIED BY STATUTE OR COMMON LAW ARE HEREBY EXCLUDED TO THE FULLEST EXTENT PERMITTED BY LAW.

#### 23.4 No Exclusion for Fraud

Nothing in this Agreement will operate to limit or exclude a Party's liability for fraud.

## 24. AMENDMENTS

No amendment or variation of this Agreement shall be valid and effective unless in writing and signed by or on behalf of each Party.

#### GOVERNING LAW AND JURISDICTION

#### 25.1 Governing Law

This Agreement shall be governed and construed in accordance with the laws of the State of Delaware, without giving effect to the conflicts of laws principles thereof.

#### 25.2 Dispute Resolution

Except as provided in Clause 3.5.1, or in relation to any matter which is to be finally determined by an independent expert in accordance with this Agreement, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection with this Agreement, then either Party shall have the right to refer such dispute to the Senior Officers who shall seek to resolve such dispute. Any final decision mutually agreed to by the Senior Officers shall be in writing and shall be conclusive and binding on the Parties. If the Senior Officers are not able to agree on the resolution of an issue within twenty (20) days after such issue was first referred to them (or such longer period as they may agree), Clause 25.3 shall apply.

#### 25.3 Jurisdiction

Subject to Clause 25.2, all disputes between the Parties arising in connection with this Agreement shall be referred to and finally resolved by the courts located in the State of Delaware and the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of such courts for any action, suit or proceeding arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding arising out of or relating to this Agreement in such courts, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum

#### 25.4 Process Agents

Without prejudice to any other mode of service allowed under any relevant law:

- (a) Emergent irrevocably appoints Emergent Biosolutions, Inc as its agent for service of process in relation to any proceedings before the courts located in the State of Delaware in connection with this Agreement and further agrees that service of any process, summons, notice or document by U.S. registered mail to the General Counsel of Emergent Biosolutions, Inc at the address for that company set out in Clause 17.3 (or such other address in the United States as may have been notified to sanofi pasteur in accordance with Clause 17) shall be effective service of process for any action, suit or proceeding brought against it under this Agreement; and
- (b) sanofi pasteur irrevocably appoints Connaught Technology Corp. as its agent for service of process in relation to any proceedings before the courts located in the State of Delaware in connection with this Agreement and further agrees that service of any process, summons, notice or document by U.S. registered mail to Kathleen Winter, President of Connaught Technology Corp. (or any successor President) at 3711 Kennett Pike, Suite 200 Greenville, Delaware 19807; (or such other address in the United States as may have been notified to Emergent in accordance with Clause 17) shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

#### 25.5 Interim Relief

Nothing in this Agreement shall prohibit a Party from seeking interim relief in any court of competent jurisdiction.

#### 26. SUCCESSORS AND ASSIGNS

This Agreement shall be binding upon and enure for the benefit of both Parties and their successors and permitted assigns, as the case may be.

## 27. COUNTERPARTS

This Agreement may be executed in any number of counterparts and all the counterparts when taken together will constitute one agreement. Each Party may enter into this Agreement by executing a counterpart.

#### 28. LANGUAGE

This Agreement is drawn up and executed in the English language. If there is any conflict between this Agreement and any translation of this Agreement, the English language version of this Agreement will prevail.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorised representatives.

## EMERGENT EUROPE LIMITED

By: /s/ S.N. Chatfield

Name: Dr. Steve Chatfield PhD

Title: President

## SANOFI PASTEUR, S.A.

By: /s/ Dominique Carouge

Name: Dominique Carouge Title: Chief Financial Officer

By: /s/ Michel DeWilde

Name: Michel DeWilde

Title: Sr. Vice President of Research & Development

#### Schedule 1

#### Appendix 1

#### Outline Candidate Evaluation and Selection Plan

#### 1. Introduction

This appendix is intended to serve as supporting documentation to the main body of the Agreement. It has been compiled on the basis of a number of face to face interactions and represents the parties shared view of the work-plan required to fully evaluate the Candidate Antigens and to select Candidate Antigens for clinical development. The plan will be subject to change as agreed by the Steering Committee (SC), but it is recognised that the plan will require both parties to commit resources (personnel and equipment) that cannot be redeployed easily.

Sanofi pasteur and Emergent propose to enter a collaboration to develop a Meningitis B vaccine based on one or more of the potential [\*\*] Candidate Antigens that Emergent has identified. These Candidate Antigens were identified as virulence genes encoding probable surface located proteins in a signature—tagged mutagenesis (STM) screen, or as surface located or secreted proteins in a leaderless PhoA functional screen. The Candidate Antigens are described and claimed in the Emergent owned patent applications [\*\*] and [\*\*] and related national filings and divisionals (as listed in Schedule 5 under Emergent Independent Patent Rights).

The starting point of the Co-Development Programme is to evaluate the pool of approximately [\*\*] Candidate Antigens as potential meningitis vaccine candidates. An effective vaccine providing broad coverage against multiple menB strains or even potentially against multiple meningitis serogroups may contain multiple antigens ([\*\*] antigens). In order to select Candidate Antigens or Programme Antigens for clinical development the Parties have agreed the Outline Candidate Evaluation and Selection plan detailed within this Appendix. This plan describes the main tasks to be performed and the Party or Parties responsible for performing each task. This plan may be refined periodically as necessary upon the agreement of the SC. In the following plan the evaluation and selection steps apply equally to Programme Antigens as to Candidate Antigens, however only the term Candidate Antigen is used for simplicity.

The aim of the candidate evaluation process is to comprehensively evaluate the pool of Candidate Antigens and to ensure that a suitable preclinical data package (with emphasis on functional assays and conservation) is generated on each of the Candidate Antigens in a systematic and objective manner to enable selection of individual Candidate Antigens for clinical development within an appropriate timeframe. However, if promising Candidate Antigens are

Schedule 1 Appendix 1

identified early in the evaluation process that meet the pre-clinical selection criteria for clinical development, the SC will consider these Candidate Antigens for immediate entry into clinical development, ahead of completing evaluation of the remaining Candidate Antigens. In addition, promising Candidate Antigens will also be evaluated in combinations where appropriate.

The selection criteria for selecting Candidate Antigens for clinical development are to be finalised and agreed by the SC, but will be based on the selection criteria listed below.

#### 2. Prioritisation of Candidate Antigens for Pre-Clinical Screening

Given the large number of potential Candidate Antigens [\*\*], the Candidate Antigens will first be evaluated on the basis of [\*\*] and [\*\*] to enable a prioritised Candidate Antigen list to be compiled.

## 2.1 [\*\*] (Task Responsibility; Emergent and sanofi pasteur)

Emergent has performed some initial screens for [\*\*]. Sanofi pasteur has also performed [\*\*].

[\*\*] Candidate Antigens have been identified that have potentially significant [\*\*] and which may require further [\*\*].

Sanofi pasteur has strong [\*\*] capabilities, particularly in the areas of [\*\*]. It is proposed that sanofi pasteur lead the [\*\*] analysis of these Candidate Antigens.

If the [\*\*], then a decision will be taken on whether the [\*\*]. The collaboration will then consider the use of these [\*\*] proteins. Candidate Antigens that [\*\*] will be excluded.

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#### 2.2 Intellectual property review (Task Responsibility; Emergent and sanofi pasteur)

Sanofi pasteur and Emergent will agree on the patentability and freedom to operate position for each Candidate Antigen or Programme Antigen. It is envisaged that the [\*\*] will be key to and underpin the product development and that additional Intellectual Property [\*\*] is likely to be generated during the collaboration which will provide further patent protection for any collaboration Product.

#### 2.3 [\*\*] (Task Responsibility; Emergent and sanofi pasteur)

Emergent and sanofi pasteur have performed a number of [\*\*] screens to rank the Candidate Antigens (see below). Sanofi pasteur and Emergent have agreed to a prioritised list of Candidate Antigens [\*\*].

