As filed with the Securities and Exchange Commission on October 20, 2006.

Registration No. 333-136622

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 3 TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

EMERGENT BIOSOLUTIONS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	2834	14-1902018
(State or Other Jurisdiction of Incorporation or Organization)	*(Primary Standard Industrial Classification Code No.)*	*(I.R.S. Employer Identification No.)*

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 El-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:

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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 offering. o _____

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 Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common stock, $0.001 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. This amount has been paid previously.

(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 October 20, 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 shares of 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 additional shares of common stock to cover over-allotments. We will not receive any proceeds from the sale of shares by the selling stockholders.

Investing in our common stock involves a high degree of risk. See “Risk factors” beginning on page 9.

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, $127.3 million in 2005 and $61.3 million in the nine months ended September 30, 2006. 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 nine million doses of BioThrax through September 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 5.7 million doses of BioThrax. Our current contract with the DoD provides for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. 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. We have delivered approximately one million doses of BioThrax under this contract modification through September 2006.

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 and a next generation anthrax vaccine program with product candidates in preclinical and Phase I clinical 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, which we are developing in part with funding from NIAID;
- *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. In September 2006, we submitted three separate proposals in response to a request for proposals issued by NIAID in June 2006 for the advanced development and testing of next generation anthrax vaccine candidates. One of our proposals relates to a vaccine candidate that has completed a Phase I clinical trial.

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 fourth quarter 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 to:

- maximize the commercial potential of BioThrax;
- continue to develop a balanced portfolio of immunobiotic products;
- focus on core capabilities in product development and manufacturing;
- build a large scale manufacturing infrastructure;
- selectively establish collaborations; and
- seek governmental and other third party grants and support.

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, including the following:

- 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 and modification 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. We subsequently renamed BioPort as Emergent BioDefense Operations Lansing Inc.

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	shares
Common stock offered by the selling stockholders	shares if the underwriters exercise their over-allotment option in full
Common stock to be outstanding after this offering	shares
Preferred stock purchase rights	Each share of common stock offered hereby will have associated with it one preferred stock purchase right under a rights agreement that we will enter into in connection with this offering. The preferred stock purchase rights will initially trade together with the common stock. See “Description of capital stock — Stockholder rights plan.”
Use of proceeds	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 development of our biodefense and commercial product candidates and a portion of the construction costs of our new manufacturing facility in Lansing, Michigan and the balance for 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.
Risk factors	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	EBSI

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 September 30, 2006, and excludes:

- 1,091,779 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2006 at a weighted average exercise price of $7.30 per share;
- 128,206 additional shares of common stock reserved for issuance under our employee stock option plan as of September 30, 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.

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, $0.01 par value per share, has been reclassified as common stock, $0.001 par value per share, 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.

In addition, unless otherwise indicated, all information in this prospectus gives effect to the -for-one stock split of our common stock that will be effective prior to the completion of this offering.

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 nine-month periods ended September 30, 2005 and 2006 and as of September 30, 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.

(in thousands, except share and per share data)	Year ended December 31,			Nine months ended September 30,	
	2003	2004	2005	2005	2006
				(unaudited)	
Statements of operations data:					
Revenues:					
Product sales	$ 55,536	$ 81,014	$ 127,271	$ 85,807	$ 61,263
Collaborative research and grants	233	2,480	3,417	1,093	4,580
Total revenues	55,769	83,494	130,688	86,900	65,843
Operating expenses (income):					
Cost of product sales	22,342	30,102	31,603	23,147	11,645
Research and development	6,327	10,117	18,381	9,632	26,640
Selling, general & administrative	19,547	30,323	42,793	28,924	32,952
Purchased in-process research and development	1,824	—	26,575	26,575	477
Settlement of State of Michigan obligation	—	(3,819)	—	—	—
Litigation settlement	—	—	(10,000)	(10,000)	—
Total operating expenses	50,040	66,723	109,352	78,278	71,714
Income (loss) from operations	5,729	16,771	21,336	8,622	(5,871)
Other income (expense):					
Interest income	100	65	485	338	405
Interest expense	(293)	(241)	(767)	(575)	(778)
Other income (expense), net	168	6	55	(24)	291
Total other income (expense)	(25)	(170)	(227)	(261)	(82)
Income (loss) before provision for (benefit from) income taxes	5,704	16,601	21,109	8,361	(5,953)
Provision for (benefit from) income taxes	1,250	5,129	5,325	2,109	(2,617)
Net income (loss)	$ 4,454	$ 11,472	$ 15,784	$ 6,252	$ (3,336)
Earnings (loss) per share — basic	$ 0.68	$ 1.74	$ 2.21	$ 0.90	$ (0.43)
Earnings (loss) per share — diluted	$ 0.63	$ 1.61	$ 2.00	$ 0.82	$ (0.43)
Weighted average number of shares — basic	6,570,856	6,576,019	7,136,866	6,927,289	7,775,263
Weighted average number of shares — diluted	7,061,537	7,104,172	7,908,023	7,663,468	7,775,263

(in thousands)	As of September 30, 2006	
	Actual	As adjusted
		(unaudited)
Balance sheet data:		
Cash and cash equivalents	$ 19,906	$
Working capital	18,726	
Total assets	130,831	
Total long-term liabilities	35,606	
Total stockholders' equity	56,759	

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, our only marketed product, 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 and our only marketed product. We currently supply BioThrax to the DoD for immunization of military personnel and to HHS for placement into the strategic national stockpile. In 2005 and the nine months ended September 30, 2006, we derived substantially all of our revenue from our BioThrax contracts with the DoD and HHS. Our current contract with the DoD provides for the supply of BioThrax to the DoD through September 2007. Although the DoD has 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, the DoD has not issued a formal request for proposals for such a contract. We may not be awarded a follow-on contract on favorable terms or at all. For example, the DoD's minimum purchase obligations under any follow-on contract could be less than under our current contract with the DoD. 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.

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 any other company is successful in developing a next generation anthrax vaccine, U.S. government customers may purchase only the next generation vaccine and not 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. The failure to fund 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. We expect that any future contract that we enter into with the DoD will be structured in a similar manner. 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.

The success of our business with the U.S. government depends on our compliance with additional regulations and obligations under our U.S. government contracts.

Our business with the U.S. government is 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.

In addition, before awarding us any future contracts, the U.S. government could require that we respond satisfactorily to a request to substantiate our commercial viability and industrial capabilities. 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 substantial rights and remedies, many of which 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;
- exercise an option to purchase only the minimum amount specified in a contract;
- decline to exercise an option to purchase the maximum amount specified in a contract;
- claim rights in products, including intellectual property, developed 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.

Generally, government contracts, including our U.S. government contracts for BioThrax, contain provisions permitting unilateral termination or modification, 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.

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.

Ongoing legal proceedings or any future similar lawsuits could limit future purchases of BioThrax by the U.S. government.

The results of ongoing or future 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 on a mandatory basis without informed consent of the recipient or a Presidential waiver. Although we are not a party to this lawsuit, if further proceedings or any similar lawsuits 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. In October 2006, the DoD announced that it is resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency-essential and comparable civilian personnel. Furthermore, lawsuits brought against us by third parties, even if not successful, require us to spend time and money defending the related litigation.

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 addition, we were not profitable for the nine months ended September 30, 2006. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis. Our profitability is substantially dependent on revenues from BioThrax product sales. Revenues from BioThrax product sales have fluctuated significantly in recent quarters and may continue to fluctuate significantly from quarter to quarter based on the timing of our fulfilling orders from the U.S. government. 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 September 30, 2006, we had $36.5 million principal amount of debt outstanding and remaining borrowing availability of $7.8 million under our revolving lines of credit. Our business plan also contemplates that we will raise $10 million to $20 million of additional external debt financing to fund our facility expansion in Lansing, Michigan and to provide additional financial flexibility. We also may incur additional indebtedness beyond such amount.

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. In addition, a failure to comply with the covenants under our existing debt instruments could result in an event of default under those instruments. In the event of an acceleration of amounts due under our debt instruments as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness. 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 expect to require 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 our facility expansion in Lansing, Michigan. 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 and qualification activities required for regulatory approval and initiation of manufacturing. We anticipate that we will incur up to approximately $35 million for these purposes during 2006, of which we had incurred approximately $21 million through September 2006. 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 anticipate that we will incur up to $1 million related to initial engineering design and preliminary utility build out for these facilities during 2006, of which we had incurred approximately $234,000 through September 30, 2006. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that will be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project.

We expect to continue to fund a significant portion of our development and commercialization costs for our product candidates with internally generated funds from sales of BioThrax. 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. Our business plan currently contemplates that we will raise $10 million to $20 million of additional external debt financing to fund our facility expansion in Lansing and to provide additional financial flexibility. We may not be able to obtain this financing or otherwise be able 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 September 30, 2006, we had $19.9 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 and timing 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;
- our ability to obtain development funding from government entities and non-government and philanthropic organizations; 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. In addition to purchase obligations and orders under our contracts with the DoD and HHS for BioThrax sales, our only committed external sources of funds are remaining borrowing availability under our revolving lines of credit, development funding under our collaboration agreement with Sanofi Pasteur, funding from NIAID for animal efficacy studies of our anthrax immune globulin candidate 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 all.

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. 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 and qualification activities required for regulatory approval and initiation of manufacturing. We anticipate that we will incur up to approximately $35 million for these purposes during 2006, of which we had incurred approximately $21 million through September 30, 2006. In addition, we own two buildings in Frederick, Maryland that we plan to build out as future manufacturing facilities. We anticipate that we will incur up to $1 million related to initial engineering design and preliminary utility build out for these facilities during 2006, of which we had incurred approximately $234,000 through September 30, 2006. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that will be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project.

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 commercial sale. Cost overruns associated with constructing either our Lansing or Frederick facilities could require us to raise additional funds from external sources. We may not be able to do so on favorable terms or at all.

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. For example, under our BioThrax supply contract with the DoD, 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. If the DoD elects to purchase the maximum number of doses of BioThrax under the contract, we may not have sufficient available production capacity at our existing manufacturing facility in Lansing to allow us to increase sales of BioThrax to customers other than the U.S. government. 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.

Our only long-term manufacturing agreements are our agreement with Talecris Biotherapeutics, Inc., for purification and fractionation of plasma for our anthrax immune globulin candidate, and our collaboration with HPA, under which HPA provides specialized manufacturing capabilities for our recombinant bivalent botulinum vaccine candidate and the bivalent botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin candidate. Third party 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.

Our general liability and umbrella insurance policies provide for coverage up to annual aggregate limits of $12 million with a deductible of $15,000 per occurrence, but exclude coverage for liabilities relating to the release of pollutants. We do not currently hold insurance policies expressly providing for coverage relating to our use of hazardous materials other than storage tank liability insurance for our Lansing, Michigan facility with a $1 million annual aggregate limit and a deductible of $10,000 per claim. The

insurance that we currently hold may not be adequate to cover all liabilities relating to accidental contamination or injury as a result of pollution conditions or other extraordinary or unanticipated events.

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, which is 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 trials or animal studies 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 studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. A failure of one or more of our clinical trials or animal efficacy studies can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial or animal efficacy study 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 studies produce negative or inconclusive results;
- we might have to suspend or terminate our clinical trials if the participants 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. We plan to conduct a Phase I clinical trial to evaluate the safety of the botulinum toxoid vaccine. If the results are favorable, we expect that the Phase I clinical trial will provide data sufficient to support an acceptable dose for the vaccine and the optimal dosing schedule. As a result, we anticipate that the FDA will not require us to conduct a Phase II clinical trial for the botulinum toxoid vaccine before permitting us to initiate a donor stimulation program for our botulinum immune globulin candidate. However, the FDA has not approved our plan to proceed directly to a donor stimulation program without conducting a Phase II clinical trial for the botulinum toxoid vaccine and may not do so. 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. These potential customers include the U.S. Postal Service, foreign governments, state and local governments, which we expect will be interested in BioThrax to protect first responders, such as police, fire and emergency medical personnel, multinational companies, non-governmental organizations and hospitals. 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. To date, we have made only minimal sales to these customers. In particular, we have supplied small amounts of BioThrax directly to several foreign governments. 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. We expect to complete construction of our new manufacturing facility in Lansing in mid 2007. We anticipate that we will initiate large scale manufacturing of BioThrax for commercial sale at the new facility in 2008. Until the new manufacturing facility 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. Recombinant technology comprises scientific techniques that allow for the manipulation of genetic material. Scientists apply these techniques to disease-causing organisms known as pathogens. Using recombinant technology, it is possible to delete a virulent gene from a pathogen or isolate the gene directing the production of the component of a pathogen known as an antigen and move the antigen into a harmless organism from which it can be purified and used as a vaccine. Because BioThrax is not a recombinant vaccine, BioThrax was precluded from consideration under that procurement program.

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 June 2006, NIAID issued a request for proposals for the advanced development and testing of next generation anthrax vaccine candidates with specified properties, including shelf life of three years or longer at room temperature, 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, one of which has completed a Phase I clinical trial, and have submitted three separate proposals in response to the NIAID request for proposals, we may not be successful in our development efforts or receive any funding from NIAID.

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.

The use of vaccines carries a risk of adverse health effects that must be weighed against the expected health benefit of the product. The adverse reactions that have been associated with the administration of BioThrax are similar to those observed following the administration of other adult vaccines and include local reactions, such as redness, swelling and limitation of motion in the inoculated arm, and systemic reactions, such as headache, fever, chills, nausea and general body aches. In addition, some serious adverse events have been reported to the vaccine adverse event reporting system database maintained by the CDC and the FDA with respect to BioThrax. The report of any such adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event. These serious adverse events, including diabetes, heart attacks, autoimmune diseases, including Guillian Barre syndrome, lupus and multiple sclerosis, lymphoma and death, have not been causally linked to the administration of BioThrax.

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, including related litigation, 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 on a mandatory basis 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 limit demand for BioThrax and our biodefense product candidates and harm our future business. In October 2006, the DoD announced that it is resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency-essential and comparable civilian personnel.

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.

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. We believe our most significant competitor for the supply of BioThrax to the U.S. government is VaxGen. HHS has awarded VaxGen a contract to supply 75 million doses of recombinant protective antigen vaccine for the strategic national stockpile.

We also face significant competition for our biodefense immunobiotic product candidates. We face significant competition for NIAID funding for development and testing of a next generation anthrax vaccine from other companies who responded to the NIAID request for proposals issued in June 2006. If we continue to pursue the development of a next generation anthrax vaccine, we also expect that we will face significant competition for the supply of our product candidate to the U.S. government. HHS has awarded strategic national stockpile supply contracts to Cangene for an anthrax immune globulin and Human Genome Sciences for a monoclonal antibody to *Bacillus anthracis* as a post-exposure therapeutic for anthrax infection. Several companies have botulinum vaccines in early clinical or preclinical development. HHS has awarded Cangene a contract to develop a heptavalent botulinum immune globulin derived from equine plasma and supply a botulinum immune globulin for the strategic national stockpile.

One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the United States and Europe. Numerous companies have vaccine candidates in development that would compete with any of our commercial immunobiotic product candidates for which we obtain marketing approval.

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.

In August 2006, the Department of Homeland Security approved our application 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 product. Although 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. The plaintiff in each of these three lawsuits claims different injuries and seeks varying amounts of damages. The first plaintiff alleges that the vaccine caused erosive rheumatoid arthritis and requests damages in excess of $1 million. The second plaintiff alleges that the vaccine caused Bell's palsy and other related conditions and requests damages in excess of $75,000. The third plaintiff alleges that the vaccine caused a condition that originally was diagnosed as encephalitis related to a gastrointestinal infection and caused him to fall into a coma for many weeks and requests damages in excess of $10 million.

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 Emergent BioDefense Operations, 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 small usage fee for 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 II 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 BioThrax as a post-exposure prophylaxis, our immune globulin candidates, our recombinant bivalent botulinum vaccine candidate and a next generation anthrax vaccine 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.

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. Our application is based on an interim analysis of data from an ongoing clinical trial being conducted by the CDC to evaluate whether as few as three doses of BioThrax, administered over six months, will confer adequate immune response over as long as 42 months. 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. We currently are awaiting the final data from the CDC trial, which we expect at the end of 2007.

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 products or 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 may 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 do so, our ability to maintain and defend our intellectual property rights 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 participate in monthly meetings with the trial investigators and in the annual review meeting for this trial and provide input to the CDC for responses to FDA questions and requests for additional information. We expect to rely on data from these development efforts in seeking marketing approval for our product candidates. For example, our BLA supplement for a label expansion of BioThrax for a regimen of fewer doses is based on the interim trial report provided to us by the CDC from its ongoing clinical trial. We currently are awaiting the final data from the CDC trial, which we expect at the end of 2007. 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.

If we are unable to in license the necessary components of a next generation anthrax vaccine, we will not be successful in developing or commercializing such a product candidate.

If we continue to pursue the development of a next generation anthrax vaccine, including a product candidate relating to any of the proposals we submitted in September 2006 in response to a NIAID request for proposals, we expect that we will need to in license various components of the product candidate, including an adjuvant and novel delivery technologies. There are a limited number of companies from whom we can license these components. We may be unable to obtain licenses to the necessary components of a next generation anthrax vaccine on acceptable terms, or at all. If we are unable to obtain these licenses, we could be prevented from continuing further development of a product candidate that we select for development. Ultimately, even if our development efforts are successful, we could be prevented from commercializing a next generation anthrax vaccine if we are unable to enter into licenses on acceptable terms.

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 patent 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.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may 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 these third parties do not do so, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties. Under our collaboration agreement with Sanofi Pasteur for our meningitis B vaccine candidate, we have the right to prosecute and maintain our patent rights under the collaboration agreement. Sanofi Pasteur is responsible for prosecuting and maintaining joint patent rights under the collaboration agreement, although we have the right to support the continued prosecution or maintenance of the joint patent rights if Sanofi Pasteur fails to do so. In addition, Sanofi Pasteur has the first right to pursue claims against third parties for infringement of the patent rights under the collaboration agreement and assume the defense of any infringement claims that may arise, although we have the right to pursue infringement claims against third parties and assume the defense of infringement claims if Sanofi Pasteur fails to do so. Under 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, HPA is responsible for prosecuting and maintaining patent rights, although we have the right to support the continued prosecution or maintenance of the patent rights if HPA fails to do so. In addition, we have the first right to pursue claims against third parties for infringement of the patent rights and assume the defense of any infringement claims that may arise.

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 and other intellectual property rights of third parties under which we do not hold licenses or other rights. Third parties may own or control these patents and intellectual property rights 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 or other similar 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 or other similar 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. For example, we are aware of and are monitoring ongoing litigation between Bavarian Nordic and Acambis relating to the manufacture of the modified vaccinia virus Ankara, or MVA, as a smallpox vaccine for biodefense use by the U.S. government. We have licensed from the Bavarian State Ministry of the Environment, Public Health and Consumer Protection rights to materials and technology related to MVA. Our MVAtor™ platform technology, which is based on these licensed rights, could potentially be used as a viral vector for delivery of multiple vaccine antigens for different disease-causing organisms, including influenza, using recombinant technology. As a result, our licensed rights and our ability to use our MVAtor platform technology could be negatively affected by the outcome of this ongoing litigation. It also is possible that we could be named as a defendant in future similar litigation relating to MVA. 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. For example, we have filed an opposition in the European Patent Office against Bavarian Nordic's patent covering certain aspects of the MVA 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, including through his ability to control the election of the members of our board of directors, 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 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, 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.

Our stockholder rights plan could prevent a change in control of our company in instances in which some stockholders may believe a change in control is in their best interests.

In connection with this offering, we will enter into a rights agreement that establishes our stockholder rights plan. Under the rights agreement, 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 its 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 at the same time the initial public offering price of our common stock is determined. Our stockholder rights plan is 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. The 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.

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. Based on 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, investors in this offering will incur immediate dilution of $ per share. To the extent outstanding options are exercised, you will incur further dilution. In addition, based on 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, investors in this offering will have contributed approximately % of the total consideration paid by all purchasers of our common stock but will own only approximately % of our common stock outstanding 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, 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. 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 and assuming no exercise of options outstanding as of September 30, 2006. Of the shares to be outstanding after the completion of this offering, the shares of common stock sold in this offering will be freely tradable without restriction under 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.

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.”

Upon expiration of the 180-day lock-up period, 7,782,016 shares of our common stock outstanding as of September 30, 2006, representing approximately % of our common stock outstanding after this offering, will be eligible for sale under Rule 144. In general, shares eligible for sale under Rule 144 are subject to volume limitations. However, within 180 days after the date of this prospectus, 30,015 shares of our common stock outstanding as of September 30, 2006 will be eligible for sale under Rule 144(k) without regard to volume limitations. Mr. El-Hibri has the power to dispose of or direct the disposition of 5,108,718 shares of our common stock outstanding as of September 30, 2006, representing approximately % of our common stock outstanding after this offering. These shares are eligible for sale under Rule 144, subject to volume limitations.

Moreover, after this offering, holders of an aggregate of 7,752,001 shares of our common stock outstanding as of September 30, 2006 will have the right to require us to register these shares of common stock under specified circumstances.

In addition, of the 1,091,779 shares of our common stock that may be issued upon the exercise of options outstanding as of September 30, 2006, approximately shares will be vested and eligible for sale within 180 days after the date of this prospectus, subject to any lock-up agreements applicable to these shares. Promptly following this offering, we intend to file a registration statement on Form S-8 registering the sale of up to 2,678,985 shares of common stock subject to outstanding options and options and other awards issuable pursuant to our equity incentive plans. Shares registered under this registration statement on Form S-8 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.

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,” “will,” “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.

If we fund the following solely with the net proceeds from this offering without allocating funds from other sources, we currently estimate that we will use:

- approximately $13 million of these net proceeds to fund development of our biodefense product candidates, comprised of approximately $3 million for label expansions and improvements for BioThrax, approximately $5 million for a next generation anthrax vaccine candidate and approximately $5 million for our anthrax immune globulin candidate;
- approximately $19 million of these net proceeds to fund clinical development of our commercial product candidates, comprised of approximately $6 million for our typhoid vaccine candidate and approximately $13 million for our hepatitis B therapeutic vaccine candidate;
- approximately $20 million of these net proceeds to fund a portion of the construction costs of our new manufacturing facility in Lansing, Michigan; and
- the balance of these net proceeds for general corporate purposes, which may include the build out of our manufacturing facilities in Frederick, Maryland, the expansion of our sales and marketing organization, the acquisition or in license of technologies, products or businesses, working capital and capital expenditures.

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 facility 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.

Based on our planned use of proceeds described above, we expect that the net proceeds from this offering will be sufficient to enable us to complete:

- for our biodefense product candidates, the work necessary to support our applications to the FDA to further extend the shelf life and reduce the number of required doses for BioThrax, stability testing of a next generation anthrax vaccine candidate, including manufacture of bulk drug substance, and animal efficacy studies and a Phase I safety and pharmacokinetic trial of our anthrax immune globulin candidate; and

- for our commercial product candidates, a Phase II clinical trial, a disease surveillance study to prepare for a Phase III clinical trial and the manufacture of initial clinical material for such Phase III clinical trial of our typhoid vaccine candidate and a Phase II clinical trial of our hepatitis B therapeutic vaccine candidate.

It is possible that we will not achieve the progress that we expect because the actual costs and timing of development, particularly clinical trials, are difficult to predict, subject to substantial risks and often vary depending on the particular indication and development strategy.

We do not expect that our existing cash and cash equivalents, committed sources of funds and net proceeds from this offering alone will be sufficient to enable us to fund the completion of the development of any of our product candidates or all of the construction costs of our new manufacturing facility in Lansing. We expect to continue to fund a significant portion of our development and commercialization costs with internally generated funds from sales of BioThrax. In particular, our planned use of proceeds described above assumes that we will fund continued development of our recombinant bivalent botulinum vaccine candidate, our botulinum immune globulin candidate, our group B streptococcus vaccine candidate and our commercial preclinical product candidates with funds from sales of BioThrax and grant funding without allocating any of the net proceeds from this offering. Accordingly, our need for additional external sources of funds for these purposes will depend significantly on the level and timing of our sales of this product. Our business plan also contemplates that we will raise $10 million to $20 million of additional external debt financing to fund the Lansing facility construction and to provide additional financial flexibility. If we do not obtain this additional debt financing, we may need to reduce spending for other purposes in order to complete this construction project.

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 September 30, 2006:

- on an actual basis; and
- on an as adjusted basis to give effect to:
  - the reclassification of our class A common stock, $0.01 par value per share, as common stock, $0.001 par value per share, 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 September 30, 2006	
(in thousands, except share and per share data)	**Actual**	**As adjusted(1)**
		(unaudited)
Long-term indebtedness, including current portion	$36,410	$
Notes payable to employees	63	
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 30,015 shares issued and outstanding, actual; no shares authorized, issued or outstanding, as adjusted	—	
Common stock, $0.001 par value per share; no shares authorized, issued or outstanding, actual; 100,000,000 shares authorized and shares issued and outstanding, as adjusted	—	
Preferred stock, $0.01 par value per share, 3,000,000 shares authorized, actual; $0.001 par value per share, 15,000,000 shares authorized, as adjusted; no shares issued or outstanding, actual and as adjusted	—	
Additional paid-in capital	35,024	
Accumulated other comprehensive loss	(182)	
Retained earnings	21,839	
Total stockholders' equity	56,759	
Total capitalization	$93,232	$

(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:

- 1,091,779 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2006 at a weighted average exercise price of $7.30 per share;
- 128,206 additional shares of common stock reserved for issuance under our employee stock option plan as of September 30, 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 September 30, 2006 was $56.8 million or $7.29 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 September 30, 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 September 30, 2006	$ 7.29	
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 September 30, 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		Total consideration		Average price per share
	Number	Percentage	Amount	Percentage	
Existing stockholders	7,782,016	%	$ 35,102,225	%	$ 4.51
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 September 30, 2006 and excludes:

- 1,091,779 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2006 at a weighted average exercise price of $7.30 per share;
- 128,206 additional shares of common stock reserved for issuance under our employee stock option plan as of September 30, 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 , 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 , or approximately % of the total number of shares of our common stock outstanding after this offering.

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 nine-month periods ended September 30, 2005 and 2006 and the consolidated balance sheet data as of September 30, 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,					Nine months ended September 30,	
(in thousands, except share and per share data)	**2001**	**2002**	**2003**	**2004**	**2005**	**2005**	**2006**
						(unaudited)	
Statements of operations data:							
Revenues:							
Product sales	$ 45,309	$ 78,541	$ 55,536	$ 81,014	$ 127,271	$ 85,807	$ 61,263
Collaborative research and grants	—	—	233	2,480	3,417	1,093	4,580
Total revenues	45,309	78,541	55,769	83,494	130,688	86,900	65,843
Operating expenses (income):							
Cost of product sales	34,367	24,569	22,342	30,102	31,603	23,147	11,645
Research and development	382	2,808	6,327	10,117	18,381	9,632	26,640
Selling, general & administrative	10,924	13,397	19,547	30,323	42,793	28,924	32,952
Purchased in-process research and development	—	—	1,824	—	26,575	26,575	477
Settlement of State of Michigan Obligation	—	—	—	(3,819)	—	—	—
Litigation settlement	—	—	—	—	(10,000)	(10,000)	—
Total operating expenses	45,673	40,774	50,040	66,723	109,352	78,278	71,714
Income (loss) from operations	(364)	37,767	5,729	16,771	21,336	8,622	(5,871)
Other income (expense):							
Interest income	122	80	100	65	485	338	405
Interest expense	(193)	(451)	(293)	(241)	(767)	(575)	(778)
Other income (expense), net	(119)	(271)	168	6	55	(24)	291
Total other income (expense)	(190)	(642)	(25)	(170)	(227)	(261)	(82)
Income (loss) before provision for (benefit from) income taxes	(554)	37,125	5,704	16,601	21,109	8,361	(5,953)
Provision for (benefit from) income taxes	—	733	1,250	5,129	5,325	2,109	(2,617)
Net income (loss)	$ (554)	$ 36,392	$ 4,454	$ 11,472	$ 15,784	$ 6,252	$ (3,336)
Earnings (loss) per share — basic	$ (0.10)	$ 5.68	$ 0.68	$ 1.74	$ 2.21	$ 0.90	$ (0.43)
Earnings (loss) per share — diluted	$ (0.10)	$ 5.05	$ 0.63	$ 1.61	$ 2.00	$ 0.82	$ (0.43)
Weighted average number of shares — basic	5,651,192	6,409,661	6,570,856	6,576,019	7,136,866	6,927,289	7,775,263
Weighted average number of shares — diluted	5,561,192	7,212,903	7,061,537	7,104,172	7,908,023	7,663,468	7,775,263

(in thousands)	2001	2002	2003	2004	As of December 31, 2005	As of September 30, 2006 (unaudited)
Balance sheet data:						
Cash and cash equivalents	$ 5,854	$ 4,891	$ 7,119	$ 6,821	$ 36,294	$ 19,906
Working capital	(35,299)	1,130	(3,147)	7,509	29,023	18,726
Total assets	25,423	22,790	37,127	69,056	100,332	130,831
Total long-term liabilities	4,857	4,592	1,228	11,921	10,502	35,606
Total stockholders' equity (deficit)	(32,295)	4,155	8,448	22,949	59,737	56,759

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 subsequently renamed BioPort as Emergent BioDefense Operations Lansing Inc. 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 Limited. 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 and a next generation anthrax vaccine program with product candidates in preclinical and Phase I clinical 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 nine million doses of BioThrax through September 2006 for immunization of military personnel. Our current contract with the DoD provides for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. 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 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 delivered approximately one million doses of BioThrax under this contract modification through September 2006.

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, $127.3 million in 2005 and $61.3 million in the nine months ended September 30, 2006. 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, in part with funding from NIAID. We have submitted three separate proposals for testing and development of three distinct next generation anthrax vaccine product candidates, featuring attributes such as self-administration and a longer shelf life, in response to a request for proposals issued by NIAID. We are actively pursuing additional government sponsored development grants and working with various government agencies to encourage them to conduct studies relating to BioThrax and our other 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 candidate.

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 and qualification activities required for regulatory approval and initiation of manufacturing. We anticipate that we will incur up to approximately $35 million for these purposes during 2006, of which we had incurred approximately $21 million through September 2006. We expect to complete construction of this facility in mid 2007, with validation and qualification activities required for regulatory approval continuing thereafter. 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 for commercial sale 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 $1 million related to initial engineering design and preliminary utility build out for these facilities during 2006, of which we had incurred approximately $234,000 through September 30, 2006. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that will be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the 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 cannot sell BioThrax to our customers without written FDA approval for each lot that we manufacture. As part of the FDA review process, we submit a detailed lot protocol for each BioThrax lot that we produce for external sale. We also are required to submit product samples to the FDA for testing. Although we generally submit lot protocols and product samples promptly following the satisfactory completion of internal testing, we are permitted to submit product samples in advance of the lot protocols. The length of the FDA review process is approximately four to six weeks. However, individual lots may be released sooner or later depending on factors including: reviewer questions, license supplement approval, reviewer availability and whether our internal testing of product samples is completed before or concurrently with FDA testing. During the period covered by our financial statements included in this prospectus, the FDA has not denied the sale of any BioThrax lots that we have submitted for approval.

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. The earnings process is complete 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. We do not record allowances for sales returns, rebates or special promotional programs for sales of BioThrax or provisions for sales made in prior periods.

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 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 upfront license fee, the development work and the milestone payments under our agreement with Sanofi Pasteur should be accounted for as a single unit of accounting. We recognize amounts received under this agreement over the estimated development period as we perform services. We recorded the amount of the upfront license fee as deferred revenue. We are recognizing this revenue over the estimated development period under the contract, currently estimated at seven years, as adjusted from time to time for any delays or acceleration in the development of the product candidate. Under the collaboration agreement, we are entitled to payments up to specified levels for development work we perform for Sanofi Pasteur. 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. Under the collaboration agreement, we also will be entitled to royalty payments on any future net sales of this product candidate.

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. We capitalize the costs associated with the manufacture of BioThrax as inventory from the initiation of the manufacturing process through the completion of manufacturing, labeling and packaging.

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. 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 September 30, 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 $385,000 for the nine months ended September 30, 2006 related to stock options that were outstanding and had not completely vested as of January 1, 2006. During the nine months ended September 30, 2006, we granted 90,000 stock options. We recorded additional stock-based compensation expense of $57,000 related to these options during the nine months ended September 30, 2006. Both basic and diluted loss per share for the nine months ended September 30, 2006 are $0.03 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 September 30, 2006, total compensation expense not yet recognized related to unvested options is approximately $970,000, after tax. We expect to recognize that expense over a weighted average period of 2.8 years. Based on options granted to employees as of September 30, 2006, we expect to recognize amortization of stock-based compensation, after tax, of approximately $143,000 during the remainder of 2006, $464,000 in 2007, $250,000 in 2008 and $113,000 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 results of operations;
- our prospects for growth, including potential contracts for BioThrax product sales;
- our available cash, assets and financial condition;
- 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 risks related to and the lack of a liquid market for the shares;
- the time frame in which a liquid market would likely be available for the shares;
- business developments involving our direct competitors; and
- general economic trends and the economic outlook and market conditions 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.

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. We delivered approximately 5.2 million total doses of BioThrax, representing 97% of our total revenues, in 2005. We delivered approximately 2.5 million total doses of BioThrax, representing 93% of our total revenues, in the nine months ended September 30, 2006. 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. These items accounted for 3% of our total revenues in 2005 and 7% of our total revenues in the nine months ended September 30, 2006. 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. We have delivered approximately one million doses of BioThrax under this contract modification through September 2006. We expect to deliver to HHS between 1.25 million and 1.75 million doses of BioThrax in each of November 2006 and December 2006, with the balance, if any, to be delivered in the first half of 2007 prior to expiration of the contract.

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 the original terms of this contract, we were required to deliver a minimum of approximately 3.8 million total doses through September 2006. We delivered approximately 4.9 million total doses in 2004, 2005 and the nine months ended September 30, 2006 under DoD purchase orders. We have amended our current contract with the DoD to provide for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. We expect to deliver to the DoD approximately 480,000 of these doses by December 2006, with the balance to be delivered by September 2007. 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 September 30, 2006, the amount of our deferred revenue for DoD sales was $8.4 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, the DoD has not issued a formal request for proposals for such a contract and 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 recognize the upfront license fee, 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 our fulfilling orders for BioThrax. We expect collaborative research and grant revenues to increase in 2006 compared to 2005 as we receive reimbursement for development expenses under our meningitis B collaboration with Sanofi Pasteur, 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 and funding from NIAID for costs associated with our animal efficacy studies in rabbits of our anthrax immune globulin candidate.

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;
- our ability to obtain adequate supplies of our product candidates required for later stage clinical trials, including from third party manufacturers;
- 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, cost associated with manufacturing our product candidates on a large scale basis for later stage clinical trials, 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 the term loan that we entered into in August 2006, as well as any borrowings under our revolving lines 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

Nine months ended September 30, 2006 compared to nine months ended September 30, 2005

Revenues

Product sales revenues, which relate only to the biodefense segment, decreased by $24.5 million, or 29%, to $61.3 million for the nine months ended September 30, 2006 from $85.8 million for the nine months ended September 30, 2005. This decrease in product sales revenues was primarily due to a 29% decrease in the number of doses we delivered as a result of the timing of our fulfilling orders from the DoD and HHS. Product sales revenues in the nine months ended September 30, 2006 consisted of BioThrax sales to HHS of $35.4 million, sales to the DoD of $25.3 million and sales to the Canadian government of $630,000. Product sales revenues in the nine months ended September 30, 2005 consisted of BioThrax sales to HHS of $69.9 million, sales to the DoD of $14.5 million, sales to the Canadian government of $1.1 million and other sales of $291,000.