## 2.3.1. [\*\*] (Task Responsibility; Emergent)

An [\*\*] screen has been performed to determine the level of [\*\*]. Candidate Antigens have been ranked in the following order;

• [\*\*

## 2.3.2. [\*\*] (Task Responsibility; Emergent and sanofi pasteur)

Candidate Antigens have been updated for [\*\*] using [\*\*] Candidate Antigens have been predicted to be [\*\*]. The work plan below is focused on these [\*\*] candidates. [\*\*] of remaining Candidate Antigens will be experimentally confirmed at a later stage.

The Candidate Antigens clearly predicted to be [\*\*] have been prioritised, followed by those with [\*\*].

#### 2.3.3. Literature search (Task Responsibility; Emergent)

The literature search for each Candidate Antigen will be updated. Candidate Antigens known to be [\*\*] have been identified [\*\*].

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#### 3. Preclinical Evaluation - [\*\*]

[\*\*] Candidate Antigens will be evaluated for [\*\*]. Expressed Candidate Antigen proteins will be used to [\*\*]. Of those [\*\*] prioritized Candidate Antigens, [\*\*]

## 3.1 Candidate Antigen [\*\*] (Task Responsibility; Emergent)

The high degree of [\*\*] seen within the [\*\*] of the Candidate Antigens [\*\*] suggests that the Candidate Antigens are likely to be [\*\*].

[\*\*] screening of each Candidate Antigen will be performed initially for approximately [\*\*]. This involves using [\*\*]. These would first be checked [\*\*], but would be underwritten by [\*\*]. This approach should pick up Candidate Antigens that have [\*\*] and will be used as a criterion to exclude Candidate Antigens from further progress on the basis of [\*\*]. However, even if [\*\*] is poor, this data may be valuable in later decisions on [\*\*].

It is likely that many if not all Candidate Antigen will pass this [\*\*] screen and that a significant number of Candidate Antigens will require extended [\*\*] screening against a [\*\*] at a later point in the Co-Development Programme, particularly if selected as a Clinical Candidate.

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#### 3.2. Candidate Antigen [\*\*] (Task Responsibility; Emergent)

It is likely that [\*\*] of Candidate Antigens will prove to be a significant rate-limiting step within the pre-clinical screening programme. The approach taken will be to [\*\*]. Less emphasis will be applied in producing a [\*\*] for a given Candidate Antigen at this initial evaluation stage, with the emphasis on producing [\*\*] as quickly as possible for [\*\*] evaluation

[\*\*]. Emergent propose to use the [\*\*] that should be suitable for down-stream process (DSP) development. [\*\*] Candidate Antigens may not be at suitable levels or be deemed as unsuitable for further process development and alternate [\*\*] may be considered.

Given that many of the Candidate Antigens are predicted to be [\*\*] proteins, it is likely that they will be [\*\*] that contain highly pure Candidate Antigen [\*\*]. This can be advantageous for [\*\*]. However, the [\*\*]. Once in a [\*\*] state the protein is [\*\*]. The aim of the [\*\*] step is to obtain protein in a [\*\*] form suitable for [\*\*]. Emergent proposes to assess the success of the [\*\*] using [\*\*]. The [\*\*] protein should [\*\*].

Particular attention will be given to protein [\*\*], as maintaining [\*\*] may be important in generating [\*\*], particularly in the case of [\*\*]. A [\*\*] screen will be performed to assess a range of [\*\*]. As [\*\*] assays are not available, it is proposed that the [\*\*] of the protein [\*\*] will be defined as the [\*\*]. The success of [\*\*] will initially be assessed by [\*\*]. Samples which show [\*\*] will then be further analysed by [\*\*].

Emergent propose to [\*\*] only once [\*\*] is demonstrated.

Candidate Antigen proteins that are successfully [\*\*]. This ensures that the material is sufficiently [\*\*] to allow material to be [\*\*].

#### 3.3. [\*\*] (Task Responsibility; Emergent)

[\*\*] assays depend on the ability of [\*\*]. Different [\*\*], and in particular, different [\*\*] vary [\*\*]. Therefore they can be expected to vary in [\*\*]. Overall, there is not a clear [\*\*] among [\*\*], although in most systems, [\*\*] has lowest activity in terms of [\*\*] regimen that induces [\*\*] would give the best chances of [\*\*]. Therefore [\*\*] are selected for pre-clinical studies, as the priority should be [\*\*] will thus initially be selected on the basis of [\*\*], rather than whether or not [\*\*].

Accordingly Emergent proposes to use the [\*\*] may be included at a later stage with Candidate Antigens firstly selected with [\*\*].

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- [\*\*] obtained from [\*\*] will be analysed in a specific protein [\*\*] in order to confirm that a [\*\*] each Candidate Antigen. [\*\*] will then be analysed [\*\*] in order to identify [\*\*] from those [\*\*] which are seen to [\*\*] will not be processed any further. All remaining [\*\*] will be [\*\*] tested in the remaining pre-clinical assays.
- [\*\*] will only be performed if time and resource permits, priority will be given to performance of the [\*\*] assays.

## 3.4 Pre-clinical [\*\*] evaluation (Task Responsibility; Emergent and sanofi pasteur)

Pre-clinical [\*\*] testing will be used to establish which Candidate Antigens will be selected for further clinical development. Selection can be based upon [\*\*]

[\*\*] used in the pre-clinical assays may be very important for each antigen and [\*\*] in some or all of the pre-clinical assays. [\*\*] will be evaluated, first under [\*\*] and alternate [\*\*].

## 3.5 [\*\*] (Task Responsibility; Emergent)

[\*\*] will be used to measure if [\*\*] the Candidate Antigens [\*\*]. Furthermore, a number of [\*\*] will be evaluated to demonstrate [\*\*]. Alternatively, [\*\*] may be used to [\*\*].

#### 3.6 [\*\*] (Task Responsibility; Emergent and sanofi pasteur)

A reliable and well-understood [\*\*] is a key functional activity test for each Candidate Antigen as this assay is currently the [\*\*]. Both Emergent and sanofi pasteur will perform [\*\*]. Candidates that meet the [\*\*] selection criteria set by the SC, will be considered by the SC for entry into clinical development.

A candidate that does not demonstrate [\*\*], or in another agreed [\*\*] assay [\*\*], is unlikely to be taken forward into clinical development.

## 3.7 [\*\*] assays (Task Responsibility; Emergent or sanofi pasteur),

Assays that utilise [\*\*] will be used as an alternative [\*\*] measure [\*\*]. Both [\*\*] assays provide [\*\*] measurement, although these assays can be [\*\*]. However, the assay may be more sensitive than the [\*\*]. Positive activity in either assay format is valuable, however

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[\*\*] will be analysed in this assay.

## 3.8 [\*\*] (Task Responsibility; sanofi pasteur)

[\*\*] can give valuable characterisation data on individual Candidate Antigens. Demonstration of [\*\*] for a Candidate Antigen is valuable as [\*\*]. The parties intend that only Candidate Antigens that fail to generate [\*\*] but are positive in pre-clinical [\*\*] assays [\*\*], should be further evaluated for the [\*\*]. Further [\*\*] work may be performed once a Candidate Antigen has been selected for clinical development.

A flow chart of the proposed Candidate Evaluation and Selection Plan is shown below.

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## 4. Task Responsibilities

The table below summarises the main tasks and responsible parties for the Candidate Evaluation and Selection Plan.

## Table 1. Task responsibilities for the Candidate Evaluation and Selection Plan

Task			
no.		Task Description	Responsible Party
	Prioritisation of Candidate Antigens		
1	[**]		Joint
2	[**]		Joint
3	[**]		Emergent
4	[**]		Joint
5	[**]		Emergent
•	1 1		
	Preclinical Evaluation		
	Troumbut Evaluation		
6	[**]		Emergent
7	[**]		Emergent
8	[**]		Emergent
9	[**]		Emergent
10	[**]		Joint
11	[**]		Emergent
12	[**]		sanofi pasteur

## 5. Project Management and Resources Required (Task Responsibility; Joint)

The current project work-plan to evaluate the [\*\*] Candidate Antigens will be completed within approximately [\*\*] with the proposed level of resource below. A Gantt chart outlining the main tasks and associated timelines follows.

[\*\*]

Schedule 1 Appendix 1 8 The Gantt chart assumes that full preclinical testing [\*\*] will be performed for a maximum of [\*\*] candidates, to allow for an attrition rate of those candidates that are deprioritised during the evaluation process, for instance if the [\*\*].

## 5.2 Emergent Resource Required

In order to resource the programme adequately, Emergent will need to dedicate the necessary number of skilled Full Time Equivalents (FTEs) to the project. Whilst it is recognised that the work-plan may be modified by the SC, the following represents Emergent's best estimate of the Emergent resource that will be required to execute the work-plan illustrated in the Gantt chart above. Resource levels assume a [\*\*]. The proposed resource levels do not include any contingency resource [\*\*]

## Year 1

Function	M1	M2	М3	M4	M5	M6	M7	M8	М9	M10	M11	M12
Mol Biol	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Purification	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Purification management	• •											
Pre-clinical	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Pre-clinical management	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Project Leader	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Total (FTE)	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

## Year 2

Function	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24
Mol Biol												
Purification	[**]											
Purification management												
Pre-clinical	[**]	[**]	[**]	[**]								
Pre-clinical management	[**]	[**]	[**]	[**]	[**]	[**]	[**]					
Project Leader	[**]	[**]	[**]	[**]	[**]	[**]	[**]					
Total (FTE)	[**]	[**]	[**]	[**]	[**]	[**]	[**]					

5.3 [\*\*]

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The major external cost associated with the project work-plan will be [\*\*].

At the present time, based on current rates, this is estimated as being approximately [\*\*].

#### 5.4 Capital Expenditure Equipment

At this point it is anticipated that the following capital expenditure equipment will be required to meet the projected needs of the project work-plan. Any further capital expenditure required will be discussed and agreed at the Joint Project Team level and approved as necessary by the SC. This equipment remains the property of [\*\*].

	No.	Unit	lotai
Equipment	Req.	Cost (£)	Cost (£)
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]

# 6. Selection of Candidate Antigens for clinical development (Emergent and sanofi pasteur)

Following completion of the pre-clinical evaluation of the Candidate Antigens a final ranking of the Candidate Antigens will be performed to facilitate selection of the best Candidate Antigens for clinical development.

Candidate Antigens will only be selected for clinical development by the SC if they pass certain criteria, currently anticipated to include the following;

[\*\*]

These criteria will be defined and agreed by the SC in advance of any Candidate Antigen selection for clinical development.

Assuming all of the above criteria are met for more than one Candidate Antigen, each criterion ranking, together with the ability to develop a scalable commercial process will be used to prioritise the Candidate Antigens for entry into full-scale development and ultimately clinical development.

At the SC's discretion, there is also the option to [\*\*] into the clinic ahead of completing the evaluation of all Candidate Antigens, if the Candidate Antigens meet the agreed preclinical selection criteria.

The Parties envisage that [\*\*] Candidate Antigens will be selected for clinical development, with the final vaccine comprising [\*\*].

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### Appendix 2

### **Early Development Phase**

### **Phase I Product and Clinical Development Plan**

This appendix is intended to serve as supporting documentation to the main body of the agreement.

It is recognised that it is difficult to plan precisely the further one goes out from the commencement of the project. In this regard it is acknowledged that the following plan may change, subject to approval by the Steering Committee (SC). However the material below represents an overview of the work that will be required to take one protein through from selection for clinical development to the end of Phase I.

Specifically, this plan highlights the work that will be required to take one protein from the point at which it becomes a Clinical Candidate in the evaluation and selection phase to the point at which the data from a Phase I will have been analysed and reported.

It is recognised that there may need to be a Transition Plan to attain smooth and efficient handover of pilot scale processes and associated data to Sanofi after completion of Phase I trials.

If more than one Clinical Candidate were to be chosen for clinical development then the plan will need to be modified appropriately to take account of the extra resource (and potential synergies) required by such a decision.

Following the selection of Clinical Candidates(s) for clinical development, the Steering Committee will finalise and agree the details of a Phase I Product and Clinical Development Plan for each selected antigen including the main activities to be performed, allocation of responsibilities, an appropriate level of product compliance, the resource requirements (financial, FTEs, contractors, hardware and reagents) and expected timelines. The general principles and the anticipated major components of the plan are listed below.

### **General Principles**

Emergent will be responsible for manufacture of Phase I clinical material, for interactions with regulatory bodies relating to Phase I, and for conducting/managing Phase I clinical trials.

The components of a Phase I Product and Clinical Development Plan will include the following;

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[\*\*]
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[\*\*]
[\*\*]
[\*\*]
[\*\*]

An outline description of the anticipated tasks is given below.

### 1. Further Preclinical Characterisation (Task responsibility; Emergent and Sanofi)

The intention of the pre-clinical screening and evaluation process is to select candidates that are suitable for development as a vaccine against *N. meningitidis* serogroup B within an appropriate timeframe. When a Clinical Candidate moves from pre-clinical screening into clinical development further pre-clinical characterisation will be performed. Whilst the additional pre-clinical work required is likely to be Clinical Candidate specific, further [\*\*] studies may be performed, [\*\*].

Following selection of a Clinical Candidate for clinical development, one of the first steps will be to demonstrate that the [\*\*] profile for the Clinical Candidate remains consistent following [\*\*]. For this purpose the Clinical Candidate [\*\*] Clinical Candidate protein will then be [\*\*].

The [\*\*] assays used to demonstrate [\*\*] in the preclinical selection screen will then be repeated for [\*\*]. Depending on the [\*\*] assay selected, these assays may be performed at both Emergent and Sanofi. The corresponding [\*\*] will be repeated alongside the [\*\*] as a positive control. This will confirm that the [\*\*]. However, if the [\*\*] fails to demonstrate [\*\*] activity, this may indicate a technical problem, which will

result in the investigation of the [\*\*] methods employed. Assuming comparability in [\*\*] activity between [\*\*] is demonstrated, the next steps in the development pathway will commence.

As further Clinical Candidates move into clinical development, detailed pre-clinical studies will be performed to support [\*\*] that would support the clinical development strategy

### 2. Product Development (Task responsibility; Emergent)

[\*\*] characterisation will be performed on the [\*\*].

### 2.1 [\*\*] and Selection

Emergent will [\*\*] and select the [\*\*] in-house. The criteria for selection are:

- i) [\*\*
- ii) [\*\*]
- iii) [\*\*]

If a [\*\*] meets all of these criteria, a [\*\*] will be manufactured in-house. This [\*\*] will be progressed into development. No animal-derived materials will be used in the [\*\*] in-house or at Contract Manufacturing Organisations (CMOs).

#### 2 2 [\*\*]

The [\*\*] will be transferred to the selected Contract Manufacturing Organisation (CMO) and will be tested to ensure that it is pure and free from adventitious agents before being accepted into the CMO facility. The [\*\*] will be manufactured from the [\*\*]. This manufacture will be performed by [\*\*]. Phase I clinical supplies will be manufactured directly from the [\*\*]. It is anticipated that the [\*\*] will be manufactured following successful completion of Phase I.

## 2.3 Process Development and Manufacturing Strategy

[\*\*] purification processes suitable for transfer to a CMO will be developed in-house and will immediately focus on deriving both a commercially and regulatory acceptable process. Emergent will systematically screen each process step to find the optimal process conditions e.g. [\*\*]

The selected skeleton process will be refined and scaled up at a CMO so that it is suitable for the manufacture of clinical trials material. Emergent will provide the necessary support to the CMO to ensure that a suitable manufacturing process is developed in a timely manner. Emergent will manage the transfer of

the process, further process development and manufacture at the CMO of material for use in toxicology and clinical studies.

### 2.3.1 Development of Processes

### 2.3.1.1 Early Process Development

The purpose of early process development, undertaken in the laboratories of Emergent, is to determine a skeleton process that will be transferred to a CMO for refinement and scale-up.

### 2.3.1.2 Upstream Development

[\*\*] will be determined, [\*\*] for the Clinical Candidate performed. The [\*\*] will be determined. [\*\*] will be performed.