Collaborative research and grant revenues increased by $3.5 million to $4.6 million for the nine months ended September 30, 2006 from $1.1 million for the nine months ended September 30, 2005. Collaborative research and grant revenues for the nine months ended September 30, 2006 consisted of $3.2 million in upfront and development program revenue from the Sanofi Pasteur collaboration and $1.5 million in grant revenue from the Wellcome Trust. Collaborative research and grant revenues for the nine months ended September 30, 2005 resulted from reimbursement from the DoD for expenses related to production development and supply chain management improvements for BioThrax incurred in prior periods, and for 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, which relate only to the biodefense segment, consists of expenses incurred in the manufacture of BioThrax. Cost of product sales decreased by $11.5 million, or 50%, to $11.6 million for the nine months ended September 30, 2006 from $23.1 million for the nine months ended September 30, 2005. This decrease was attributable to the delivery of 1.0 million fewer doses of BioThrax in the nine months ended September 30, 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 reduction in costs of approximately $6.8 million. Manufacturing efficiencies resulted in a cost savings of approximately $4.7 million.

Research and development expenses

Research and development expenses increased by $17.0 million to $26.6 million for the nine months ended September 30, 2006 from $9.6 million for the nine months ended September 30, 2005. This increase reflects increased expenses of $9.1 million in the biodefense segment and $8.8 million in the commercial segment, offset by a reduction of $892,000 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. This increase primarily reflects additional personnel and contract service costs. The increase in spending for BioThrax enhancements is related to preparing for animal efficacy studies to support applications for marketing approval of these enhancements, which we expect to submit to the FDA in 2008. 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

program, which is in preclinical development, resulted from advancing this program to the process development stage and the manufacture of clinical trial material. The increase in spending for the next generation anthrax vaccine program, which has product candidates in preclinical and Phase I clinical development, resulted from formulation development and the manufacture of clinical trial material.

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. This increase primarily reflects additional personnel and contract service costs. Research and development spending by Microscience prior to our acquisition of Microscience in June 2005 is not included in our results for the nine months ended September 30, 2005. The spending in the nine months ended September 30, 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 nine months ended September 30, 2006 for our hepatitis B therapeutic vaccine candidate resulted from preparing for our Phase II clinical trial that we plan to initiate in the fourth quarter of 2006. The spending in the nine months ended September 30, 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 nine months ended September 30, 2005 and 2006 are shown in the following table:

	Nine months ended September 30,	
(in thousands)	**2005**	**2006**
Biodefense:		
BioThrax enhancements	$ 1,815	$ 2,678
Immune globulin development	2,154	6,947
Recombinant bivalent botulinum vaccine	718	1,323
Next generation anthrax vaccine	180	3,032
Total biodefense	4,867	13,980
Commercial:		
Typhoid vaccine	897	4,483
Hepatitis B therapeutic vaccine	727	2,508
Group B streptococcus vaccine	411	1,764
Chlamydia vaccine	431	1,225
Meningitis B vaccine	670	1,943
Total commercial	3,136	11,923
Other	1,629	737
Total	$ 9,632	$ 26,640

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $4.0 million, or 14%, to $33.0 million for the nine months ended September 30, 2006 from $28.9 million for the nine months ended September 30, 2005. Selling, general and administrative expenses related to the biodefense segment decreased by $194,000, or 1%, to $24.4 million for the nine months ended September 30, 2006 from $24.6 million for the nine months ended September 30, 2005. Selling, general and administrative expenses related to the commercial segment increased by $4.2 million, or 98%, to $8.5 million for the nine months ended September 30, 2006 from $4.3 million for the nine months ended September 30, 2005. The increase in the commercial segment was primarily attributable to an increase in general and administrative expenses of $3.6 million resulting from the addition of personnel and facilities for Emergent Product Development UK following our acquisition of Microscience in June 2005.

Purchased in-process research and development

In June 2005, we recorded a non-cash charge for purchased in-process research and development 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 are amortizing this charge for tax purposes over 15 years.

In July 2006, we recorded a non-cash charge for purchased in-process research and development of $477,000 associated with our acquisition of ViVacs GmbH, a German limited liability company. We paid total purchase consideration of $250,000 and assumed a net deficit of liabilities in excess of assets of $47,000. We valued the acquisition at $430,000 after the inclusion of acquisition costs. Of this amount, we identified $153,000 as current assets, $97,000 as fixed assets, $297,000 as current liabilities and $477,000 as the value attributable to development programs and technology. Because we determined that, for accounting purposes, the development programs and technology had no future alternative use, we charged the value attributable to the development programs and technology as purchased in-process research and development. We will amortize this charge for tax purposes over 15 years.

Litigation settlement

In June 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 for the nine months ended September 30, 2006.

Total other income (expense)

Total other expense decreased by $179,000 to $82,000 for the nine months ended September 30, 2006 from $261,000 for the nine months ended September 30, 2005. The decrease resulted principally from an increase in interest income of $67,000 as a result of higher investment return on increased average cash balances, an increase in interest expense of $203,000 related primarily to the mortgage loan we entered into in April 2006 and the term loan we entered into in August 2006, and an increase in other income (expense) of $315,000.

Income taxes

We recorded a benefit from income taxes of $2.6 million for the nine months ended September 30, 2006 compared to a provision for income taxes of $2.1 million for the nine months ended September 30, 2005. The benefit from income taxes for the nine months ended September 30, 2006 resulted primarily from our loss before benefit from income taxes of $6.0 million and an estimated effective annual tax rate of 44%. The provision for income taxes for the nine months ended September 30, 2005 resulted primarily from our income before provision for income taxes of $8.4 million and an estimated effective annual tax rate of 25%. The increase in the estimated effective annual tax rate by 19% is due primarily to an increase in the valuation allowance related to estimated 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 for such tax assets 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. This increase in product sales revenues was primarily due to a 52% increase in the number of doses delivered. 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.

Collaborative research 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 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 development 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:

(in thousands)	Year ended December 31, 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 additional personnel professional service providers 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 Emergent Product Development UK 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, as described above, we recorded a non-cash charge of $26.6 million for purchased in-process research and development associated with our acquisition of Microscience.

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. This increase in product sales revenues was primarily due to a 45% increase in the number of doses delivered. 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.

Collaborative research 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 approximately 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 and consisted primarily of personnel and contract service costs. 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 and increased costs for professional service providers. 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. We paid total purchase consideration of $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 are amortizing 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 September 30, 2006 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases, revenues under our collaboration agreement with Sanofi Pasteur, development funding from government entities and non-government and philanthropic organizations 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, but incurred a loss in the nine months ended September 30, 2006. As of September 30, 2006, we had cash and cash equivalents of $19.9 million.

Cash flows

The following table provides information regarding our cash flows for the years ended December 31, 2003, 2004 and 2005 and the nine months ended September 30, 2005 and September 30, 2006.

	Year ended December 31,			Nine months ended September 30,	
(in thousands)	2003	2004	2005	2005	2006
Net cash provided by (used in):					
Operating activities(1)	$11,072	$ 9,196	$41,974	$21,581	$ (8,032)
Investing activities	(7,917)	(18,175)	(5,841)	(2,317)	(32,741)
Financing activities	(927)	8,681	(6,660)	(6,574)	24,385
Total net cash provided (used)	$ 2,228	$ (298)	$29,473	$12,690	$(16,388)

(1) Includes the effect of exchange rate changes on cash and cash equivalents.

Net cash used in operating activities of $8.0 million in the nine months ended September 30, 2006 resulted principally from our net loss of $3.3 million, an increase in inventories of $11.6 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 $4.9 million, reflecting our net loss before provision for income taxes for the period, offset by an increase in accounts payable of $6.1 million related to expenses incurred but unpaid at September 30, 2006 and an increase in deferred revenue of $4.6 million related to amounts billed under our contract with the DoD and deferral of a portion of the upfront license fee from Sanofi Pasteur. The net loss for the period and the increase in inventory are primarily related to the timing of our fulfilling orders from the DoD and HHS. The increase in deferred revenue primarily reflects progress billings to the DoD, pursuant to our contract, for product not yet released or shipped and, therefore, not recorded as revenue during the period.

Net cash provided by operating activities of $21.6 million in the nine months ended September 30, 2005 resulted principally from our net income of $6.3 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 in accounts receivable of $16.3 million as a result of the collection of amounts due from the DoD during 2005 for invoices outstanding at the end of 2004 for progress in the manufacture of BioThrax lots, offset by a reduction in deferred revenue of $10.9 million, reflecting the recognition of revenue related to the delivery to the DoD of BioThrax lots for which we had previously invoiced the DoD for progress payments and been paid, and an increase in deferred tax assets of $10.3 million, reflecting a deferred tax asset recorded to reflect the timing differences between the book charge and the tax deferral of expense related to the purchased in-process research and development expense related to the Microscience acquisition.

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 related 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 outstanding 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 been paid and an increase in deferred tax assets of $11.0 million, reflecting a deferred tax asset recorded to reflect the timing differences between the book charge and the tax deferral of expense related to 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, an increase in income taxes payable of $5.8 million related to the timing of payment of taxes and related deferred tax assets, and an increase in deferred revenue of $3.9 million, reflecting invoices to and payments from the DoD for progress in 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 and payments from the DoD for progress in 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 nine months ended September 30, 2006 and 2005 and in 2005, 2004 and 2003 resulted principally from the purchase of property, plant and equipment. Capital expenditures in the nine months ended September 30, 2006 relate primarily to costs for construction of our new building in Lansing, Michigan and the acquisition of our second facility in Frederick, Maryland. Capital expenditures in 2005 were primarily attributable to investments in information technology upgrades and miscellaneous facility enhancements. Capital expenditures in 2004 include infrastructure investments of $4.7 million, $3.8 million for an enterprise resource planning system and $8.5 million for the purchase of one of our facilities in Frederick, Maryland. 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 provided by financing activities of $24.4 million in the nine months ended September 30, 2006 resulted primarily from proceeds from notes payable related to the financing of the purchase of our Frederick facility in May 2006 and the financing of a portion of the costs related to the construction of our new building in Lansing. Net cash used in financing activities of $6.6 million in the nine months ended September 30, 2005 resulted principally from the payment of a special dividend from a portion of the proceeds of a litigation settlement and 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 September 30, 2006.

							Payments due by period
(in thousands)	**Total**	**2006**	**2007**	**2008**	**2009**	**2010**	**After 2010**
Contractual obligations:							
Short and long-term debt(1)	$ 49,707	$ 3,504	$ 5,627	$ 5,297	$ 5,287	$ 5,286	$ 24,707
Operating lease obligations	15,919	422	1,699	1,801	686	647	10,664
Contractual settlement liabilities	200	100	100	—	—	—	—
Total contractual obligations	$ 65,826	$ 4,026	$ 7,426	$ 7,098	$ 5,973	$ 5,933	$ 35,371

(1) Includes scheduled interest payments.

The preceding table excludes contingent contractual payments that we may become obligated to make upon achievement of specified research, development and commercialization milestones and contingent contractual royalty payments. We are not obligated to pay any minimum royalties under our existing contracts.

Debt financing

As of September 30, 2006, we had $36.5 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;
- $8.4 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;
- $1.3 million outstanding under a term loan from Fifth Third Bank used to finance the purchase of an enterprise resource planning system;
- $2.2 million outstanding under a $10.0 million revolving line of credit with Fifth Third Bank;
- $10.0 million outstanding under a term loan from HSBC Realty Credit Corporation used to finance a portion of the costs of our facility expansion in Lansing, Michigan; and
- $5.0 million outstanding under a $5.0 million revolving line of credit with HSBC Realty Credit Corporation.

We can borrow under the line of credit with Fifth Third Bank through November 2006 and under the line of credit with HSBC Realty Credit Corporation through October 2007.

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 of not less than $5.0 million. In addition, we are required to maintain at all times 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 term loan and revolving line of credit with HSBC Realty Credit Corporation, we are required to maintain on an annual basis a minimum tangible net worth of not less than the sum of 85% of our tangible net worth for the most recently completed fiscal year plus 25% of current net operating profit after taxes. In addition, we are required to maintain on a quarterly basis a ratio of earnings before interest, taxes, depreciation and amortization for the most recent four quarters to the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable for the following four quarters, of not less than 1.25 to 1.00.

- Under our line of credit with Fifth Third Bank, our wholly owned subsidiary, Emergent BioDefense Operations, is 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. Our term loan and revolving line of credit with HSBC Realty Credit Corporation limit the ability of Emergent BioDefense Operations to incur indebtedness and liens, sell assets, make loans, advances or guarantees, enter into merger or similar transactions and enter into transactions with affiliates. Our term loan and revolving line of credit with HSBC Realty Credit Corporation also limit our ability to incur indebtedness and liens, enter into merger or similar transactions and enter into transactions with affiliates. Our line of credit with Fifth Third Bank limits the ability of Emergent BioDefense Operations to incur indebtedness and liens, sell assets, make loans, advances or guarantees, enter into merger or similar transactions, 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. Our term loan and revolving line of credit with HSBC Realty Credit Corporation are secured by substantially all of Emergent BioDefense Operations' assets, other than 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 upon maturity in October 2011. Interest is payable monthly and accrues at an annual rate of 6.625% through October 2009. In October 2009, the interest rate is scheduled to be adjusted to a fixed annual rate equal to 3.20% over the yield on U.S. government securities adjusted to a constant maturity of two years.

Under our mortgage loan from HSBC Realty Credit Corporation, we are required to make monthly principal payments. A residual principal repayment of approximately $7.5 million is due upon maturity in April 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.00%.

Under our term loan from Fifth Third Bank, we make monthly principal payments through maturity in September 2007. Interest is payable monthly and accrues at an annual rate equal to 0.375% less than the prime rate of interest established from time to time by Fifth Third Bank.

Under our revolving line of credit with Fifth Third Bank, any outstanding principal is due upon maturity in November 2006. Interest is payable monthly and accrues at an annual rate equal to 0.375% less than the prime rate of interest established from time to time by Fifth Third Bank.

Under our term loan with HSBC Realty Credit Corporation, we are required to make monthly principal payments beginning in April 2007. A residual principal payment of approximately $4.0 million is due upon maturity in August 2011. Upon our request, the term loan is subject to an extension term in the sole discretion of HSBC Realty Credit Corporation for five additional years until August 2016 for an extension fee of 1.00% of the principal balance of the loan. If the term of the loan were extended, we would be required to continue to make monthly principal payments through maturity in August 2016 in lieu of the residual principal payment otherwise due in August 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.75%.

Under our revolving line of credit with HSBC Realty Credit Corporation, we are not required to repay outstanding principal until October 2007. In October 2007, the outstanding principal under the revolving line of credit will convert to a term loan with required monthly principal payments through maturity in August 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.75%. We also are required to pay a fee on a quarterly basis equal to 0.50% of the average daily difference between $5.0 million and the amount outstanding under the revolving line of credit.

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. We expect to continue to fund a significant portion of our development and commercialization costs for our product candidates with internally generated funds from sales of BioThrax. There are numerous risks and uncertainties associated with BioThrax product sales and with the development and commercialization of our product candidates. Our business plan also contemplates that we will raise $10 million to $20 million of additional external debt financing to fund our facility expansion in Lansing and to provide additional financial flexibility. In addition to purchase obligations and orders under our contracts with the DoD and HHS for BioThrax sales, our only committed external sources of funds are remaining borrowing availability under our revolving lines of credit with HSBC Realty Credit Corporation and Fifth Third Bank, development funding under our collaboration agreement with Sanofi Pasteur, funding from NIAID for animal efficacy studies of our anthrax immune globulin candidate 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 and timing 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;
- our ability to obtain development funding from government entities and non-government and philanthropic organizations; 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 us.

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 September 2006, the FASB issued Statement No. 157, *Fair Value Measurements*, or SFAS No. 157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 emphasizes

that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. The provisions of SFAS No. 157 are effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Prior to adoption, we will evaluate the impact of adopting SFAS No. 157 on our financial statements.

In June 2006, the FASB 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.

In March 2006, the FASB issued Statement No. 156, *Accounting for Servicing of Financial Assets — an amendment of FASB Statement No. 140*, or SFAS No. 156. SFAS No. 156 requires an entity to recognize a servicing asset or servicing liability each time it undertakes an obligation to service a financial asset by entering into a servicing contract based on certain conditions. The provisions of SFAS No. 156 are effective for fiscal years beginning after September 15, 2006. SFAS No. 156 will have no immediate impact on our consolidated financial statements.

In February 2006, the FASB issued Statement No. 155, *Accounting for Certain Hybrid Financial Instruments — an amendment of FASB Statements No. 133 and 140*, or SFAS No. 155. SFAS No. 155 permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement No. 133, establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives and amends Statement No. 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. The provisions of SFAS No. 156 are effective for fiscal years beginning after September 15, 2006. SFAS No. 155 will have no immediate impact on our consolidated 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, $127.3 million in 2005 and $61.3 million in the nine months ended September 30, 2006. 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 nine million doses of BioThrax through September 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. Our current contract with the DoD provides for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. 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 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 delivered approximately one million doses of BioThrax under this contract modification through September 2006.

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 have three biodefense immunobiotic product candidates in preclinical development and a next generation anthrax vaccine program with product candidates in preclinical and Phase I clinical development. Our biodefense product candidates in preclinical development are:

- *Anthrax immune globulin* — for post-exposure treatment of anthrax infection, which we are developing in part with funding from NIAID;
- *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. In September 2006, we submitted three separate proposals in response to a request for proposals issued by NIAID in June 2006 for the advanced development and testing of next generation anthrax vaccine candidates. One of our proposals relates to a vaccine candidate that has completed a Phase I clinical trial.

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 fourth quarter 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 a 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 for commercial sale at the 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, NIAID has completed an independent animal

efficacy study of BioThrax in combination with antibiotics as a post-exposure prophylaxis for anthrax infection. NIAID has awarded us grant funding for animal efficacy studies of our anthrax immune globulin candidate. 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 that use 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 antigens, are often used in combination with weaker antigens, 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 directing the production of 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. For more information about our agreements with HPA, see “Intellectual property and licenses — License agreements — HPA agreements.” For more information about our collaboration with Sanofi Pasteur, see “— Sanofi Pasteur collaboration.”

Immunobiotic	Therapeutic/ prophylactic	Stage of development	Status	Collaboration/external relationship
Biodefense				
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 clinical trial ongoing	CDC — independent clinical trial
	Prophylactic	Post-approval label expansion	Single dose syringe development program initiated	
BioThrax (anthrax vaccine adsorbed)*	Post-exposure prophylactic	Post-approval label expansion	Phase I clinical trial ongoing; two proof-of-concept animal studies completed	
Next generation anthrax vaccine*	Pre-exposure and post-exposure prophylactic	Phase I and preclinical	Responses submitted to NIAID request for proposals	
Anthrax immune globulin*	Therapeutic	Preclinical	Plasma donor stimulation program ongoing; animal efficacy studies planned; plan to file IND in late 2006 or early 2007	NIAID — funding for animal efficacy studies in rabbits
Botulinum				
Recombinant bivalent botulinum vaccine*	Prophylactic	Preclinical	Proof-of-concept animal study completed	HPA — collaboration
Botulinum immune globulin*	Therapeutic	Preclinical	Proof-of-concept animal studies planned	HPA — collaboration for development of a new botulinum toxoid vaccine
Commercial				
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

* 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."

No assessment of the safety or efficacy of our vaccine candidates can be considered definitive until all clinical trials needed to support a submission for marketing approval are completed. The results of our completed preclinical tests and Phase I clinical trials do not ensure that our planned later stage clinical trials for our vaccine candidates will be successful. A failure of one or more of our clinical trials can occur at any stage of testing.

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 nine million doses of BioThrax through September 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 5.7 million doses of BioThrax. Our current contract with the DoD provides for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. In October 2006, the DoD announced that it is resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency-essential and comparable civilian personnel. For personnel not deployed in high threat areas or no longer assigned designated special mission roles, vaccination will be 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. We have delivered approximately one million doses of BioThrax under this contract modification through September 2006.

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, $127.3 million in 2005 and $61.3 million in the nine months ended September 30, 2006.

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 the 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 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 BioThrax.

As with any pharmaceutical product, the use of vaccines carries a risk of adverse health effects that must be weighed against the expected health benefit of the product. The adverse reactions that have been associated with the administration of BioThrax are similar to those observed following the administration of other adult vaccines and include local reactions, such as redness, swelling and limitation of motion in the inoculated arm, and systemic reactions, such as headache, fever, chills, nausea and general body aches. In addition, some serious adverse events have been reported to the vaccine adverse event reporting system database maintained by the CDC and the FDA with respect to BioThrax. The report of any such adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event. These serious adverse events, including diabetes, heart attacks, autoimmune diseases, including Guillian Barre syndrome, lupus and multiple sclerosis, lymphoma and death, have not been causally linked to the administration of BioThrax.

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 in late 2006.
- *Reduce doses for pre-exposure prophylaxis.* 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. Our application is based on an interim analysis of data from an ongoing clinical trial being conducted by the CDC to evaluate whether as few as three doses of BioThrax, administered over six months, will confer adequate immune response over as long as 42 months. 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 final data from the CDC trial, which we expect at the end of 2007,

are favorable, we plan to apply to the FDA in 2008 for approval of a three dose regimen of BioThrax for pre-exposure prophylaxis, with a booster dose once every three years thereafter.

- *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, NIAID 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 additional 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 initiate the rabbit efficacy study in late 2006 and the nonhuman primate efficacy study in late 2007. The timing of our nonhuman primate efficacy study depends upon the successful development of a nonhuman primate model by NIAID. In September 2006, we initiated a Phase I clinical trial of BioThrax for this indication using three doses of BioThrax given two weeks apart. The purpose of this trial is to obtain additional immunogenicity data regarding BioThrax using the planned three dose regimen. Depending on the results of this ongoing clinical trial, the FDA could require us to conduct a second human immunogenicity clinical trial. Under the FDA animal rule, we believe that, if the results are favorable, the rabbit and nonhuman primate animal efficacy studies together with the human immungenicity clinical trial data would be sufficient to support the filing with the FDA of a biologics license application, or BLA, supplement for marketing approval of BioThrax for this indication.

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 September 2006, we submitted three separate proposals in response to a request for proposals issued by NIAID in June 2006 for the advanced development and testing of next generation anthrax vaccine candidates. One of our proposals relates to BioThrax combined with VaxImmune. VaxImmune, a product of Coley Pharmaceuticals Group, is an adjuvant intended to enhance immune response. We are designing our product candidate to be administered by needle-free intramuscular injection.
The DoD's Defense Advanced Research Projects Agency, or DARPA, previously funded a double-blind Phase I clinical trial of this product candidate pursuant to a collaboration among DARPA, Coley Pharmaceuticals and us. This trial, which was completed in 2005, was designed to

evaluate the safety and immunogenicity of this product candidate compared to BioThrax alone and VaxImmune alone. In this trial, the product candidate was administered in three doses by intramuscular injection in 69 healthy volunteers. The immunogenicity results from this trial were statistically significant.

The results of a clinical trial are statistically significant if they are unlikely to have occurred by chance. We determined the statistical significance of the trial results based on a widely used, conventional statistical method that establishes the p-value of the results. Under this method, a p-value of 0.05 or less represents statistical significance. Immune responses observed in a group of vaccine trial participants can be compared with those observed in other groups of trial participants or with an assumed response rate. Immunogenicity alone does not establish efficacy for purposes of regulatory approval. Immunogenicity data only provide indications of efficacy and are neither required nor sufficient to enable a product candidate to proceed to Phase II clinical development. Phase I clinical trials are required to establish the safety of a product candidate, not its immunogenicity, before Phase II clinical trials may begin.

The immunogenicity parameters for this trial were the mean peak antibody concentration in trial participants who received the product candidate as compared to trial participants who received BioThrax alone and the median time between first injection and mean peak immune response. In this trial, the mean peak concentration of antibodies to anthrax protective antigen in participants who received the product candidate was approximately 6.3 times higher than in participants who received BioThrax alone. This result was statistically significant, with a p-value of less than 0.001. Participants who received BioThrax alone achieved a mean peak concentration of antibodies to anthrax protective antigen approximately 42.5 days after first injection. Participants who received the product candidate achieved this same mean antibody concentration approximately 21 days earlier. This result was statistically significant, with a p-value of less than 0.001. In this trial, there was a slightly higher frequency of moderate injection site reactions and systemic adverse events in the volunteers who received the product candidate as compared to volunteers who received BioThrax alone or VaxImmune alone. One volunteer withdrew from this trial because of an adverse event. There were no serious adverse events reported that the trial investigators considered related to the product candidate, BioThrax or VaxImmune.

The NIAID request for proposals specified 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. 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. In August 2004, HHS issued a request for proposals in which HHS indicated that it was seeking between 10,000 and 200,000 therapeutic courses of treatment of a product to treat inhalational anthrax disease. The products sought by HHS included monoclonal and polyclonal antibodies, human immune globulin and other protein therapeutic products. Pursuant to this request 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. NIAID has provided us grant funding of up to $3.7 million for the studies designed to assess the tolerability, pharmacokinetics and efficacy of this product candidate in infected rabbits and the development and validation of product assays. 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 supply 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 at 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 serotype B derived from the starting material for the pentavalent vaccine developed by the Michigan Department of Public Health and serotype A from HPA. 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 to confirm the suitability of the vaccine for further development. If the results of this proof-of-concept study are favorable, based on a demonstration of protective efficacy or an immune response associated with protection, we plan to file an IND to initiate a Phase I clinical trial to evaluate the safety of this vaccine in healthy volunteers. We expect that the Phase I clinical trial will provide data sufficient to support an acceptable dose for the vaccine and the optimal dosing schedule. 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. This data includes the results of a Phase II safety and immunogenicity clinical trial conducted by the DoD from July 1998 to May 2000, animal efficacy data and the extensive use of the pentavalent vaccine by the CDC in immunizing at risk laboratory personnel. 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. However, the FDA has not approved our plan to proceed directly to a donor stimulation program without conducting a Phase II clinical trial for the botulinum toxoid vaccine and may not do so.

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. The immunogenicity parameter for this trial was the proportion of trial participants with an immune response to the product candidate on day seven after dosing or day 28 after dosing. To be considered adequately immunogenic, 50% of the participants receiving a vaccine dose had to satisfy the primary immunogenicity endpoint. We performed analyses on both an intent to treat and a per protocol basis. An intent to treat analysis is based on the participants who receive a dose of vaccine. A per protocol analysis is based on the participants who complete a trial and substantially comply with the trial protocol. In both the intent to treat population and the per protocol population, 100% of the trial participants in the highest dose group and 56% of the participants in the lowest dose group had an immune response on day seven or day 28. The immune response rate for the highest dose group was statistically significantly greater than the immune response rate for the lowest dose group, with a p-value of 0.0068 in the intent to treat population and 0.0073 in the per protocol population.
- 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. The immunogenicity parameter for this trial was the proportion of trial participants with a humoral antibody response to *S. typhi* following administration of a single dose of the vaccine candidate. The immune response rate was 94% for the participants who received the bottled water presentation and 93% for the participants who received the tap water presentation. The response rate for both groups was statistically significantly higher than the assumed response rate of 50%. The p-value was 0.0005 for the participants who received the bottled water presentation and 0.0010 for the participants who received the tap water presentation. 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. Based on initial data from 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. We are continuing to analyze the data from this trial.

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 S*almonella* 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 primary immunogenicity parameter for this trial was the proportion of trial participants with an immune response to the product candidate on day 28 after dosing or day 84 after dosing. In this trial, 50% of the participants in the low dose group

and 40% of the participants in the high dose group demonstrated an immune response on day 28 or day 84. The results in the low dose group reflect a confidence interval of 19.0% to 81.0%. The results in the high dose group reflect a confidence interval of 18.5% to 61.5%. These confidence intervals indicate a 95% likelihood that the true value is within the range specified. In addition, the vaccine elicited a cellular immune response in all participants after two doses, indicating that the antigen had been successfully delivered to the immune system. The secondary immunogenicity endpoint for this trial was the proportion of participants who demonstrated the type of immune response known to be important in promoting clearance of hepatitis B at any point during the trial. In this trial, 100% of the participants in the high dose group and 90% of the participants in the low dose group demonstrated such a response. We did conduct a statistical analysis of the results from the secondary immunogenicity endpoint. 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 trial participants 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 trial participants in the fourth quarter of 2006.

If the results of this Phase II clinical trial are favorable, we expect to submit an IND to the FDA to conduct one or more clinical trials of this vaccine candidate in the United States as may be appropriate. The IND must become effective before we can conduct any clinical trials in the United States.

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. We performed analyses on both an intent to treat and a per protocol basis. In both the intent to treat population and the per protocol population, the immunogenic response rate was 83% at the lowest dose tested and 100% at the highest dose tested. The response rate for both the highest dose group and the lowest dose group was statistically significantly higher than the assumed response rate of 50%. For the lowest dose group, the p-value was 0.0386 in both the intent to treat population and the per protocol population. For the highest dose group, the p-value was 0.0039 in the intent to treat population and 0.0078 in the per protocol population. 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. If the results of these Phase I clinical trials are favorable, we expect to submit an IND to the FDA to conduct more advanced clinical trials in the United States. The IND must become effective before we can conduct any clinical trials in the United States.

We are in active discussions with NIH to provide clinical development support for this product candidate.

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 approximately 92 million new cases of *Chlamydia trachomatis* infection occur annually worldwide, approximately 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 bacterial meningitis occur annually worldwide, resulting in approximately 135,000 deaths. The World Health Organization estimates that approximately 500,000 of these cases and 50,000 of these deaths are caused by the bacterium *Neisseria meningitidis*. 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 an initial fee 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 uncured material breach of the agreement or bankruptcy.

Facilities

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

Location	Use	Segment	Approximate square feet	Owned/leased
Lansing, Michigan	Manufacturing operations facilities and office space	Biodefense	214,000	Owned
Frederick, Maryland	Future manufacturing facilities	Biodefense/ Commercial	290,000	Owned
Gaithersburg, Maryland	Office and laboratory space	Biodefense/ Commercial	36,000	Leases expire 2008
Rockville, Maryland	Office space	Biodefense/ Commercial	23,000	Lease expires 2016
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 egress 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 for commercial sale 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. Our Lansing facilities and substantially all of the other assets of our wholly owned subsidiary, Emergent BioDefense Operations Lansing Inc., other than accounts receivable under our DoD and HHS contracts, 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.”

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 product development and a portion of our potential future product manufacturing requirements. Our preliminary plans contemplate that the site would be designed to provide product development and pilot plant production capabilities, full scale commercial manufacturing operations, warehouse and storage facilities, fill and finish operations and administrative office space. We expect that we will complete the build out of this site in several stages. Our preliminary plans contemplate a build out of one of the two buildings on this site to accommodate product development, pilot plant, initial product launch capabilities and administrative office space during 2008 and 2009. Our preliminary plans also contemplate that we will build out commercial manufacturing operations two to three years after establishing initial product launch capabilities.

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 current 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. We plan to relocate our executive offices to our Rockville facility in late 2006.

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. However, we also expect that we will continue to use third parties for production of preclinical and clinical supplies of some 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 remains 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 also 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 and contract fill and finish operations.

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 co-commercialization 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.

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. 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:

- *Next generation anthrax vaccine.* We expect that NIAID will issue multiple contracts to fund future development and testing of a next generation anthrax vaccine pursuant to its request for proposals issued in June 2006. We face significant competition for NIAID funding from other companies that have responded to this NIAID request for proposals. If we continue to pursue the development of a next generation anthrax vaccine, we also expect that we will face significant competition for the supply of our product candidate to the U.S. government.
- *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.
- *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 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 government funding from other defensive measures, including medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures.

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 NIAID.
- *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 September 30, 2006, we owned or licensed a total of 20 U.S. patents and 44 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 28 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 34 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 S*almonella* 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 40 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 develop 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 current product portfolio or development pipeline are our agreements

with HPA, which are described below. We also have a license agreement with the Bavarian State Ministry of the Environment, Public Health and Consumer Protection, or StMUGV, relating to a viral vector technology that we may use in the development of future product candidates, which is also 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 paid minimum contractual commitments of $1.0 million under each development agreement 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 terminated.

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.

MVAtor Platform Technology. In July 2006, in connection with our acquisition of ViVacs GmbH, a German limited liability company, we acquired a license agreement with StMUGV that provides us the non-exclusive, worldwide right to develop and produce viruses and viral products, including recombinant viral vectors, using the modified vaccinia virus Ankara, or MVA. Our MVAtor platform technology, which is based on these licensed rights, could potentially be used as a viral vector for delivery of multiple vaccine antigens for different disease-causing organisms, including influenza, using recombinant technology.

Under the license agreement, we are required to pay StMUGV:

- a percentage of the net revenue or license fees, as applicable, that we receive from products developed using MVA that are used for research or other purposes; and
- a percentage of the license fees that we receive from products developed using MVA that are licensed as starting material for the production of a smallpox vaccine.

The license agreement does not have a specified term. Each party may terminate the license agreement as a result of an uncured material breach by the other party. In addition, StMUGV may terminate the license agreement upon the insolvency or liquidation of our wholly owned subsidiary, Emergent Product Development GmbH, formerly ViVacs GmbH.

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. We amended this contract in October 2006. As amended, this contract provides for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. We expect to deliver to the DoD approximately 480,000 of these doses by December 2006, with the balance to be delivered by September 2007. The DoD may submit additional orders under this contract through February 2007.

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. We expect to complete delivery of all five million additional doses by the first half of 2007. Our contract with 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. In August 2006, the Department of Homeland Security approved our application 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 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 filing, 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 trial.

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 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.

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, the 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 manufacturers 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. Although sales of BioThrax are subject to the protections of the Safety Act, our 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, 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 or modification 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. The plaintiffs in each of these three lawsuits claim different injuries and seek varying amounts of damages. The first plaintiff alleges that the vaccine caused erosive rheumatoid arthritis and requests damages in excess of $1 million. The second plaintiff alleges that the vaccine caused Bell's palsy and other related conditions and requests damages in excess of $75,000. The third plaintiff alleges that the vaccine caused a condition that originally was diagnosed as encephalitis related to a gastrointestinal infection and caused him to fall into a coma for many weeks and requests damages in excess of $10 million.

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. We expect to rely on contractual indemnification provisions with the DoD and statutory protections to limit our potential liability resulting from these three lawsuits.