### 2.3.1.3 Downstream Development

In the case that the protein is [\*\*], then scouting of [\*\*] will be performed. Where the protein is [\*\*], then [\*\*] will be performed and optimised. [\*\*] will be evaluated [\*\*] and the data analysed using [\*\*] analysis, [\*\*]. Scouting of the [\*\*], where possible. No animal components will be used in the manufacturing process for any of the candidates.

This small-scale material will likely be used to begin performing the primary pharmacodynamic studies and analytical method development and formulation studies. Additionally, degradation and stability studies will begin at once to assess the degradation profile of the material and selection of suitable methods to perform longer-term stability studies.

This material may form an early reference preparation for use in various analytical and pre-clinical assays.

### 2.4 Process Transfer, Scale Up and Consistency Runs

Once the small-scale process is transferred to the CMO, it will be refined/optimised [\*\*]. Finally the process will be performed several times to ensure reasonable process robustness and consistency as part of process understanding studies. Material from this stage may also be used for ongoing pre-clinical work in addition to the continued development of In-Process Control (IPC) and Drug Substance (DS) assays.

### 2.5 Manufacturing Scale Batch

After successful completion of consistency runs at small scale, the process will be operated at the pilot manufacturing scale under non-GMP conditions to verify

its scalability by comparing appropriate parameters of both the small and large-scale batches. This also gives the opportunity for the GMP operators in the manufacturing plant to learn the manufacturing process and to develop appropriate batch manufacturing records. The material generated from this batch represents the first large-scale batch that would be comparable to that planned for the clinical batch. This material will be used in the pre-clinical package and also to qualify methods used for release of the toxicology and clinical batches as well as providing the basis for the setting of specifications. Stability studies will also be performed on the material.

### 2.6 Toxicology Batch

The toxicology batch will be produced at the same scale as the clinical batch [\*\*], will be released to specification and will be used primarily for toxicology studies. It will also undergo analytical characterisation suitable for incorporation within a Clinical Trial Application (CTA). Stability studies will also be performed on the material and it may also be used as a reference preparation for use as reference controls and standards in assays.

### 2.7 Clinical Batch (GMP)

The clinical batch will be produced to GMP and released for use in a clinical study. Again, this batch will undergo product characterisation and stability testing.

### 2.7.1 Method Development

Analytical methods for IPC, DS and Drug Product (DP) will be developed and qualified prior to initiation of Phase I clinical trials. Methods will be developed in-house or contracted to a CMO depending on the complexity or nature of the assay. This will initially be performed on early process material once available. Qualification of assays will be performed upon large-scale process derived material. Assays will be transferred to the QC laboratory of the CMO or nominated sub-contractor, as appropriate, where QC release testing of cGMP lots will be undertaken.

### 2.8 Formulation

At the current time, it is anticipated that the DP formulation will be based on [\*\*] will be evaluated [\*\*]. Conditions for the optimum [\*\*] will be determined and these initial experiments will be carried out using protein prepared from the in-house skeleton process. Once material manufactured at the CMO is available, formulation experiments will be repeated using the knowledge gained from the initial formulation development work using the early material from the skeleton process.

The formulation process will then be transferred to a secondary manufacturer for the manufacture of transfer, toxicology and clinical batches of DP.

### 2.9 Stability of Product

Stability studies will be performed on both DS and DP. Tests used will be shown to be stability indicating and will selectively be used throughout the stability assessment. [\*\*] will be used to predict a suitable shelf life for the product.

### 2.10 Product Characterisation

Preliminary product characterisation will be performed upon the active pharmaceutical ingredient (API). This will assess [\*\*] of the product, potentially using state of the art techniques indicated in ICH guidelines, e.g. [\*\*].

### 2.11 Generation of a Pre-Clinical package for a Clinical Trial Application [\*\*]

### 2.11.1 Primary Pharmacodynamic Studies

Data obtained from the pre-clinical screening of the candidate will be detailed in this section of the application, including [\*\*]. Dosing studies in animals will help to determine [\*\*]. These studies will also support the formulation studies as described above.

### 2.11.1.1 [\*\*] Studies

[\*\*] will be assessed. [\*\*] will be evaluated in an appropriate [\*\*]. The [\*\*] will then be assessed by [\*\*].

### 2.11.1.2 [\*\*] Studies

The effect of [\*\*] will be evaluated for each candidate [\*\*]. This may well be performed as part of the [\*\*] studies outlined above.

### 2.11.2 Secondary Pharmacodynamic Studies

### 2.11.2.1 Screening of [\*\*]

[\*\*] will be assessed in a [\*\*]. Furthermore, [\*\*].

### 2.11.3 Toxicology Studies

Repeat dose toxicology and local tolerance will be performed [\*\*]. Studies will be reflective of the clinical dosing regimen.

### 2.12 GMP Manufacturing

The Parties intend that GMP manufacturing will be performed by the same CMO that is carrying out the process development work for an individual protein candidate.

### 2.12.1 Transfer of Process from Development to GMP

Emergent will oversee the transfer of the process from the in-house development group to the GMP group at the chosen CMO. GMP operators from the CMO will be trained on the details of the process by Emergent. Emergent will approve the GMP batch records prior to commencement of manufacturing.

### 2.12.2 Manufacturing

The CMO will produce a transfer batch (non-GMP) at full (pilot) scale, one GMP-like toxicology/stability batch and one GMP clinical batch of Drug Substance. The final process developed by the CMO will yield [\*\*].

### 3. Phase I Clinical and Regulatory Plan (Task responsibility; Emergent)

### 3.1 General Principles

It is anticipated that Clinical Candidate(s) selected for clinical development will have demonstrated the ability to [\*\*]. However, Clinical Candidates may have demonstrated [\*\*]. The objective of the Phase I studies will be to determine safety and immunogenicity (serum antibody levels) of Clinical Candidates. However, it is important for ease of clinical development that [\*\*] antibodies generated by the Clinical Candidate(s) demonstrate [\*\*].

The final vaccine product may contain [\*\*] Clinical Candidate. It is considered unlikely that the final vaccine product will contain [\*\*] Clinical Candidates [\*\*] raises a number of challenges in the clinical development path. Hence the early clinical research work will be designed to demonstrate [\*\*], safely and that the immune response induced is likely to be protective [\*\*].

The Parties intend that the Phase I safety and immunogenicity studies will be undertaken by Emergent in the UK, under Clinical Trial Applications (CTA). This is considered to be the [\*\*]. The Phase I studies will be Emergent sponsored studies and each study will require its own CTA. In support of each CTA, each Clinical Candidate will require its own Investigational Medicinal Product Dossier (IMPD), as each Clinical Candidate will be classified as a different product.

Each [\*\*] studied is also likely to require its own IMPD as it is potentially classified as a separate product. [\*\*].

An outline of the likely Phase I clinical development path is provided below. Detailed clinical development plans will be compiled following further discussion between the Parties and agreed by the SC ahead of selection of candidate antigens for clinical development. [\*\*]. In addition, the preferred optimal study design needs to be decided on the basis of a number of factors and it is not possible to be definitive about the final study design at this stage of development.

## 3.2 Phase I Clinical Studies

### 3.2.1 Objectives

The key objective for the Phase I studies will be to demonstrate for individual Clinical Candidates [\*\*] that a range of doses can be administered, that the Clinical Candidates have an acceptable safety profile and induce a potentially protective immune response [\*\*] against [\*\*].

### 3.2.2 Previous Study

Emergent have already undertaken a Phase I study in healthy volunteers [\*\*]. However, the design of the [\*\*] study can however be used to assist the design of future Phase I studies.