MilVax 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 MilVax 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 on a mandatory basis 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. 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, Emergent BioDefense Operations is a defendant, along with many other vaccine manufacturers, in a series of lawsuits that have been filed 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, including brain damage, central nervous system damage and autism. No specific dollar amount of damages has been claimed. Emergent BioDefense Operations 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 September 30, 2006, we had 466 employees, including 127 employees engaged in product development, 240 employees engaged in manufacturing, six employees engaged in sales and marketing and 93 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 September 30, 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, Emergent BioDefense Operations Lansing Inc.
Steven N. Chatfield, Ph.D.	49	President, Emergent Product Development UK Limited, and Chief Scientific Officer
Daniel J. Abdun-Nabi	52	Senior Vice President Corporate Affairs, General Counsel and Secretary
Kyle W. Keese	44	Senior Vice President Marketing and Communications
Thomas K. Zink, M.D.	50	Senior Vice President and Chief Medical Officer
R. Don Elsey	53	Vice President Finance, Chief Financial Officer and Treasurer
Joe M. Allbaugh	55	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. We subsequently renamed BioPort as Emergent BioDefense Operations Lansing Inc. 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 chairman 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 Emergent BioDefense Operations Lansing Inc., formerly 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 wholly owned 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.

Thomas K. Zink, M.D. Dr. Zink has served as senior vice president of medical affairs and chief medical officer since May 2006. Dr. Zink served as the director of immunization practices and scientific affairs of

GlaxoSmithKline Vaccines, USA, a subsidiary of GlaxoSmithKline plc**,** a pharmaceutical company, from September 1999 to November 2004. After leaving GlaxoSmithKline and prior to joining Emergent, Dr. Zink served as a pro bono consultant on issues of patient safety and consumer-driven healthcare. Prior to joining GlaxoSmithKline, Dr. Zink served as the medical director for Prudential HealthCare of Kansas City, Missouri Region and as the chief medical officer of the Medicare Peer Review Organization of the State of Missouri. Dr. Zink also spent over a decade as a practicing physician specializing in emergency medicine. Dr. Zink received his joint B.A./M.D. from the University of Missouri-Kansas City and holds a current medical license as a physician and surgeon in good standing.

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 of Ecosphere Systems, Inc., a subsidiary of Ecosphere Technologies, a technology company serving the homeland security, disaster response and defense markets, since September 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. From August 2002 to February 2003, Mr. Richard served as president of Stem Cell Preservation, Inc., a start-up medical research company. After leaving Stem Cell Preservation and prior to joining Emergent, Mr. Richard served as a strategic business advisor for IGEN International, Inc., a biotechnology company. 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:

- Mr. El-Hibri, Mr. Hauer and Mr. Richard will serve as class I directors, and their terms will expire at our 2007 annual meeting;
- Dr. Harsanyi and Dr. Sullivan will serve as class II directors, and their terms will expire at our 2008 annual meeting; and
- Mr. Allbaugh and Dr. Malik 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.

In October 2006, Mr. Hauer was hospitalized with a serious, unexpected medical condition from which he is beginning to recover. We cannot determine when, or if, Mr. Hauer will be able or willing to resume active participation as a member of our board of directors.

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. The nominating and corporate governance committee meeting fee is $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. Each member of our nominating and corporate governance committee receives 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 under our 2006 stock incentive plan.

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

Name and principal position	Annual compensation			Long-term compensation	All other compensation(1)
	Salary	Bonus	Other annual compensation	Shares underlying options	
Fuad El-Hibri President, Chief Executive Officer and Chairman of the Board of Directors	$ 490,818	$ 237,215	$ —	75,000	$ 7,000
Edward J. Arcuri, Ph.D. Executive Vice President and Chief Operating Officer	280,192	94,517	—	40,000	—
Robert G. Kramer, Sr. President and Chief Executive Officer, Emergent BioDefense Operations Lansing Inc.	371,192	140,816	—	40,000	7,000
Steven N. Chatfield, Ph.D. President, Emergent Product Development UK Limited and Chief Scientific Officer	225,162	82,250	38,752(2)	20,000	—
Daniel J. Abdun-Nabi Senior Vice President Corporate Affairs, General Counsel and Secretary	272,631	110,400	—	—	7,000

(1) Represents the value of our contributions on behalf of the named executive officer to our 401(k) savings plan.

(2) 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	Potential realizable value at assumed annual rates of stock price appreciation for option term(1)	
					5% ($)	10% ($)
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	—	—	—	—		

(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

Name	Number of shares acquired on exercise	Value realized	Number of securities underlying unexercised options at December 31, 2005		Value of unexercised in-the-money options at December 31, 2005	
			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 September 2006, 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. Emergent Product Development UK may terminate Dr. Chatfield's employment for cause, as defined in the agreement, upon providing the statutory minimum period of notice required under English law. 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 agreement, Dr. Chatfield is entitled to protections substantially similar to those in our severance plan and termination protection program, except Dr. Chatfield is not entitled to a gross-up payment with respect to applicable taxes in the circumstances provided in the severance plan and termination protection program. See "— Severance plan and termination protection program" for additional information about our severance plan and termination protection program. If Emergent Product Development UK terminates Dr. Chatfield's employment without cause, as defined in the agreement, then Dr. Chatfield is entitled to 75% of his annual base salary and continued eligibility for employee benefits for a period of nine months following the date of termination. Dr. Chatfield is entitled to 100% of his annual base salary and continued eligibility for employee benefits for a period of

12 months following the date of termination of his employment under the circumstances described in the severance plan and termination protection program in connection with a change of control, as defined in the agreement.

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
Thomas K. Zink, M.D.	75	9 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, general manager of Intervac, L.L.C. and Intervac Management, L.L.C., 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
Thomas K. Zink, M.D.	75	9 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 September 30, 2006, options to purchase 1,091,779 shares of our class B common stock at a weighted average exercise price of $7.30 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 142,951 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.

Rule 10b5-1 trading plans

We expect that many of our executive officers and directors will adopt written plans, known as Rule 10b5-1 trading plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 trading plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The officer or director may amend or terminate the plan in some circumstances. Our executive officers and directors may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information. Under the terms of the lock-up agreements that our executive officers and directors have signed with the underwriters for this offering, our executive officers and directors can enter into Rule 10b5-1 trading plans during the 180-day lock-up period, provided that such plan does not provide for any transfers of common stock during the lock-up period or any extension thereof pursuant to the lock-up agreement.

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. We subsequently renamed BioPort as Emergent BioDefense Operations Lansing Inc.

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. We filed the lawsuit in 2002 in an effort to clarify intellectual property rights and recover royalties that we 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 September 30, 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, Emergent BioDefense Operations 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 Emergent BioDefense Operations 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 November 2007. The agreement will automatically extend for an additional five years if Emergent BioDefense Operations achieves $5.0 million of sales in the territory during the initial three-year term of the agreement.

In January 2000, Emergent BioDefense Operations entered into a termination and settlement agreement with Intergen. Under the agreement, Emergent BioDefense Operations 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, Emergent BioDefense Operations 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 El-Hibri is the chairman of East West Resources and was president of East West Resources from September 1990 to January 2004. Fuad El-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, Emergent BioDefense Operations 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 $19,741 in the nine months ended September 30, 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. We paid East West Resources $5,482 in the nine months ended September 30, 2006 under the agreement. 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 hold 100% of the ownership 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 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 and $320,765 in 2004. We paid total cash compensation to Mr. Gibellini of $278,969 for 2005, including an annual bonus for 2005 paid in 2006. 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 September 30, 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 and $63,282 in 2004. We paid total cash compensation to Mr. Grunenwald of $69,337 for 2005, including an annual bonus for 2005 paid in 2006. 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 Emergent BioDefense Operations, 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, Emergent BioDefense Operations entered into an employment agreement with Dr. Myers in his role as senior policy and science advisor to Emergent BioDefense Operations. 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 September 30, 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 September 30, 2006 by:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors 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 September 30, 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 additional shares of our common stock to cover over-allotments. For more 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 September 30, 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.

Name of beneficial owner	Number of shares beneficially owned	Percentage of shares 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 (14 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 September 30, 2006.

If the underwriters exercise their over-allotment option in full, Mr. El-Hibri 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.;
- shares held by Microscience Investments Limited; and

• 30,000 shares subject to stock options held by Mr. El-Hibri exercisable within 60 days of September 30, 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 September 30, 2006.

(3) Consists of 178,500 shares of common stock subject to stock options exercisable within 60 days of September 30, 2006.

(4) Consists of 6,667 shares of common stock subject to stock options exercisable within 60 days of September 30, 2006.

(5) Consists of 25,900 shares of common stock subject to stock options exercisable within 60 days of September 30, 2006.

(6) Consists of 10,000 shares of common stock subject to stock options exercisable within 60 days of September 30, 2006.

(7) Consists of 5,000 shares of common stock subject to stock options exercisable within 60 days of September 30, 2006.

(8) Consists of 5,000 shares of common stock subject to stock options exercisable within 60 days of September 30, 2006.

(9) Consists of 286,901 shares of common stock subject to stock options exercisable within 60 days of September 30, 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. 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 September 30, 2006.

If the underwriters exercise their over-allotment option in full, Dr. Myers 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 Michigan Biologics Products, Inc.; and
- 159,604 shares subject to stock options held by Dr. Myers exercisable within 60 days of September 30, 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 September 30, 2006.

If the underwriters exercise their over-allotment option in full, Mr. and Mrs. Gibellini 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 Biologika LLC; and
- 25,000 shares subject to stock options held by Mr. Gibellini exercisable within 60 days of September 30, 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 additional shares 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.

Name	Number of shares of 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. A description of these voting agreements and additional information regarding the beneficial ownership of the shares held by our principal stockholders are set forth 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 and Exchange Commission under the Securities Act or pursuant to Rule 144 under 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. El-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 our wholly owned subsidiary, Emergent BioDefense Operations Lansing Inc., 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 100,000,000 shares of common stock, $0.001 par value per share, and 15,000,000 shares of preferred stock, $0.001 par value per share.

As of September 30, 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 September 30, 2006, we also had outstanding options to purchase 1,091,779 shares of class B common stock at a weighted average exercise price of $7.30 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 100,000 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 September 30, 2006, we will have outstanding options to purchase an aggregate of 1,091,779 shares of our common stock at a weighted average exercise price of $7.30 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, or % 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 at the same time the initial public offering price of our common stock is determined. We will enter into the rights agreement with American Stock Transfer & Trust Company, 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 El-Hibri and his wife, Nancy El-Hibri, and any entity controlled by Fuad El-Hibri or Nancy El-Hibri;
- Microscience Investments Limited, unless and until such time as Microscience Investments, 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 Investments 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 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
- more than 50% 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. The event described in this paragraph is referred to as a flip-over event. A flip-over event 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 series A 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 $0.001 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 September 30, 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 and assuming no exercise of options outstanding as of September 30, 2006.

Of the shares to be outstanding after the completion of this offering, the shares of common stock sold in this offering will be freely tradable without restriction under 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 outstanding as of September 30, 2006 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, 30,015 shares of common stock outstanding as of September 30, 2006 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, 30,015 shares of our common stock outstanding as of September 30, 2006 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 outstanding as of September 30, 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 September 30, 2006, we had outstanding options to purchase 1,091,779 shares of class B common stock, of which options to purchase 811,347 shares of class B common stock were vested as of September 30, 2006. As of September 30, 2006, options to purchase shares of common stock will be vested and eligible for sale within 180 days after the date of this prospectus, subject to any lock-up agreements applicable to these shares. 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. Promptly following this offering, we intend to file a registration statement 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 and 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 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.

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, 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 (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 for $8.5 million that we entered into in April 2006 in connection with the purchase of a building in Frederick, Maryland, a term loan for $10.0 million that we entered into in August 2006 to finance a portion of the costs of our facility expansion in Lansing, Michigan and a revolving line of credit for up to $5.0 million that we entered into in August 2006. 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, 2004 and 2005, 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 Commission.

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.

Index to consolidated financial statements

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

(in thousands, except share and per share data)	December 31, 2004	December 31, 2005	As of September 30, 2006 (unaudited)
ASSETS			
Current assets:			
Cash and cash equivalents	$ 6,821	$ 36,294	$ 19,906
Accounts receivable	18,637	2,530	3,273
Inventories	13,253	16,441	28,068
Income taxes receivable	—	763	3,542
Deferred tax assets	978	1,989	252
Restricted cash	1,250	—	190
Prepaid expenses and other current assets	756	1,099	1,961
Total current assets	41,695	59,116	57,192
Property, plant and equipment, net	27,269	30,645	59,632
Deferred tax assets, net of current	24	9,981	10,785
Other assets	68	590	3,222
Total assets	$ 69,056	$100,332	$ 130,831
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable, related party	$ 15	$ 22	$ —
Accounts payable, operations	5,505	10,403	16,571
Accrued compensation	3,710	6,177	4,898
Indebtedness under lines of credit	—	—	2,168
Long-term indebtedness, current portion	572	902	1,687
Notes payable to employees, current portion	474	506	63
Income taxes payable	3,761	2,134	—
Deferred revenue, current portion	18,256	7,340	8,978
Other current liabilities	1,893	2,609	4,101
Total current liabilities	34,186	30,093	38,466
Long-term indebtedness, net of current portion	11,347	10,471	32,555
Notes payable to employees, net of current portion	474	31	—
Deferred revenue, net of current portion	—	—	3,001
Other liabilities	100	—	50
Total liabilities	46,107	40,595	74,072
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 September 30, 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 September 30, 2006, respectively	65	78	78
Common Stock, Class B, $0.01 par value; 2,000,000 shares authorized, 0, 7,400 and 30,015 shares issued and outstanding at December 31, 2004 and 2005 and September 30, 2006, respectively	—	—	—
Additional paid-in capital	7,564	34,539	35,024
Accumulated other comprehensive loss	—	(276)	(182)
Retained earnings	15,320	25,396	21,839
Total stockholders' equity	22,949	59,737	56,759
Total liabilities and stockholders' equity	$ 69,056	$100,332	$ 130,831

The accompanying notes are an integral part of these consolidated financial statements.

Emergent BioSolutions Inc. and subsidiaries
Consolidated statements of operations

(in thousands, except share and per share data)	Year ended December 31,			Nine months ended September 30, (unaudited)	
	2003	2004	2005	2005	2006
Revenues:					
Product sales	$ 55,536	$ 81,014	$ 127,271	$ 85,807	$ 61,263
Collaborative research and grants	233	2,480	3,417	1,093	4,580
Total revenues	55,769	83,494	130,688	86,900	65,843
Operating expense (income):					
Cost of product sales	22,342	30,102	31,603	23,147	11,645
Research and development	6,327	10,117	18,381	9,632	26,640
Selling, general and administrative	19,547	30,323	42,793	28,924	32,952
Purchased in-process research and development	1,824	—	26,575	26,575	477
Settlement of State of Michigan obligation	—	(3,819)	—	—	—
Litigation settlement	—	—	(10,000)	(10,000)	—
Income (loss) from operations	5,729	16,771	21,336	8,622	(5,871)
Other income (expense):					
Interest income	100	65	485	338	405
Interest expense	(293)	(241)	(767)	(575)	(778)
Other income (expense), net	168	6	55	(24)	291
Total other income (expense)	(25)	(170)	(227)	(261)	(82)
Income (loss) before provision for (benefit from) income taxes	5,704	16,601	21,109	8,361	(5,953)
Provision for (benefit from) income taxes	1,250	5,129	5,325	2,109	(2,617)
Net income (loss)	$ 4,454	$ 11,472	$ 15,784	$ 6,252	$ (3,336)
Earnings (loss) per share — basic	$ 0.68	$ 1.74	$ 2.21	$ 0.90	$ (0.43)
Earnings (loss) per share — diluted	$ 0.63	$ 1.61	$ 2.00	$ 0.82	$ (0.43)
Weighted average number of shares — basic	6,570,856	6,576,019	7,136,866	6,927,289	7,775,263
Weighted average number of shares — diluted	7,061,537	7,104,172	7,908,023	7,663,468	7,775,263
Cash dividends per share — basic	$ —	$ —	$ 0.76	$ 0.78	$ —

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)	Class A no-par common stock Shares	Class A no-par common stock Amount	Class B no-par common stock Shares	Class B no-par common stock Amount	Class A $0.01 par value common stock Shares	Class A $0.01 par value common stock Amount	Class B $0.01 par value common stock Shares	Class B $0.01 par value common stock Amount	Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Total stockholders' equity
Balance at December 31, 2002	6,262,554	$ 2,940	$ 254,384	$ 69	—	$ —	—	$ —	$ —	$ —	$ 1,146	$ 4,155
Redemption of common stock	—	—	(25,000)	(7)	—	—	—	—	—	—	(193)	(200)
Issuance of common stock	—	—	152,676	39	—	—	—	—	—	—	—	39
Net income	—	—	—	—	—	—	—	—	—	—	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 $0.01 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 $0.01 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	—	—	—	—	—	—	—	—	—	—	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	—	—	—	—	—	—	—	—	—	—	15,784	15,784
Foreign currency translation	—	—	—	—	—	—	—	—	—	(276)	—	(276)
Comprehensive income	—	—	—	—	—	—	—	—	—	—	—	15,508
Balance at December 31, 2005	—	—	—	—	7,752,001	78	7,400	—	34,539	(276)	25,396	59,737
Redemption of common stock	—	—	—	—	—	—	—	—	—	—	(221)	(221)
Issuance of common stock	—	—	—	—	—	—	22,615	—	43	—	—	43
Stock-based compensation expense	—	—	—	—	—	—	—	—	442	—	—	442
Net loss	—	—	—	—	—	—	—	—	—	—	(3,336)	(3,336)
Foreign currency translation	—	—	—	—	—	—	—	—	—	94	—	94
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(3,242)
Balance at September 30, 2006 (unaudited)	—	$ —	—	$ —	7,752,001	$ 78	30,015	$ —	$ 35,024	$ (182)	$ 21,839	$ 56,759

The accompanying notes are an integral part of these consolidated financial statements.

Emergent BioSolutions Inc. and subsidiaries
Consolidated statements of cash flows

(in thousands)	Year ended December 31, 2003	2004	2005	Nine months ended September 30, (unaudited) 2005	2006
Cash flows from operating activities:					
Net income (loss)	$ 4,454	$ 11,472	$ 15,784	$ 6,252	$ (3,336)
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)	—	4,310	(17)	—	442
Non-cash gain on settlement	—	(3,819)	—	—	—
Depreciation and amortization	1,214	1,867	3,549	2,495	3,265
Deferred income taxes	(467)	(418)	(10,968)	(10,313)	933
Other obligations	—	200	—	—	—
Loss on disposal of property and equipment	13	43	32	31	82
Purchased in-process research and development	1,824	—	26,575	26,575	477
Cash payment on State of Michigan obligation	540	—	—	—	—
Changes in operating assets and liabilities:					
Accounts receivable	(528)	(15,664)	16,107	16,299	(744)
Inventories	(4,656)	(1,609)	(3,189)	(3,009)	(11,627)
Income taxes	(1,713)	5,794	(2,390)	(2,509)	(4,913)
Prepaid expenses and other assets	(244)	50	(865)	(939)	(3,653)
Accounts payable	983	2,472	5,463	(1,275)	6,146
Accrued compensation	(583)	585	2,466	(1,163)	(1,279)
Other current liabilities	(1,617)	44	619	103	1,442
Deferred revenue	11,852	3,869	(10,916)	(10,916)	4,639
Net cash provided by (used in) operating activities	11,072	9,196	42,250	21,631	(8,126)
Cash flows from investing activities:					
Purchases of property, plant and equipment	(4,123)	(17,072)	(6,532)	(2,300)	(32,333)
Acquisitions, net of cash received	(3,794)	—	(559)	—	(218)
Restricted cash deposits	—	(1,250)	1,250	(17)	(190)
Proceeds from investment maturities	—	147	—	—	—
Net cash used in investing activities	(7,917)	(18,175)	(5,841)	(2,317)	(32,741)
Cash flows from financing activities:					
Proceeds from long-term debt and lines of credit	172	10,992	31	—	35,853
Proceeds from notes payable to employees	—	947	123	123	—
Repayments on product supply and royalty obligations	(900)	(2,351)	—	—	—
Issuance of Class B common stock	39	12	33	—	43
Redemption of Class B common stock	(200)	(665)	(337)	(339)	(221)
Principal payments on long-term debt and lines of credit	(38)	(184)	(1,110)	(958)	(11,290)
Debt issuance costs	—	(70)	—	—	—
Payment of dividend	—	—	(5,400)	(5,400)	—
Net cash provided by (used in) financing activities	(927)	8,681	(6,660)	(6,574)	24,385
Effect of exchange rate changes on cash and cash equivalents	—	—	(276)	(50)	94
Net increase (decrease) in cash and cash equivalents	2,228	(298)	29,473	12,690	(16,388)
Cash and cash equivalents at beginning of period	4,891	7,119	6,821	6,821	36,294
Cash and cash equivalents at end of period	$ 7,119	$ 6,821	$ 36,294	$ 19,511	$ 19,906
Supplemental disclosure of cash flow information:					
Cash paid during the year for interest	$ 99	$ 170	$ 696	$ 501	$ 665
Cash paid during the year for income taxes	$ 4,280	$ —	$ 17,985	$ 3,835	$ 1,470
Supplemental information on non cash investing and financing activities:					
Issuance of common stock to acquire Microscience Limited	$ —	$ —	$ 27,001	$ 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 Inc. (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 has renamed BioPort as Emergent BioDefense Operations Lansing Inc. (Emergent BioDefense Operations). 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 September 30, 2006, the statements of operations and cash flows for the nine months ended September 30, 2005 and 2006 and the consolidated statement of changes in stockholders' equity for the nine months ended September 30, 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 nine months ended September 30, 2005 and 2006. The results for the nine months ended September 30, 2006 are not necessarily indicative of the results to be expected for the year ending

December 31, 2006. All references to September 30, 2006 or to the nine months ended September 30, 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 September 30, 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 $35,606 and $34,998, respectively, at September 30, 2006.

Restricted cash

Restricted cash at December 31, 2004 and September 30, 2006 consists, in each case, of a certificate of deposit held by a bank as collateral for a letter of credit acting as a security deposit on a loan. The certificate of deposit outstanding as of December 31, 2004 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 nine months ended September 30, 2005 and 2006, sales of BioThrax to the DoD and HHS comprised 100%, 99% and 96% and 96% and 92% of total revenues, respectively. As of December 31, 2004 and 2005 and September 30, 2006, the Company's receivable balances were comprised of 96% and 38% and 98%, respectively, from these customers. Unbilled accounts receivable, included in accounts receivable, totaling $3,772 and $1,418 and $107 as of December 31, 2004 and 2005 and September 30, 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 September 30, 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 costs associated with 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.

Under the Company’s contract with the DoD, title to the product passes to the DoD upon submission of the first invoice. The earnings process is complete upon FDA release of the product for sale and distribution. Following FDA release of the product, the product is segregated for later shipment, and all deferred revenue related to the released product is recognized in accordance with the “bill and hold” requirements under SAB 104.

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. This interpretation is applicable to the Company’s contracts with HHS, but because the Company recognizes revenue upon delivery of product, the Company has not applied this guidance.

The Company recognizes revenue from upfront and 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 No. 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 nine months ended September 30, 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) 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 or modification 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:

	Year ended December 31,			Nine months ended September 30,	
	2003	2004	2005	2005	2006
Numerator:					
Net income (loss)	$ 4,454	$ 11,472	$ 15,784	$ 6,252	$ (3,336)
Denominator:					
Weighted-average number of shares — basic	6,570,856	6,576,019	7,136,866	6,927,289	7,775,263
Dilutive securities — stock options	490,681	528,152	771,157	736,179	—
Weighted-average number of shares — diluted	7,061,537	7,104,172	7,908,023	7,663,468	7,775,263
Earnings (loss) per share — basic	$ 0.68	$ 1.74	$ 2.21	$ 0.90	$ (0.43)
Earnings (loss) per share — diluted	$ 0.63	$ 1.61	$ 2.00	$ 0.82	$ (0.43)

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 September 30, 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 nine months ended September 30, 2006 is approximately $442 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 nine months ended September 30, 2006 are $0.03 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 September 30, 2006, total compensation expense not yet recognized related to unvested options is approximately $970, after tax. The Company expects to recognize that expense over a weighted average period of 2.8 years.

The Company has utilized the Black-Scholes valuation model for estimating the fair value of all stock options granted. 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:

	Year ended December 31,			Nine months ended September 30,	
	2003	2004	2005	2005	2006
Expected dividend yield	0%	0%	0%	0%	0%
Expected volatility	100%	52%	50%	50%	50%
Risk-free interest rate	3.15%	2.93%	3.68%	4.18%	4.69%
Expected average life of options (years)	2.7	2.5	2.9	2.7	2.9
Forfeiture rate	0%	0%	0%	0%	5%

- *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 of 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 September 30, 2006.

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 nine months ended September 30, 2005 and 2006. The reported and pro forma net income (loss) and net income (loss) per share for the nine month period ended September 30, 2006 are the same because stock-based compensation expense is recorded under the provisions of SFAS No. 123(R) for that period.

	Year ended December 31,			Nine months ended September 30,	
	2003	2004	2005	2005	2006
Net income, as reported	$4,454	$11,472	$15,784	$6,252	$(3,336)
Add: Stock-based compensation in reported net income, net of taxes	—	2,801	—	—	248
Deduct: Total stock-based compensation expense determined under the fair value based method for all awards, net of taxes	(133)	(3,185)	(258)	(161)	(248)
Pro forma net income	$4,321	$11,088	$15,526	$6,091	$(3,336)
Net income (loss) attributable to common stockholders per common share — basic	$ 0.68	$ 1.74	$ 2.21	$ 0.90	$ (0.43)
Net income (loss) attributable to common stockholders per common share — diluted	$ 0.63	$ 1.61	$ 2.00	$ 0.82	$ (0.43)
Pro forma net income (loss) attributable to common stockholders per common share — basic	$ 0.66	$ 1.69	$ 2.18	$ 0.88	$ (0.43)
Pro forma net income (loss) attributable to common stockholders per common share — diluted	$ 0.61	$ 1.56	$ 1.96	$ 0.77	$ (0.43)

Recent accounting pronouncements

In September 2006, the FASB issued Statement No. 157, *Fair Value Measurements* (SFAS No. 157). SFAS No. 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. The provisions of SFAS No. 157 are effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Prior to adoption, the Company will evaluate the impact of adopting SFAS No. 157 on the financial statements.

In June 2006, the FASB 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 its 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.

In March 2006, the FASB issued Statement No. 156, *Accounting for Servicing of Financial Assets — an amendment of FASB Statement No. 140* (SFAS No. 156). SFAS No. 156 requires an entity to recognize a servicing asset or servicing liability each time it undertakes an obligation to service a financial asset by entering into a servicing contract based on certain conditions. The provisions of SFAS No. 156 are effective for fiscal years beginning after September 15, 2006. SFAS No. 156 will have no immediate impact on the Company's consolidated financial statements.

In February 2006, the FASB issued Statement No. 155, *Accounting for Certain Hybrid Financial Instruments — an amendment of FASB Statements No. 133 and 140* (SFAS No. 155). SFAS No. 155 permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement No. 133, establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives and amends Statement No. 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. The provisions of SFAS No. 155 are effective for fiscal years beginning after September 15, 2006. SFAS No. 155 will have no immediate impact on the Company's consolidated financial statements.

Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation.

3. Acquisitions

ViVacs GmbH

On July 14, 2006, Emergent International, Inc., a wholly owned subsidiary of the Company incorporated in Delaware (EII), completed the acquisition of ViVacs GmbH, a German limited liability company (ViVacs), pursuant to the terms and conditions of the Share Exchange Agreement dated July 14, 2006 by and between EII and ViVacs. EII paid $150 in cash on the closing date of the agreement and agreed to pay $50 on each of the first and second anniversaries of the closing date. The acquisition agreement also provides for a potential variable earn-out purchase price of up to $220, based on future payments from third party licensees of the technology. As of September 30, 2006, the Company has not received any such payments from third party licensees. Because ViVacs 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.

Total purchase consideration consisted of:

Cash (including the present value of future guaranteed cash payments of $100)	$250
Direct acquisition costs	180
Total purchase consideration	$430

The assets acquired were accounted for in accordance with the provisions of SFAS No. 141, *Business Combinations* (SFAS No. 141). All of the tangible and intangible assets acquired and liabilities assumed of ViVacs were recorded at their estimated fair market values on the acquisition date.

The purchase price was allocated as follows:

Current assets	$ 153
Property and equipment	97
Current liabilities	(297)
Net liabilities acquired	47
In-process research and development	477
Total purchase consideration	$ 430

In connection with the transaction, the Company recorded a charge of $477 for acquired research projects associated with product candidates in development for which, at the acquisition date, technological feasibility had not been established and, for accounting purposes, no alternative future use existed.

Microscience Limited

On June 23, 2005, Emergent Europe, Inc. (EEI) completed the acquisition of Microscience pursuant to the terms and conditions of the Share Exchange Agreement dated June 23, 2005 by and between 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 based on a determination of the estimated fair value by the Company's board of directors. 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.

Total purchase consideration consisted of:

Fair value of common stock	$27,001
Direct acquisition costs	1,194
Total purchase consideration	$28,195

The assets acquired were accounted for in accordance with the provisions of SFAS No. 141. All of the tangible and intangible assets acquired and liabilities assumed of Microscience were recorded at their estimated fair market values on the acquisition date.

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.

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. 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.

Total purchase consideration consisted of:

Purchase price	$	3,400
Direct acquisition costs		394
Total purchase consideration	$	3,794

The assets acquired were accounted for in accordance with the provisions of SFAS No. 141. All of the tangible and intangible assets acquired and liabilities assumed of Antex were recorded at their estimated fair market value on the acquisition date.

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.

4. Accounts receivable

Accounts receivable consist of the following:

	December 31,		September 30,
	2004	2005	2006
Billed	$ 14,865	$ 1,112	$ 3,166
Unbilled	3,772	1,418	107
Total	$ 18,637	$ 2,530	$ 3,273

5. Inventories

Inventories consist of the following:

	December 31, 2004	December 31, 2005	September 30, 2006
Raw materials and supplies	$ 1,947	$ 2,229	$ 2,165
Work-in-process	6,674	9,547	24,195
Finished goods	4,632	4,665	1,708
Inventories	$ 13,253	$ 16,441	$ 28,068

6. Property, plant and equipment

Property, plant and equipment consist of the following:

	December 31, 2004	December 31, 2005	September 30, 2006
Land and improvements	$ 2,963	$ 2,995	$ 5,124
Buildings and leasehold improvements	13,496	14,143	22,569
Furniture and equipment	10,563	12,520	14,597
Internal-use software	3,818	3,937	3,937
Construction in-progress	2,086	6,197	25,506
	32,925	39,792	71,733
Less: Accumulated depreciation and amortization	(5,657)	(9,147)	(12,101)
Property, plant and equipment, net	$27,269	$30,645	$ 59,632

Depreciation and amortization expense was $1,214, $1,867 and $3,549 for the years ended December 31, 2003, 2004 and 2005, respectively, and $2,495 and $3,265 for the nine months ended September 30, 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 nine months ended September 30, 2005 and 2006, depreciation and amortization expense included approximately $943 and $943, 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 $468. The deposit remains in effect as of December 31, 2005 and September 30, 2006.

8. Other current liabilities

Other current liabilities consist of the following:

	December 31,		September 30,
	2004	2005	2006
Contract costs	$ 3	$ 445	$ 1,948
Professional fees	1,462	1,390	1,056
Interest payable	71	146	259
Property taxes and other	357	628	838
	$ 1,893	$ 2,609	$ 4,101

9. Long-term debt and related party notes payable

The components of long term-debt and related party notes payable are as follows:

	December 31,		September 30
	2004	2005	2006
Term loan dated August 2006, 9.151%, due August 2011	$ —	$ —	$ 10,000
Convertible Line of Credit dated August 2006	—	—	5,000
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 dated August 2004; prime less 0.375%, due September 2007	2,280	1,760	1,280
Term Loan dated April 2006; LIBOR plus 3%, due April 2011	—	—	8,428
Employee notes payable for stock redemption; 6%, due 2006	947	537	63
Other	140	113	34
Total notes payable	12,867	11,909	34,305
Less current portion of notes payable	(1,046)	(1,408)	(1,750)
Long-term portion of notes payable	$11,821	$10,502	$ 32,555

In August 2006, the Company entered into a term loan for $10,000 and a revolving credit loan for up to $5,000. Under the term loan, the Company is required to make monthly principal payments beginning in April 2007. A residual principal payment of approximately $4,000 is due upon maturity in August 2011. At the Company's request, the term loan is subject to an extension term in the sole discretion of the lender for five additional years until August 2016 for an extension fee of 1.00% of the principal balance of the loan. If the term of the loan were extended, the Company would be required to continue to make monthly principal payments through maturity in August 2016 in lieu of the residual principal payment otherwise due in August 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.75% (9.48% as of September 30, 2006).

Under the revolving credit loan, the Company is not required to repay outstanding principal until October 2007. In October 2007, the outstanding principal under the revolving credit loan will convert to a term loan with required monthly principal payments through maturity in August 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.75% (9.48% as of September 30, 2006).

The Company also is required to pay a fee on a quarterly basis equal to 0.50% of the average daily difference between $5,000 and the amount outstanding under the revolving credit loan.

The term loan and revolving credit loan are secured by substantially all of Emergent BioDefense Operations' assets, other than accounts receivable under BioThrax supply contracts with the DoD and HHS. The Company is required to maintain on an annual basis a minimum tangible net worth of not less than the sum of 85% of tangible net worth for the most recently completed fiscal year plus 25% of current net operating profit after taxes. In addition, the Company is required to maintain on a quarterly basis a ratio of earnings before interest, taxes, depreciation and amortization for the most recent four quarters to the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable for the following four quarters, of not less than 1.25 to 1.00.

In April 2006, the Company completed the acquisition of a 150,000 square foot facility in Frederick, Maryland for $9,750. 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 remaining balance with a bank loan in the amount of $8,500. This loan requires monthly principal and interest payments from May 2006 through April 2011 of $72 with a balloon payment for the remaining unpaid principal and interest due in April 2011. The interest rate is a floating rate based on the three month LIBOR plus 3% (8.37% as of September 30, 2006). The loan is collateralized by the 150,000 square foot facility. The loan requires the Company to comply with certain non-financial covenants.

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 guaranteed 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% (8.63% as of September 30, 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		317
2009		2,838
2010 and thereafter		6,045
	$	11,910

Line of credit

On April 1, 2005, the Company, through Emergent BioDefense Operations, formerly BioPort, obtained a line of credit that provides for borrowings of up to $10,000. The line of credit is scheduled to expire on November 15, 2006. The line of credit is secured by accounts receivable and bears interest at the prime rate less 0.375% (8.63% as of September 30, 2006). Emergent BioDefense Operations is subjected to certain covenants, including maintenance of specified equity levels on a quarterly basis. Emergent BioDefense Operations is currently in compliance with those covenants. There was $2,168 outstanding under this line of credit as of September 30, 2006. No borrowings were outstanding under this line of credit as of December 31, 2005.

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 September 30, 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 law.

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 the Company 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 the Company 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 $0.76 per share, for $337.