### 3.2.3 Design of Study

Phase I studies are exploratory and are usually performed in small groups of twenty (20) to forty (40) adults to assess the safety of the product and to detect the expected immune response [\*\*]. Phase I studies might also be extended to the final target population [\*\*]. The following general design is proposed at present. Each Phase I study will investigate a number of different dose levels (normally up to 4 dose levels) of Clinical Candidates [\*\*]

and involve [\*\*] subjects per dose group. The studies will enrol male and female adult volunteer subjects [\*\*]. Each subject will receive up to [\*\*] doses of a single dose level. The doses will be administered at Time [\*\*] month and [\*\*] months after the first injection [\*\*]. For reasons of safety, dose escalation will be [\*\*]. Subjects will be dosed [\*\*], such that the first [\*\*] to be dosed will receive the lowest dose, the second [\*\*] will receive the next highest dose with the third and fourth [\*\*] receiving the third and fourth highest doses. Consideration of administering only [\*\*] doses on Days [\*\*] and [\*\*] may also be appropriate. Alternatively, planning the study to administer [\*\*] doses, but with a review of the [\*\*] data after the second dose, might be worthy of consideration as this will shorten the Phase I development timelines.

It is proposed that [\*\*] dose levels will be included to establish a no effect/minimal effect dose group and to investigate if there is a dose response.

Safety will be of primary importance. For this reason dose escalation will be done [\*\*] with the lowest dose group dosed first and safety reviewed prior to the second dose group receiving their first dose. Following an appropriate safety review the third [\*\*] will receive their first dose and if appropriately safe the final [\*\*] will receive their first dose. Hence, the dosing of each subsequent [\*\*] will occur approximately [\*\*] days after dosing the preceding [\*\*]. Subjects will receive their second dose [\*\*] days after the first dose and their third dose [\*\*] months after the first dose. Eligibility for administration of the second and third doses to individual volunteers will depend on the safety profile in the individual subjects following the first and second doses and will only be administered if a subject tolerates the first/second injection. Safety reviews will be conducted after each [\*\*] receives their second and third dose to determine if it is appropriate to administer the second/third doses to the next [\*\*].

### 3.2.4 Immunological and Safety Endpoints

Immunological endpoints will be [\*\*]. The [\*\*] will be evaluated [\*\*] will also be evaluated. Emergent will be responsible for ensuring suitable clinical assays exist that have been qualified and may be performed within Emergents's clinical assay laboratory or at a suitable contractor that is skilled in the testing of clinical samples that possess suitable experience in the techniques proposed.

Safety endpoints will be adverse events, incidence of flu-like illnesses (myalgia, fever, muscle/joint aches, general malaise and headache), serious adverse events and injection site

reactions assessed by the modified Draize score.

### 3.2.5 Phase I Study Costs and Timelines

The costs of a Phase I study are estimated in section 4.3. These are Emergents' best estimates of potential costs, at this stage, based on previous Phase I trial experience. The budget for Phase I studies will be agreed by the SC on an annual basis, or at the appropriate time during development. The estimates in section 4.3 includes the contract fees for a Phase I unit to run the study along with the project management fees, monitoring costs and performing immunological analysis of clinical samples. Each study will run for approximately a total of [\*\*] in clinic [\*\*].

If more than one Clinical Candidate becomes available for clinical evaluation at any time [\*\*].

### 3.2.6 [\*\*] Phase I Studies

The final vaccine formulation may contain [\*\*] Clinical Candidate to provide an effective immune response against [\*\*]. Therefore there may need to be a need to study [\*\*]. Broadly, there are [\*\*] potential strategies for a Phase I clinical programme investigating the safety and immunogenicity [\*\*] and these are outlined below. Emergent's proposed approach to Phase I clinical evaluation is the [\*\*] approach, however these plans are for indicative purposes only, until the number of Clinical Candidates for evaluation and the timing of availability of GMP manufactured material is known.

### 3.2.6.1 [\*\*] Approach (Emergent Proposed Approach)

A Phase I clinical trial will be performed as outlined above, to evaluate the first Clinical Candidate available for clinical evaluation. Assuming that the protein in the study has an acceptable safety profile, [\*\*] and a second suitable protein is available to move into clinical research a second Phase I study will be planned that investigates a [\*\*].

The second study in the series will utilise [\*\*]. In this way information on the safety and immunogenicity [\*\*] will be determined and [\*\*].

(Note non-clinical and toxicology work [\*\*] will be required, as will an IMPD for Clinical Candidate 2 [\*\*]). The study will need to investigate up to [\*\*] dose levels of Clinical Candidate 2 as outlined above and [\*\*] at doses identified to be immunogenic and to have an acceptable safety profile. This could result in up to [\*\*] groups or [\*\*] subjects as outlined below and using assumed doses as indicated: -

- Clinical Candidate 2 at [\*\*] escalating dose levels ([\*\*] groups). These groups to be dosed in escalating [\*\*] before [\*\*].
- [\*\*] at escalating dose levels (same quantity of each protein).

Hence, [\*\*] groups could be involved [\*\*]. The duration of the [\*\*] study will depend on how many groups are dosed, but could be up to [\*\*] weeks in clinic if there are [\*\*] dose groups and [\*\*] dose levels of each product.

When a third protein is available the next study will investigate [\*\*] doses of Clinical Candidate 3 [\*\*].

The advantage of this approach over screening all proteins [\*\*] is that the safety and efficacy [\*\*] are potentially looked at much earlier. [\*\*] as soon as Clinical Candidates become available and this approach is thought to be the quickest route through the Phase I clinical research.

The limitation of this design is that the timings of when [\*\*] become available is unknown. Also, prior to starting a study where a [\*\*] is to be used all materials for the study will need to have been manufactured. At this time it will not be known if the new protein [\*\*].

### 3.2.6.2 Alternative Approaches

Alternative strategies for clinical evaluation [\*\*] include a direct [\*\*] approach where [\*\*] are selected for clinical studies based on preclinical data. The [\*\*] will then be tested in human subjects directly in a study as outlined above. The dose groups will be made up of [\*\*]. The study will be conducted under a

single CTA but again there will need to be an IMPD for each product used in the study. The size of the study is difficult to determine, [\*\*] cannot easily be predicted at this time.

The main advantage of this approach is that it could reduce the number of early clinical trials to be conducted (potentially to one Phase I clinical study) and thus provide a rapid development path. However, there is a potential risk that a [\*\*]. A further risk of this approach is that a safety issue [\*\*] could prevent further development of potential safe and effective vaccine [\*\*]. It may also be more difficult to evaluate [\*\*]. The Clinical Candidates will also have to be available [\*\*] for preclinical [\*\*] testing, which could delay early clinical proof of concept if a promising Clinical Candidate is identified early in the selection process.

[\*\*] Phase I studies of Clinical Candidates may also be performed. The safety and immunogenicity of all the Clinical Candidates is then established [\*\*]. This is the most protracted route of clinical development and requires extensive resources, particularly if multiple Phase I studies are to be performed [\*\*].

### 3.2.6.3 Selection of Phase I Approach

The choice of which approach to take to Phase I development may not be ideally determined at present, however it seems probable that the proposed series approach will be the most expedient.

### 4. Project Management and Resources Required; (Task Responsibility; Joint)

### 4.1 Project Timelines

The parties recognise that it is important to try to perform the clinical studies in as timely a manner as possible, without compromising the quality or integrity of the programme. As such this plan will be subject to periodic review by the SC and Joint Project Team. It is anticipated that the timeline for the Phase I clinical development of a single Clinical Candidate (with the proposed level of Emergent resource below) will be approximately [\*\*].

These estimates are based upon Emergent's past experience of Phase I clinical development of protein vaccine candidates. While the intention is to use a contract manufacturer for manufacture of GMP clinical material and a contract clinical trial unit for the performance of the clinical trial, Emergent staff will closely manage and interact with these contract organisations. The selection of appropriate contract organisations will be agreed at the SC.

The Gantt chart below represents the main tasks and associated timelines for conducting a Phase I clinical study for a single protein.

[\*\*]

# 4.2 Emergent Resource Requirement

In order to resource the programme adequately, Emergent will need to dedicate the necessary number of skilled Full Time Equivalents (FTEs) to the project. Whilst it is recognised that the work-plan may be modified by the SC, the following represents Emergent's best estimate of the Emergent resource that will be required to execute the work-plan for the Phase I clinical development of a single Clinical Candidate.