Stock options

As of September 30, 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:

	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	—

	BioPort Plan		Emergent Plan		
	Number of shares	Weighted average exercise price	Number of shares	Weighted average exercise price	Aggregate intrinsic value
Exercisable at December 31, 2005	—	—	852,481	$ 3.50	—
Granted (unaudited)	—	—	90,000	32.68	—
Exercised (unaudited)	—	—	(22,615)	1.86	—
Forfeited (unaudited)	—	—	(67,685)	7.62	—
Outstanding at September 30, 2006 (unaudited)	—	—	1,091,779	$ 7.30	$ 33,692,300
Exercisable at September 30, 2006 (unaudited)	—	—	811,347	$ 3.81	$ 27,869,769

The weighted average remaining contractual term of options outstanding and exercisable as of December 31, 2005 and September 30, 2006 was 2.46 years and 1.82 years, and 2.12 years and 1.26 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, and $12.31 for the nine months ended September 30, 2006. The total intrinsic value of options exercised during the years ended December 31, 2003, 2004 and 2005 and during the nine months ended September 30, 2006 was $1,165, $325 and $563 and $518, 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

Options granted from October 1, 2005 through September 30, 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)
November 2005	10,000	24.52	24.52	—
June 2006	57,500	29.58	29.58	—
September 2006	32,500	38.16	38.16	—

(1) 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 December 31,			Nine months ended September 30,	
	2003	2004	2005	2005	2006
Current					
Federal	$1,717	$5,547	$ 16,093	$ 12,222	$(3,650)
State	—	—	200	200	100
Total current	1,717	5,547	16,293	12,422	(3,550)
Deferred					
Federal	(416)	(372)	(9,769)	(9,177)	833
State	(51)	(46)	(1,199)	(1,136)	100
Total deferred	(467)	(418)	(10,968)	(10,313)	933
Total provision (benefit) for income taxes	$1,250	$5,129	$ 5,325	$ 2,109	$(2,617)

The Company's net deferred tax asset consists of the following:

	December 31,		September 30,
	2004	2005	2006
Net operating loss carryforward	$ 666	$ 2,242	$ 4,180
Purchased in-process research and development	645	721	703
Stock compensation	1,457	1,696	1,393
Foreign deferrals	—	27,797	30,343
Other	883	1,219	1,245
Deferred tax asset	3,651	33,675	37,864
Fixed assets	(1,859)	(1,387)	(941)
Other	(124)	(393)	(673)
Deferred tax liability	(1,983)	(1,780)	(1,614)
Valuation allowance	(666)	(19,925)	(25,213)
Net deferred tax asset	$ 1,002	$ 11,970	$ 11,037

Net operating loss carryforwards consist of $92 million for state jurisdictions and $70 million for foreign jurisdictions. The state net operating loss carryforwards will begin to expire in 2018. The foreign net operating loss carryforwards will have an indefinite life unless the foreign entities have a change in the nature or conduct of the business in the three years following a change in ownership. 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 nine months ended September 30, 2005 and 2006, the Company paid $3,335 and $1,470 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:

	Year ended December 31,			Nine months ended September 30,	
	2003	2004	2005	2005	2006
Federal tax at statutory rates	$1,996	$5,863	$ 7,388	$ 2,926	(1,794)
State taxes, net of federal benefit	(230)	(714)	(2,329)	(1,864)	(962)
Impact of foreign operations	—	—	(17,982)	(17,368)	(3,599)
Change in valuation allowance	187	479	19,259	17,712	5,288
Tax credits	(441)	(492)	(474)	(474)	—
Other differences	(255)	11	(211)	1,198	(1,840)
Permanent differences	(7)	(18)	(326)	(21)	290
Federal tax at statutory rates	$1,250	$5,129	$ 5,325	$ 2,109	$(2,617)

The estimated effective annual tax rate for the nine months ended September 30, 2005 and 2006 was 25% and 44%, respectively. The increase in the estimated rate is due primarily to an increase in the valuation allowance related to estimated foreign and state net operating losses.

The Company is the subject of an ongoing federal income tax audit for the tax year ended December 31, 2004. The financial statement impact of the audit has been estimated at approximately $500. This amount has been accrued as of September 30, 2006.

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 nine months ended September 30, 2005 and 2006, the Company made matching contributions of approximately $384 and $431, 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 nine months ended September 30, 2005 and 2006, total rent expense was $890, $1,334 and $2,526 and $1,834 and $1,428, respectively.

Future minimum payments under operating lease obligations as of December 31, 2005 are as follows:

2006	$ 1,689
2007	1,249
2008	1,188
2009	56
Total minimum lease payments	$ 4,182

In July 2006, the Company entered into 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.

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, the Company 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 the Company believed it was entitled under a set of 1991 agreements and to clarify intellectual property rights associated with those agreements. The Company 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 nine months ended September 30, 2005 and 2006, the Company paid approximately $0, $32 and $34 and $34 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 nine months ended September 30, 2005 and 2006. These arrangements have been terminated.

For the years ended December 31, 2003, 2004 and 2005 and the nine months ended September 30, 2005 and 2006, the Company paid approximately $116, $494 and $794, and $630 and $370, 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. There was no accounts payable balance for these services at September 30, 2006. The Company currently has an

agreement with a director to perform corporate strategic issues consultation and directed project support to the marketing and communications group and an agreement with East West Resources Corporation, a company owned by the Chief Executive Officer, to provide transportation and logistical support.

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.

	Reportable segments			
	Biodefense	Commercial	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
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

	Reportable segments			
	Biodefense	Commercial	All other	Total
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				
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

shares

Common stock

Prospectus

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.

	Amount
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	$ *

* 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. The Registrant subsequently renamed BioPort as Emergent BioDefense Operations Lansing Inc.

(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 1,303,729 shares of our class B common stock as of September 30, 2006. As of September 30, 2006, options to purchase 68,999 shares of class B common stock had been exercised, options to purchase 142,951 shares of class B common stock had been forfeited and options to purchase 1,091,779 shares of class B common stock remained outstanding at a weighted average exercise price of $7.30 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 Amendment No. 3 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Gaithersburg, State of Maryland on the 20th day of October 2006.

EMERGENT BIOSOLUTIONS INC.

By: /s/ Fuad El-Hibri
Fuad El-Hibri
President, Chief Executive Officer and Chairman of the Board of Directors

Pursuant to the requirements of the Securities Act, this Amendment No. 3 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ FUAD EL-HIBRI Fuad El-Hibri	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	October 20, 2006
/s/ R. DON ELSEY R. Don Elsey	Vice President Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	October 20, 2006
* Joe M. Allbaugh	Director	October 20, 2006
* Zsolt Harsanyi, Ph.D.	Director	October 20, 2006
* Jerome M. Hauer	Director	October 20, 2006
* Shahzad Malik, M.D.	Director	October 20, 2006
* Ronald B. Richard	Director	October 20, 2006
* Louis Sullivan, M.D.	Director	October 20, 2006

*By: /s/ FUAD EL-HIBRI
Fuad El-Hibri
Attorney-in-fact

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 September 22, 2006, among the Registrant and the entities listed on Schedule 1 thereto
4.4**	Rights Agreement, to be entered into between the Registrant and the Rights Agent
5.1*	Form of Opinion of Wilmer Cutler Pickering Hale and Dorr LLP to be issued prior to effectiveness
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 August 11, 2006, between BioPharm, L.L.C. and Microscience Investments Limited
10.1*	Employee Stock Option Plan, as amended and restated
10.2*	Form of Director Stock Option Agreement
10.3**	2006 Stock Incentive Plan
10.4**	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 Emergent BioDefense Operations Lansing Inc., formerly 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 Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Department of Health and Human Services, Office of Public Health Emergency Preparedness and Office of Research and Development Coordination, as amended
10.10†*	Filling Services Agreement, dated March 18, 2002, between Emergent BioDefense Operations Lansing Inc., formerly 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†*	rBot Vaccine License Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency
10.14†*	rBot Vaccine Development Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency
10.15†*	Exclusive Distribution Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency

Exhibit Number	Description
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 September 22, 2006, 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 Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Intergen N.V., as amended
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 Emergent BioDefense Operations Lansing Inc., formerly 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., Emergent BioDefense Operations Lansing Inc., formerly 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 Emergent BioDefense Operations Lansing Inc., formerly 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
10.38*	Revolving Credit Note, dated July 29, 2005, from Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, to Fifth Third Bank
10.39*	Promissory Note, dated April 25, 2006, from Emergent Frederick LLC to HSBC Realty Credit Corporation (USA)

Exhibit Number	Description
10.40*	Loan Agreement, dated August 25, 2006, among the Registrant, Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and HSBC Realty Credit Corporation (USA)
10.41*	Promissory Note (Term Note), dated August 25, 2006, from Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, to HSBC Realty Credit Corporation (USA)
10.42*	Promissory Note (Revolving Credit Loan), dated August 25, 2006, from Emergent BioDefense Operations Lansing Inc., formerly, BioPort Corporation to HSBC Realty Credit Corporation (USA)
10.43†	Agreement, dated June 16, 2005, between the Free State of Bavaria and Emergent Product Development UK, formerly ViVacs GmbH
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)

***** Previously filed.

****** To be filed by amendment.

† Confidential treatment requested. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

Exhibit 4.1


emergent
biosolutions™
EB
COMMON STOCK
INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE
SEE REVERSE FOR CERTAIN DEFINITIONS
CUSIP 290896 10 5
THIS CERTIFIES THAT
is the registered holder of
FULLY PAID AND NON-ASSESSABLE SHARES OF THE COMMON STOCK, PAR VALUE OF $0.001 PER SHARE, OF
EMERGENT BIOSOLUTIONS INC., transferable only on the books of the corporation in person or by duly authorized attorney upon surrender of this Certificate properly endorsed. This Certificate and the shares represented hereby are issued and shall be held subject to the laws of the State of Delaware and the provisions of the Restated Certificate of Incorporation and the Amended and Restated By-laws of the corporation, as amended from time to time, to which the holder by the acceptance hereof assents.
This Certificate is not valid unless countersigned by the Transfer Agent and registered by the Registrar.
WITNESS the seal of the corporation and the facsimile signatures of its duly authorized officers.
Dated:
EMERGENT BIOSOLUTIONS INC.
CORPORATE
SEAL
2003
DELAWARE
President
Secretary
COUNTERSIGNED AND REGISTERED
AMERICAN STOCK TRANSFER & TRUST COMPANY
TRANSFER AGENT AND REGISTRAR
BY
AUTHORIZED SIGNATURE

The Corporation will furnish without charge to each stockholder who so requests the powers, 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/or rights.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM	—	as tenants in common		
TEN ENT	—	as tenants by the entireties	UNIF GIFT MIN ACT —	_____ Custodian _____
JT TEN	—	as joint tenants with right of survivorship and not as tenants in common		(Cust) (Minor) under Uniform Gifts to Minors Act _____ (State)

Additional abbreviations may also be used though not in the above list.

FOR VALUE RECEIVED, _____ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

_____

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE)

_____

_____

_____ Shares

of the common stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ Attorney

to transfer the said stock on the books of the within named Corporation with full power of substitution in the premises.

Dated _____

X _____

X _____

NOTICE: THE SIGNATURE(S) TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME(S)AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATEVER.

Signature(s) Guaranteed

By _____

THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM), PURSUANT TO S.E.C. RULE 17Ad-15.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

Exhibit 10.6

Emergent BioSolutions Inc.
Severance Plan and
Termination Protection Program

Section 1. Definitions. The following terms shall have the meaning ascribed to them below:

(A) "Applicable Bonus" shall mean the greater of the annual bonus that was paid to a Participant in respect of the most recently completed full calendar year or the maximum annual bonus that could have been paid to such Participant under an established bonus plan for such calendar year.

(B) "Base Salary" shall mean a Participant's annual base salary in effect on the date of the Change of Control or the date of termination, whichever is applicable.

(C) "Board" shall mean the board of directors of the Company or any committee of the Board that has been delegated authority to administer this Program.

(D) "Cause" shall mean each of the following that results in demonstrable harm to the Company's financial condition or business reputation: (1) Participant's conviction of or plea of guilty or no contest to any felony or crime of moral turpitude; (2) Participant's dishonesty or disloyalty in performance of duties; (3) conduct by the Participant that jeopardizes the Company's right or ability to operate its business; (4) violation by the Participant of any of the Company's policies or procedures, (including without limitation employee workplace policies, anti-bribery policies, insider trading policy, communications policy, etc) if uncured within two weeks of written notice by the Company; or (5) Participant's willful malfeasance, misconduct, or gross neglect of duty.

(E) "Change of Control" shall means an event or occurrence set forth in any one or more of subsections (a) through (d) below, including an event or occurrence that constitutes a Change in Control under one of such subsections but is specifically exempted from another such subsection:

(a) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 promulgated under the Exchange Act) 20% or more of either (x) the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (a), the following acquisitions shall not constitute a Change in Control: (i) any acquisition directly from the Company (excluding an acquisition pursuant to the exercise, conversion or exchange of any security exercisable for, convertible into or exchangeable for common stock or voting securities of the Company, unless the Person exercising, converting or exchanging such security acquired such security directly from the Company or an underwriter or agent of the Company), (ii) any acquisition by the Company or an Excluded Person, (iii) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation

controlled by the Company, or (iv) any acquisition by any corporation pursuant to a transaction which complies with clauses (i) and (ii) of subsection (c) of this Section; or

(b) at such time as the Incumbent Directors do not constitute a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company); or

(c) the consummation of a merger, consolidation, reorganization, recapitalization or statutory share exchange involving the Company or a sale or other disposition of all or substantially all of the assets of the Company in one or a series of transactions (a "Business Combination"), unless, immediately following such Business Combination, each of the following two conditions is satisfied: (i) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company's assets either directly or through one or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the "Acquiring Corporation") in substantially the same proportions as their ownership, immediately prior to such Business Combination, of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively; and (ii) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, 20% or more of the then outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or

(d) approval by the stockholders of the Company of a complete liquidation or dissolution of the Company

(F) "Code" shall mean the Internal Revenue Code of 1986, as amended, and, as applicable, the regulations promulgated thereunder.

(G) "Company" shall mean Emergent BioSolutions Inc., and each of its subsidiaries, and after a Change of Control, any successor or successors thereto, including any Acquiring Corporation (as defined in Section 1(E)(c)).

(H) "Compensation" shall mean the sum of a Participant's Applicable Bonus and Base Salary.

(I) "Effective Date" shall be April 1, 2006.

(J) "Employee Benefits" shall mean, except as otherwise specified by the Chief Executive Officer of the Company with respect to a Participant at the time such Participant is

designated as a Participant, the employee and fringe benefits and perquisites (including without limitation all medical, dental, life insurance, disability and pension (including maximum matching contributions) benefits) made available to a Participant (and his or her eligible dependents) immediately prior to a Change of Control (or the economic equivalent thereof where applicable laws prohibit or restrict such benefits).

(K) "Excluded Person" shall mean Fuad El-Hibri and his respective "Affiliates" or "Associates" (each as defined in Rule 12b-2 under the Exchange Act), their respective heirs and any trust or foundation to which either of them have transferred or may transfer the Company's voting securities.

(L) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

(M) "Good Reason" shall mean, except as otherwise specified by the Chief Executive Officer of the Company at the time a Participant is designated as a Participant (provided that such exception does not adversely affect such Participant), with respect to such a Participant, (i) a decrease in (or failure to increase in accordance with the terms of any employment contract) the Participant's base salary or bonus opportunity, (ii) a diminution in the aggregate employee benefits and perquisites provided to the Participant, (iii) a diminution in the Participant's title, reporting relationship, duties or responsibilities, (iv) relocation of the Participant's primary office more than 35 miles from its current location, or (v) the failure by any successor to the Company or any Acquiring Corporation (as defined in Section 1(E)(c)) to explicitly assume this Program and the Company's obligations hereunder and maintain the Program in effect for a period of at least eighteen (18) months.

(N) "Group" shall have the meaning ascribed to such term in the Exchange Act.

(O) "Incumbent Director" shall mean at any date a member of the Board (i) who was a member of the Board on the Effective Date or (ii) who was nominated or elected subsequent to such date by at least a majority of the directors who were Incumbent Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Incumbent Directors at the time of such nomination or election; provided, however, that there shall be excluded from this clause (ii) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board.

(P) "Participant" shall mean an employee of the Company with the title of Chief Executive Officer, President, Executive Vice President, Senior Vice President or Vice President who has been designated to participate in this Program by the Board or, with the authorization of the Board, by the Chief Executive Officer of the Company. An employee holding any of the foregoing positions shall not automatically be entitled to participate in this Program and the selection of an employee to participate in this Program shall be made in the sole and absolute discretion of the Board or the Chief Executive Officer, as applicable. Once so selected, a Participant's rights hereunder may not be diminished unless such Participant's employment with the Company is terminated in a manner that will not permit him or her to become eligible for any payments hereunder.

(Q) “Person” shall have the meaning ascribed to such term in the Exchange Act.

(R) “Program” shall mean this Severance Plan and Termination Protection Program, as it may be amended from time to time.

Section 2. Term. This Program shall be effective as of the Effective Date and shall continue in effect through December 31, 2009; provided, however, that, commencing on December 31, 2009, and on each December 31 thereafter, this Program shall be automatically extended for one additional year unless, not later than ninety (90) days prior to the scheduled expiration of the term (or any extension thereof), the Company provides written notice that the term will not be extended.

Section 3. Severance Plan.

(a) If during the term of this Program a Participant’s employment with the Company is terminated by the Company without Cause, other than under circumstances described in Section 4(a) below, then such Participant shall become entitled to:

(i) any unpaid Base Salary and accrued paid-time-off through the date of termination;

(ii) pro rata target annual bonus in respect of the year of termination;

(iii) any bonus earned but unpaid as of the date of termination for any previously completed year;

(iv) reimbursement for any unreimbursed expenses incurred by such Participant prior to the date of termination;

(v) an amount equal to 50% of such Participant’s Base Salary (or for Participants identified on **Appendix C** the greater percentage specified therein);

(vi) employee and fringe benefits and perquisites, if any, to which such Participant may be entitled as of the date of termination under the relevant plans, policies and programs of the Company; and

(vii) continued eligibility for such Participant and his/her eligible dependents to receive Employee Benefits, for a period of 6 months following such Participant’s date of termination (or for Participants identified on **Appendix C** the greater period specified therein), except where the provision of such Employee Benefits would result in a duplication of benefits provided by any subsequent employer.