#### Year 1

Function	M1-Y1	M2-Y1	M3-Y1	M4-Y1	M5-Y1	M6-Y1	M7-Y1	M8-Y1	M9-Y1	M10-Y1	M11-Y1	M12-Y1
Mol Biol	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Process Dev	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Analytical Dev	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Pre-clinical Dev	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Regulatory	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
QA	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Clinical Dev	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Project Leader	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Management	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Total (FTEs)	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

# Year 2

Function	M1-Y2	M2-Y2	M3-Y2	M4-Y2	M5-Y2	M6-Y2	M7-Y2	M8-Y2	M9-Y2	M10-Y2	M11-Y2	M12-Y2
Mol Biol	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Process Dev	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Analytical Dev	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Pre-clinical Dev	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Regulatory	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
QA	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Clinical Dev	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Project Leader	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Management	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Total (FTEs)	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Year 3												
Function	M1_V3	M2-V3	M3-V3	M/LV3	M5-V3	M6-V3	M7-V3	MR-V3	MQ_V3	M10-V3	M11_V3	M12-V3
Function Mol Biol	M1-Y3	M2-Y3 [**]	M3-Y3 [**]	M4-Y3 [**]	M5-Y3 [**]	M6-Y3 [**]	M7-Y3 [**]	M8-Y3 [**]	M9-Y3 [**]	M10-Y3 [**]	M11-Y3 [**]	M12-Y3
Mol Biol	[**]	[**]	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]	M12-Y3 [**] [**]
Mol Biol Process Dev	[**] [**]	[**] [**]	M3-Y3 [**] [**]	[**]		[**] [**]	[**] [**]	[**] [**]		[**] [**]	[**] [**]	[**]
Mol Biol	[**] [**] [**]	[**] [**] [**]	[**] [**]	[**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**]
Mol Biol Process Dev Analytical Dev Pre-clinical Dev	[**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**]
Mol Biol Process Dev Analytical Dev	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**]	[**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**]
Mol Biol Process Dev Analytical Dev Pre-clinical Dev Regulatory	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**]	[**] [**] [**] [**]
Mol Biol Process Dev Analytical Dev Pre-clinical Dev Regulatory QA	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**] [**]	[**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**] [**]
Mol Biol Process Dev Analytical Dev Pre-clinical Dev Regulatory QA Clinical Dev	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**] [**]
Mol Biol Process Dev Analytical Dev Pre-clinical Dev Regulatory QA Clinical Dev Project Leader	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**] [**]	[**] [**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**]	[**] [**] [**] [**] [**]	[**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**] [**]	[**] [**] [**] [**]	[**] [**] [**] [**] [**] [**]
Mol Biol Process Dev Analytical Dev Pre-clinical Dev Regulatory QA Clinical Dev Project Leader Management	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**] [**]	[**] [**] [**] [**] [**] [**] [**] [**]

### Year 4

Function	M1-Y4	M2-Y4	M3-Y4	M4-Y4	M5-Y4
Mol Biol	[**]	[**]	[**]	[**]	[**]
Process Dev	[**]	[**]	[**]	[**]	[**]
Analytical Dev	[**]	[**]	[**]	[**]	[**]
Pre-clinical Dev	[**]	[**]	[**]	[**]	[**]
Regulatory	[**]	[**]	[**]	[**]	[**]
QA	[**]	[**]	[**]	[**]	[**]
Clinical Dev	[**]	[**]	[**]	[**]	[**]
Project Leader	[**]	[**]	[**]	[**]	[**]
Management	[**]	[**]	[**]	[**]	[**]
Total (FTEs)	[**]	[**]	[**]	[**]	[**]

## 4.2.1 Emergent Resource for Production of Multiple Proteins

Resource estimate for clinical development of more than one candidate simultaneously will not be direct multiples of the FTE figures above but are anticipated to be less than this, as it is expected that there will be resource efficiencies in developing two or more Clinical Candidates simultaneously.

# 4.3 External Costs - Contract Manufacturing and Performance of Clinical Trials

The external costs associated with the Phase I clinical development of a single protein candidate is estimated to be approximately £[\*\*]. A break down of the estimated external costs is given below.

Function	Process / Task	Cost (£)
Molecular Biology Total Molecular Biology	[**]	[**] [**]
Product development	[**]	[**]
	[**] [**]	[**] [**]
	[**]	[**]
	[**]	[**]
	[**] [**]	[**] [**] [**] [**]
Total product Development	LJ	[**]
Analytical	[**]	[**]
·	[**]	[**] [**]
	[**] [**]	[**] [**]
Total Analytical	1 1	[**] [**]
Pre-clinical Pre-clinical	[**]	[**]
	[**] [**]	[**] 
Total Pre-Clinical		[**]
Clinical testing	[**]	[**] [**]
	[**]	[**]
Total clinical Testing		[**]
Clinical	[**]	[**] [**]
	[**]	[**]
	[**] [**]	[**] [**]
	[**]	[**]
	[**]	[**] [**]
Total Clinical	[**]	[**]
Schedule 1 Appendix 2		16

Function	Process / Task	Cost (£)
Quality	[**]	[**]
	[**]	[**] [**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
Total Quality		[**]
Regulatory	[**]	<u> </u>
Total Regulatory		<u>[**]</u>
Total Other Costs	[**]	[**]
Total Direct Project Cost		[**]
Schedule 1 Appendix 2		17

### Appendix 3

### Later Stage Clinical Development Plan

### **General Principles**

Following the completion of the Phase I activities for a Clinical Candidate, Sanofi will assume the main responsibility for subsequent Development, including later stage clinical trials (Phase II, Phase III and Phase IV or other post-marketing studies) together with the corresponding regulatory applications.

Sanofi have considerable expertise and experience in the development of paediatric and meningococcal vaccines, with marketed polysaccharide vaccines Mengivac® (A + C) and Menomune® (A/C/W/Y) and marketed polysaccharide conjugate vaccine Menactra® (A/C/W/Y). The Parties intend that Sanofi will use this expertise to benefit the Development of a serogroup B vaccine Product and will proceed with Phase II and later stage clinical Development in the most appropriate and time efficient manner.

Whilst it is not possible at the current stage of development to be definitive in the Later Stage Clinical Development Plan, the following represents the current view of the probable Later Stage Clinical Development Plan. This plan will be subject to periodic review by the Steering Committee (SC) and a more definitive Later Stage Clinical Development Plan will be agreed by the SC ahead of implementation of the Transition Plan for the relevant Clinical Candidate. For clarity, it is anticipated that the Later Stage Clinical Development Plan will include the Phase II and Phase III clinical study design, accompanying regulatory strategy, details of trial sites, investigators and any involvement or interaction with public health bodies, as well as a manufacturing strategy for clinical trial materials in support of the proposed studies.

### 1.1 Phase II studies (Task Responsibility; Sanofi Pasteur)

Once a single protein candidate [\*\*] has been determined to be immunogenic, able to induce [\*\*] and displaying an acceptable safety profile a series of Phase II studies will be undertaken. Phase II studies are carried out in the final target population for immunisation and are aimed at confirming the immunogenicity observed in Phase I and at determining the final composition of the vaccine (dose-ranging, and determination of the immunisation schedule). These Phase II studies are an important part of the regulatory submission and must be powered to confirm the statistical hypothesis. Accordingly, [\*\*] will be selected for dose-optimisation in Phase II studies of similar design to the Phase I studies. The [\*\*]

vaccine will be evaluated in descending age groups starting with adults [\*\*] with approximately [\*\*] subjects to be included. Once this is complete development would continue [\*\*] with approximately [\*\*] subjects in each age group and [\*\*] again approximately [\*\*] subjects. [\*\*]. It is anticipated that further proteins [\*\*].

## 1.2 Phase III studies (Task Responsibility; Sanofi-Pasteur)

Following on from the relatively recent licensure of Meningitis C conjugate vaccines, in the UK and some additional countries based on a correlate of protection data [\*\*] and recent comments from the UK Health Protection Agency and Department of Health and US FDA (Atlanta April 2005 – MenB Correlates of Protection Meeting), it is envisaged that a serogroup B vaccine may potentially be launched [\*\*]. The health authorities in the UK and some other countries [\*\*] appear to be particularly favouring this approach. [\*\*] and the data generated could be used for regulatory submissions for marketing approval in other territories.

If this approach is not acceptable to the regulatory authorities, [\*\*]. It is expected that the Phase III trial will be run in all age groups that previous studies have demonstrated an appropriate immune response in [\*\*]. It is also expected that the study

will have to demonstrate vaccine efficacy in all population age groups that the vaccine receives an indication for. However, once a suitable safety database has been generated, [\*\*]. However, the Parties recognise that [\*\*].

Schedule 1 Appendix 3

3

### **Indicative Cost Schedule**

As described in Clause 5.3 the Annual Budget for the First Year shall be based on the following indicative costs related to the resource, capital expenditure equipment and predicted external costs required to perform the agreed work-plan.

### 1. Emergent Resource Requirement

In order to resource the programme adequately, Emergent will need to dedicate the necessary number of skilled Full Time Equivalents (FTEs) to the project. Whilst it is recognised that the work-plan may be modified by the SC, the following represents Emergent's best estimate of the Emergent resource that will be required to execute the agreed work-plan.

#### Voor 1

Function	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12
Mol Biol	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Purification	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Purification management												
Pre-clinical	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Pre-clinical management	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Project Leader	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
Total (FTE)	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

### Year 2

Function	M13	M14	M15	M16	M17	M18	M19	M20	M21
Mol Biol									
Purification	[**]								
Purification management									
Pre-clinical	[**]	[**]	[**]	[**]	[**]	[**]	[**]		
Pre-clinical management	[**]	[**]	[**]	[**]	[**]	[**]	[**]		
Project Leader	[**]	[**]	[**]	[**]	[**]	[**]	[**]		
Total (FTE)	[**]	[**]	[**]	[**]	[**]	[**]	[**]		

### 2. Capital Expenditure Equipment

At this point it is anticipated that the following capital expenditure equipment will be required to meet the projected needs of the project work-plan. The majority of this equipment [\*\*]. The remaining [\*\*] should be included in the first quarter payment by sanofi pasteur to Emergent as described in Clause 5.13. Any further capital expenditure required will be discussed and agreed at the Joint Project Team level and approved as necessary by the Steering Committee. This equipment remains the property of [\*\*].

		OTHE	
Equipment	No. Req.	Cost (£)	Total Cost (£)
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]

### 3. Predicted External Costs

As described in Clause 2.1 it is anticipated that during the Early Development Phase the majority of activities will be undertaken by Emergent at sanofi pasteurs' cost. The major external cost associated with the project work-plan will be the [\*\*].

At the present time, based on current rates, this is estimated as being approximately [\*\*].

There will also be external costs related to [\*\*]. However, these are not anticipated to be substantial and will be agreed at the SC or JPT as appropriate ahead of commencing the work.

### 4. The FTE Costs and Emergent Expenses incurred between 1 January 2006 and the Effective Date

As described in Clause 5.13, on the Effective Date sanofi pasteur shall pay Emergent the FTE Costs and Emergent Expenses incurred between 1 January 2006 and the Effective Date as listed below;

### 4.1 FTE Costs

### **Number of FTE Months**

	Function	06	06	06
Mol Biol Purification		[**]	[**] [**]	[**] [**]
Schedule 2				2

Function	Jan 06	Feb 06	Mar 06
Purification management			
Pre-clinical Pre-clinical management	[**] [**]	[**] [**]	[**] [**]
Project leader	[**]	[**] [**]	[**] [**]
Total (FTE)	<u>[**1</u>	[**]	[**]
[**] FTE months = [**] FTEs			
FTE Cost Calculation			
FTE Cost = FTE Rate x Number of FTEs			
FTE Cost = £[**] x [**]			
FTE Cost = £[**]			
FTE Cost = £[**]			
4.2 Emergent Expenses			
4.2.2 Capital Expenditure Equipment			
Capital Expenditure Equipment purchased to date for the project work-plan is as follows. [**].			
			Total
Equipment		No.	Cost (£)
[**] [**]		[**]	[**] [**]
[**]		[**]	[**]
Total Costs to date (£)			[**]
Schedule 3			
Candidate Antigens			
Number	Candidates NMB No.	Emergent Designation	Function
[**]	[**]	[**]	[**]
Schedule 2			3
00100010 2			0

# Meningitis B — Proposed Commercialization Plan

Outline

# Executive Summary Meningitis Franchise Overview Meningococcal B vaccine — Market Strategy [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] Product Strategy [\*\*] [\*\*] [\*\*] [\*\*] [\*\*] [\*\*]

Disease & Product Communication

[\*\*]

[\*\*]

[\*\*] [\*\*]

Market Forecasts

[\*\*]

# **Emergent Independent Patent Rights**

1. Neisseria meningitidis vaccine candidates discovered using STM technology; entitled "Virulence Genes and Proteins and their use". (WO01/85772)

Document Type	Territory	Document Number (Application and Publication)
PCT		PCT/GB01/02003
		WO01/85772
National Filings	EP	01925742.7
	US	10/275026
	AU	52422/01
		776508
	AU/div	2004203417
	CA	2408738
	CN	01809191.1
	CN/div	Not Yet Known
	CZ	PV 2002-3642
	HK	03108186.4
	HU	P0302481
	JP	2001-582371
	KR	2002-7014876
	NO	2002-5329
	NZ	522277
	NZ	532297
	NZ	539912
	RU	2002132891
	RU/div	2005101623
	SG	2002068393
Continued overleaf		

Continued overleaf

# $2.\ NMB\ candidates\ discovered\ using\ PhoA\ technology;\ entitled\ ``Virulence\ Genes\ and\ Proteins\ and\ their\ use".\ (WO02/016612)$

Schedule 5

Document Type PCT	Territory	Document Number (Application and Publication) PCT/GB01/03759
rci		WO02/016612
		W 002/010012
National Filings	EP	01960908.0
National Finings		
	US	10/362327
	AU	2001/282299
	CA	2420261
	CN	01815395.X
	CZ	PV 2003495
	HK	05102145.5
	HU	P0300813
	IN	00223/DELNP/200
	JP	2002-522283
	KR	2003-7002608
	NO	2003 0821
	NZ	524277
	NZ/div	538864
	RU	2003107837
	SG	2003029345

2

# Press Announcement

[To be agreed]

Schedule 6

1

Activity Form

[To be agreed]

# The Inclusion Criteria

The goal being the development of a Product that will [\*\*].

Part I:

The Primary Inclusion Criteria for entry into Phase II clinical development

To be selected for a Phase II Study an Antigen [\*\*].

Part II:

Additional Inclusion Criteria [\*\*]

[\*\*], an antigen must [\*\*].

# **Patent Filing Countries**

[**]		
	(*)	$\mathbf{EP} =$
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]

### Worked Examples

### Net Sales, Adjusted Combination Net Sales and Royalty Burden

### Example 1: Where a Unitary Product is sold as a Unitary Product

A Unitary Product for meningitis B is sold in France. The Emergent Patent Rights in France include a Valid Claim that covers the Product. There are [\*\*] Programme Antigens and [\*\*] Additional Antigens in the Unitary Product. Net Sales of the Unitary Product in the relevant Quarter are  $\mathcal{E}[**]$ .

Step 1: Determine the applicable Royalty Rate for the Unitary Product

The royalty applicable under Clause 7.3(a) is [\*\*]% of Net Sales but as the Unitary Product contains Additional Antigens, Clause 7.4.1(a) applies. [\*\*] of the [\*\*] Antigens in the Unitary Product are Programme Antigens therefore the adjusted royalty rate is [\*\*]%.

The Royalty Burden comprises (i) the royalty payable to Emergent as set out in the royalty grid, i.e. [\*\*]% X Net Sales =  $\mathbb{E}[**]$ ; and (ii) the relevant royalties payable to Third Parties on the sale of the Unitary Product in France in the relevant Quarter (calculated in accordance with the relevant sanofi pasteur In-Licences) which in this example amount, in aggregate, to  $\mathbb{E}[**]$ .

The total royalty burden is  $\in$  [\*\*] or [\*\*]% of Net Sales of  $\in$  [\*\*]. As the royalty is increased to [\*\*]% if the Royalty Burden is [\*\*]% or less of Net Sales, the applicable royalty will be increased to [\*\*]%.

Step 2: Calculate the amount payable

The royalty payable to Emergent is [\*\*]% of  $\in$  [\*\*] =  $\in$  [\*\*].

Step 3: As the royalty has been increased from that stated in the royalty grid, recalculate the Royalty Burden to check whether it exceeds [\*\*]%.

The revised Royalty Burden is € [\*\*] plus € [\*\*] = € [\*\*] or [\*\*]%. As the revised Royalty Burden must not exceed [\*\*]%, the royalty increase is capped at [\*\*]%.

The royalty payable to Emergent is [\*\*]% of  $\in$  [\*\*] =  $\in$  [\*\*].

### Example 2: Combination Product comprising Menactra and a previously launched Unitary Product.

A Combination Product comprising Menactra and a Unitary Product for meningitis B is launched in France. The Emergent Patent Rights in France include a Valid Claim that covers the Product. There [\*\*] Programme Antigen and [\*\*] Additional Antigens in the Unitary Product. Net Sales of the Combination Product (before calculation of

Adjusted Combination Net Sales) in the relevant Quarter are  $\mathbb{C}[**]$ . The highest official list price of the Combination Product (C) is  $\mathbb{C}[**]$ .

Step 1: Calculate Adjusted Combination Net Sales using the formula A/(A+B) X Net Sales of the Combination Product

A is the highest official list price of the Unitary Product in France =  $\mathfrak{E}[**]$  B is the highest list price of Menactra in France =  $\mathfrak{E}[**]$  A/(A+B) = [\*\*]

Adjusted Combination Net Sales = [\*\*] X [\*\*]

=€[\*\*]

Step 2: Establish the applicable Royalty Rate for the Unitary Product within the Combination Product

The royalty applicable under Clause 7.3(a) is [\*\*]% of Adjusted Combination Net Sales but as the Unitary Product within the Combination Product contains Additional Antigens, Clause 7.4.1(a) applies. [\*\*] of the [\*\*] Antigens in the Unitary Product [\*\*] Programme Antigens therefore the adjusted royalty rate is [\*\*]%

The Royalty Burden comprises (i) the royalty payable to Emergent as set out in the royalty grid, i.e. [\*\*]% X Adjusted Combination Net Sales =  $\mathbb{E}[**]$ ; and (ii) the relevant royalties payable to Third Parties on the sale of the Combination Product in France in the relevant Quarter (calculated in accordance with the relevant sanofi pasteur In-Licences) which in this example amount, in aggregate, to  $\mathbb{E}[**]$ 

The total Royalty Burden is  $\in$  [\*\*] or [\*\*]% of Adjusted Combination Net Sales of  $\in$  [\*\*]. As a percentage of Adjusted Combination Net Sales, the Royalty Burden is more than [\*\*]% of Adjusted Combination Net Sales, therefore the royalty increase to [\*\*]% does not apply and the applicable royalty is [\*\*]%.

The royalty payable to Emergent pursuant to this provision is therefore [\*\*]% of Adjusted Combination Net Sales ( $\varepsilon$ [\*\*].

Step 3: Establish whether the minimum royalty applicable to Combination Products applies

(i) Apply the formula: [\*\*]% X the royalty rate applicable to the Unitary Product X (A/C) X Net Sales, which becomes

 $[**]\% \times [**]\% \times [**] \times \mathcal{E}[**] = \mathcal{E}[**]$ 

(ii) Apply the formula: [\*\*]% X Net Sales, which becomes

[\*\*]% X €[\*\*] = €[\*\*]

The royalty payable pursuant to both protection formulas is less than the royalty payable pursuant to Clause 7.3(a) (as adjusted pursuant to Clause 7.4.1) (as

Schedule 10

2

calculated as set out in Step 2 above) and therefore the minimum royalty provisions do not apply

The royalty payable to Emergent is therefore [\*\*]% of  $\in$ [\*\*] =  $\in$ [\*\*]

## Example 3: Combination Product comprising Menactra and a Unitary Product that has not been launched where a minimum royalty applies.

A Combination Product comprising Menactra and a Unitary Product for meningitis B is launched in France. The Emergent Patent Rights in France include a Valid Claim that covers the Product. There [\*\*] Programme Antigen and [\*\*] Additional Antigens in the Unitary Product, but it has not been launched in France. Net Sales of the Combination Product (before calculation of Adjusted Combination Net Sales) in the relevant Quarter are E[\*\*]. The highest official list price of the Combination Product (C) is E[\*\*].

Step 1: Calculate Adjusted Combination Net Sales using the formula A/(A+B) X Net Sales of the Combination Product. The Unitary Product has not been launched in France but there is a competitive product for the same indication. The highest official list price of the competitive product in France is E[\*\*]. B is the highest list price of Menactra in France = E[\*\*]. Therefore as in Example 2, E[\*\*] and Adjusted Combination Net Sales are E[\*\*].

Step 2: Establish the applicable Royalty Rate for the Unitary Product within the Combination Product. As in Example 2, the relevant royalty is [\*\*]% and the royalty payable to Emergent pursuant to this provision is [\*\*]% of Adjusted Combination Net Sales ( $\mathcal{E}$ [\*\*]) or  $\mathcal{E}$ [\*\*].

Step 3: Establish whether the minimum royalty applicable to Combination Products applies:

(i) Apply the formula: [\*\*]% X the royalty rate applicable to the Unitary Product X (A/C) X Net Sales, which becomes

$$[**]\% \times [**]\% \times [**] \times \mathcal{E}[**] = \mathcal{E} \ [**]$$

(ii) Apply the formula: [\*\*]% X Net Sales, which becomes

The royalty payable pursuant to the first protection formula is higher than the royalty payable pursuant to Clause 7.3(a) (as adjusted pursuant to Clause 7.4.1) (see Step 2 above) and therefore the minimum royalty provision prevails and the royalty payable is  $\in$  [\*\*].

# **Terminated Antigens**

	Candidates	Emergent	
Number	NMB No.	Designation	Function
[**]	[**]	[**]	[**]

## Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated May 23, 2006, in the Registration Statement (Form S-1) and related Prospectus of Emergent BioSolutions Inc. and Subsidiaries for the registration of an aggregate of \$86,250,000 of its common stock.

/s/ Ernst & Young LLP

McLean, Virginia August 14, 2006

# WILMERHALE

August 14, 2006

### BY ELECTRONIC SUBMISSION

Brian A. Johnson

+1 212 937 7206 (t) +1 212 230 8888 (f) brian.johnson@wilmerhale.com

Securities and Exchange Commission 100 F Street, N.E. Washington, DC 20549

Re: Emergent BioSolutions Inc.
Registration Statement on Form S-1

Dear Ladies and Gentlemen:

Submitted herewith for filing on behalf of Emergent BioSolutions Inc. (the "Company") is a Registration Statement on Form S-1 relating to the registration under the Securities Act of 1933, as amended (the "Securities Act"), of Common Stock of the Company.

This filing is being effected by direct transmission to the Commission's EDGAR System. In anticipation of this filing, the Company has caused the filing fee of \$9,229 to be wire transferred to the Commission's account at the Mellon Bank in Pittsburgh.

The Registration Statement relates to the Company's initial public offering of securities. It is the intent of the Company and the managing underwriters of the proposed offering to have the Registration Statement declared effective as early as possible.

Acceleration requests may be made orally, and the Company and the managing underwriters of the proposed offering have authorized us to represent on their behalf that they are aware of their obligations under the Securities Act with respect thereto.

Please contact the undersigned at (212) 937-7206 or David E. Redlick of WilmerHale at (617) 526-6434 with any questions or comments you may have regarding this filing.

Very truly yours,

/s/ Brian A. Johnson

Brian A. Johnson cc: David E. Redlick, Esq.

Wilmer Cutler Pickering Hale and Dorr LLP, 399 Park Avenue, New York, New York 10022

Baltimore Beijing Berlin Boston Brussels London Murich New York Northern Virginia Oxford Palo Alto Waltham Washington