(b) Notwithstanding anything to the contrary set forth in this Program, any payments payable under this Section 3 shall be paid, in the Company’s sole and absolute discretion, either as a single, lump sum payment within thirty days following the termination of employment or payable in equal monthly installments over a term of 6 months (or for Participants who are listed on **Appendix C** on the date of termination, the period specified on **Appendix C**); provided however that all payment arrangements under this Section 3 shall be structured so as not to be treated as “non-qualified deferred compensation” under Section 401A of the Code.

(c) If during the term of this Program, a Participant’s employment with the Company is terminated by the Company with Cause, then Participant shall not be entitled to receive any

compensation, benefits or rights set forth herein or in Section 5, and any stock options or other equity participation benefits vested on or prior to the date of such termination, but not yet exercised, shall immediately terminate.

(d) As a condition to payment of any of the amounts under this Section 3, Participant:

(i) shall not, for a period of six (6) consecutive months after termination of employment (or for Participants who are listed on **Appendix C** on the date of termination, the period specified therein), directly or indirectly, either alone or in association with others, (A) induce, counsel, advise, solicit or encourage, or attempt to induce, counsel, advise, solicit or encourage any employee to leave the employ of the Company, or any of its Affiliates, or accept employment with any other person or entity, (B) induce counsel, advise, solicit or encourage, or attempt to induce, counsel, advise, solicit or encourage any person who at the time of such inducement, counseling, advice, solicitation or encouragement had left the employ of the Company, or any of its Affiliates, within the previous six (6) months to accept employment with any person or entity besides the Company, or any of its Affiliates, or hire or engage such person as an independent contractor, and (C) solicit, interfere with, or endeavor to cause any customer, client, or business partner of the Company, or any of its Affiliates, to cease or reduce its relationship with the Company, or any of its Affiliates, 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 the Company, or any of its Affiliates;

(ii) shall not, for a period of six (6) consecutive months after termination of employment (or for Participants who are listed on **Appendix C** on the date of termination, the period specified therein), directly or indirectly, whether or not for compensation, and whether or not as an employee, be engaged in or have a financial interest in any business, competing with the business of the Company or of any Affiliate within any state, region or locality in which the Company or such Affiliate is then doing business or marketing products, as the business of the Company or such Affiliates may then be constituted. With respect to this sub-section, however, it is understood and agreed that a business is not competing with the business of the Company or any Affiliate if (A) Participant's duties with respect to such business relate solely to discrete business units which do not compete with the business of the Company or any Affiliate; or (B) the competitive activity is limited to geographical markets or products in which the Company or Affiliate was not engaged (whether by manufacture, distribution, sale, or development for manufacture, distribution, or sale) during the two (2) years immediately preceding the termination of Participant's employment with the Company.

(iii) shall, upon reasonable notice and at the Company's expense, cooperate fully with any reasonable request that may be made by the Company (giving due consideration for Participant's obligations with respect to any new employment or business activity) in connection with any investigation,

litigation, or other similar activity to which the Company or any Affiliate is or may be a party or otherwise involved and for which Participant may have relevant information.

(iv) shall sign and deliver a suitable waiver and release under which the Participant shall release and discharge the Company and its Affiliates from and on account of any and all claims that relate to or arise out of the employment relationship between the Company and the Participant.

(d) Should Participant breach any obligation set forth in Section 3(d), above, (which breach remains uncured for a period of 10 days following written notice) the Company shall be relieved of any obligation to make further payments to Participant and shall be entitled to receive full repayment and restitution of all amounts theretofore paid to Participant under this Section 3.

Section 4. Termination Protection. If during the term of this Program

(a) a Participant's employment with the Company is terminated by the Company without Cause, or a Participant resigns for Good Reason, in each case within eighteen (18) months following a Change of Control, or

(b) a Participant's employment with the Company is terminated prior to a Change of Control (which subsequently occurs) at the request of a party involved in such Change of Control, or otherwise in connection with or in anticipation of a Change of Control,

then in the case of each of clauses (a) and (b) such Participant shall become entitled to the compensation, benefits and rights set forth in Section 5 (a) through (g), inclusive.

Section 5. Benefits and Rights

(a) A cash lump sum, payable within thirty (30) days following the date of termination, of employment equal to the sum of:

(i) such Participant's pro rata target annual bonus in respect of the year of termination;

(ii) any unpaid Base Salary and accrued paid-time-off through the date of termination;

(iii) any bonus earned but unpaid as of the date of termination for any previously completed year;

(iv) reimbursement for any unreimbursed expenses incurred by such Participant prior to the date of termination;

(v) an amount equal to 50% of such Participant's Compensation (or for Participants identified on **Appendix C** the greater percentage specified therein).

(b) Such Employee Benefits, if any, to which such Participant may be entitled as of the date of termination of employment under the relevant plans, policies and programs of the Company.

(c) Any unvested Company stock options held by such Participant that are outstanding on the date of termination of employment shall become fully vested as of such date, and the period during which any Company stock option held by such Participant that is outstanding on such date may be exercised shall be extended to a date that is the later of the fifteenth day of the third month following the date, or December 31 of the calendar year in which, such Company stock option would otherwise have expired if the exercise period had not been extended, but not beyond the final date such Company stock option could have been exercised if the Participant's employment had not terminated, in each case based on the terms of such option at the original grant date.

(d) Continued eligibility for such Participant and his/her eligible dependents to receive Employee Benefits, for a period of 6 months following such Participant's date of termination of employment (or for Participants identified on **Appendix C** the greater period specified therein), except where the provision of such Employee Benefits would result in a duplication of benefits provided by any subsequent employer.

(e) The amounts specified in Section 6, if applicable.

(f) All rights such Participant has to indemnification from the Company immediately prior to the Change of Control shall be retained for the maximum period permitted by applicable law, and any director's and officer's liability insurance covering such Participant immediately prior to the Change of Control shall be continued throughout the period of any applicable statute of limitations.

(g) The Company shall advance to such Participant all costs and expenses, including all attorneys' fees and disbursements, incurred by such Participant in connection with any legal proceedings (including arbitration), which relate to the termination of employment or the interpretation or enforcement of any provision of this Program, and the Participant shall have no obligation to reimburse the Company for any amounts advanced hereunder where such Participant prevails in such proceeding with respect to at least one material issue, it being acknowledged that settlement of any such proceeding shall relieve the Participant from any reimbursement obligation.

Section 6. Excise Tax Gross-Up.

(a) Anything in this Program to the contrary notwithstanding and except as set forth below, in the event it shall be determined that any Payment would be subject to the Excise Tax, then the Participant shall be entitled to receive an additional payment (the "Gross-Up Payment") in an amount such that, after payment by the Participant of all taxes (and any interest or penalties imposed with respect to such taxes), including, without limitation, any income taxes (and any interest and penalties imposed with respect thereto) and Excise Tax imposed upon the Gross-Up Payment, the Participant retains an amount of the Gross-Up Payment equal to the Excise Tax imposed upon the Payments. Notwithstanding the foregoing provisions of this Section 6(a), if it shall be determined that the aggregate Parachute Value of all Payments is more than 100% but not more than 110% of the Safe Harbor Amount, then no Gross-Up Payment shall be made to the Participant and the amounts payable under this Program shall be reduced so that the Parachute Value of all

Payments, in the aggregate, equals the Safe Harbor Amount. The reduction of the amounts payable hereunder, if applicable, shall be made by first reducing the payments under Section 5(a)(vi), unless an alternative method of reduction is elected by the Participant, and in any event shall be made in such a manner as to maximize the Value of all Payments actually made to the Participant. For purposes of reducing the Payments to the Safe Harbor Amount, only amounts payable under this Program (and no other Payments) shall be reduced. If the reduction of the amount payable under this Program would not result in a reduction of the Parachute Value of all Payments to the Safe Harbor Amount, no amounts payable under this Program shall be reduced pursuant to this Section 6(a). The Company's obligation to make Gross-Up Payments under this Section 6 shall not be conditioned upon the Participant's termination of employment.

(b) Subject to the provisions of Section 6(c), all determinations required to be made under this Section 6, including whether and when a Gross-Up Payment is required and the amount of such Gross-Up Payment and the assumptions to be utilized in arriving at such determination, shall be made such certified public accounting firm as may be designated by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Participant within 15 business days of the receipt of notice from the Participant that there has been a Payment, or such earlier time as is requested by the Company. All fees and expenses of the Accounting Firm shall be borne solely by the Company. Any Gross-Up Payment, as determined pursuant to this Section 9, shall be paid by the Company to the Participant within five days of the receipt of the Accounting Firm's determination. Any determination by the Accounting Firm shall be binding upon the Company and the Participant. As a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial determination by the Accounting Firm hereunder, it is possible that Gross-Up Payments that will not have been made by the Company should have been made ("Underpayment"), consistent with the calculations required to be made hereunder. In the event that the Company exhausts its remedies pursuant to Section 6(c) and the Participant thereafter is required to make a payment of any Excise Tax, the Accounting Firm shall determine the amount of the Underpayment that has occurred and any such Underpayment shall be promptly paid by the Company to or for the benefit of the Participant.

(c) The Participant shall notify the Company in writing of any claim by the Internal Revenue Service that, if successful, would require the payment by the Company of the Gross-Up Payment. Such notification shall be given as soon as practicable after the Participant is informed in writing of such claim and shall apprise the Company of the nature of such claim and the date on which such claim is requested to be paid. The Participant shall not pay such claim prior to the expiration of the 30-day period following the date on which it gives such notice to the Company (or such shorter period ending on the date that any payment of taxes with respect to such claim is due). If the Company notifies the Participant in writing prior to the expiration of such period that it desires to contest such claim, the Participant shall:

(i) give the Company any information reasonably requested by the Company relating to such claim,

(ii) take such action in connection with contesting such claim as the Company shall reasonably request in writing from time to time, including, without limitation,

accepting legal representation with respect to such claim by an attorney reasonably selected by the Company,

(iii) cooperate with the Company in good faith in order effectively to contest such claim, and

(iv) permit the Company to participate in any proceedings relating to such claim;

provided, however, that the Company shall bear and pay directly all costs and expenses (including additional interest and penalties) incurred in connection with such contest and shall indemnify and hold the Participant harmless, on an after-tax basis, for any Excise Tax or income tax (including interest and penalties with respect thereto) imposed as a result of such representation and payment of costs and expenses. Without limitation on the foregoing provisions of this Section 6(c), the Company shall control all proceedings taken in connection with such contest and, at its sole option, may pursue or forgo any and all administrative appeals, proceedings, hearings and conferences with the taxing authority in respect of such claim and may, at its sole option, either direct the Participant to pay the tax claimed and sue for a refund or contest the claim in any permissible manner, and the Participant agrees to prosecute such contest to a determination before any administrative tribunal, in a court of initial jurisdiction and in one or more appellate courts, as the Company shall determine; provided, however, that if the Company directs the Participant to pay such claim and sue for a refund, the Company shall advance the amount of such payment to the Participant, on an interest-free basis and shall indemnify and hold the Participant harmless, on an after-tax basis, from any Excise Tax or income tax (including interest or penalties with respect thereto) imposed with respect to such advance or with respect to any imputed income with respect to such advance; and further provided that any extension of the statute of limitations relating to payment of taxes for the taxable year of the Participant with respect to which such contested amount is claimed to be due is limited solely to such contested amount. Furthermore, the Company's control of the contest shall be limited to issues with respect to which a Gross-Up Payment would be payable hereunder and the Participant shall be entitled to settle or contest, as the case may be, any other issue raised by the Internal Revenue Service or any other taxing authority.

(d) If, after the receipt by the Participant of a Gross-Up Payment or payment by the Company of an amount on the Participant's behalf pursuant to Section 6(c), the Participant becomes entitled to receive any refund with respect to the Excise Tax to which such Gross-Up Payment relates or with respect to such claim, the Participant shall (subject to the Company's complying with the requirements of Section 6(c), if applicable) promptly pay to the Company the amount of such refund (together with any interest paid or credited thereon after taxes applicable thereto).

(e) Notwithstanding any other provision of this Section 6, the Company may, in its sole discretion, withhold and pay over to the Internal Revenue Service or any other applicable taxing authority, for the benefit of the Participant, all or any portion of any Gross-Up Payment, and the Participant hereby consents to such withholding.

(f) The following terms shall have the meanings below for purposes of this Section 6.

(i) “Excise Tax” shall mean the excise tax imposed by Section 4999 of the Code, together with any interest or penalties imposed with respect to such excise tax.

(ii) “Parachute Value” of a Payment shall mean the present value as of the date of the Change of Control for purposes of Section 280G of the Code of the portion of such Payment that constitutes a “parachute payment” under Section 280G(b)(2), as determined by the Accounting Firm for purposes of determining whether and to what extent the Excise Tax will apply to such Payment.

(iii) A “Payment” shall mean any payment or distribution in the nature of compensation (within the meaning of Section 280G(b)(2) of the Code) to or for the benefit of the Participant, whether paid or payable pursuant to this Program or otherwise.

(iv) The “Safe Harbor Amount” means 2.99 times the Participant’s “base amount,” within the meaning of Section 280G(b)(3) of the Code.

(v) “Value” of a Payment shall mean the economic present value of a Payment as of the date of the Change of Control for purposes of Section 280G of the Code, as determined by the Accounting Firm using the discount rate required by Section 280G(d)(4) of the Code.

Section 7. No Mitigation or Offset. Except as provided in Section 5(d), a Participant shall not be required to mitigate the amount of any payment or benefit provided for under this Program by seeking other employment or otherwise, nor shall the amount of any payment or benefit provided for hereunder be reduced by any compensation or benefits earned or received by such Participant as the result of employment by a subsequent employer, by retirement benefits, by offset against any amount claimed to be owed by such Participant to the Company or otherwise.

Section 8. Validity. The invalidity or unenforceability of any provision of this Program shall not affect the validity or enforceability of any other provision of this Program, which other provision shall remain in full force and effect.

Section 9. Withholding. All payments hereunder shall be reduced by any applicable taxes required by applicable law to be paid or withheld by the Company.

Section 10. Modification or Waiver. No provision of this Program may be modified, waived or discharged, if such modification, waiver or discharge adversely affects a Participant, unless such modification, waiver or discharge is agreed to in writing and signed by such Participant.

Section 11. Applicable Law. This Program shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to conflicts of laws principles thereof.

Section 12. Administration of Program. This Program will be administered by the Board. The Board shall have authority to adopt, amend and repeal such administrative rules, guidelines and practices relating to this Program as it shall deem advisable. The Board may construe and interpret the terms of this Program and correct any defect, supply any omission or reconcile any inconsistency in the Program in the manner and to the extent that it shall deem expedient to carry the Program

into effect and it shall be the sole and final judge of such expediency. All decisions of the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Program. Neither the Board nor the Chief Executive Officer of the Company shall have any liability for any decision made in good faith in interpreting, implementing or operating this Program, including without limitation, any changes made to the definition Good Reason, in establishing the list of Participants, or in selecting the Participants to be included in any of the Appendices attached to this Program. The Company hereby agrees to indemnify and hold harmless each member of the Board and each officer, including without limitation the Chief Executive Officer of the Company, for (and in each case, advance) any and all costs and expenses incurred in connection with the administration, operation and implementation of the Program, including without limitation any changes made to the definition Good Reason, in establishing the list of Participants, or in selecting the Participants to be included in any of the Appendices attached to this Program. No amounts paid under this Section 12 for or on account of any of the foregoing officers or directors shall be included in Compensation under this Program.

Section 13. Section 409A. All payments and benefits provided under this Program are intended to either comply with or be exempt from Section 409A of the Code and this Program shall be administered and construed accordingly. Notwithstanding any provision of this Program to the contrary, 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) of the Code and the regulations thereunder, then any payments under this Program to the Participant that constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code shall be delayed by a period of six months and (i) all such payments that would have been made to the Participant during such six month period shall be made in a lump sum in the seventh month following the date of termination and (ii) all remaining such payments shall commence in the seventh month following the date of termination.

Emergent BioSolutions Inc.
Severance Plan and Termination Protection Program

In accordance with Addendum I of the Severance Plan and Termination Protection Program, the Chief Executive Officer of the Company may exercise any one of the following actions:

Designate the greater of seven percent (7%) of the total number of employees of the Company, or 35 employees of the Company to be Program Participants at any particular time, on the basis of name, title, function or compensation level (**Appendix A**);

Designate up to 2 Participants for whom any reason for resigning within a thirty day period following the first anniversary of a Change of Control shall constitute "Good Reason" (**Appendix B**);

Designate up to 12 Participants whose percentage specified in Sections 3(a)(v) and 5(a)(v) shall be greater than 50% and the applicable time period under Section 3(a)(vii) (Emergent Benefits) Section 3(b) (Payout) Section 3(d) (Non-Solicit/Non-Compete) and Section 5(d) (Employees Benefits) shall be longer than 6 months (**Appendix C**).

List of Participants in the Termination Protection Plan Program

In accordance with the Severance Plan and Termination Protection Program, the Chief Executive Officer of the Company may designate the greater of (a) seven percent (7%) of the total number of employees of the Company; or (b) 35 employees of the Company to be Participants in this Program at any particular time, on the basis of name, title, function, or compensation level.

Emergent BioSolutions - Gaithersburg

Name of Participant	*Title of Participant*
Fuad El-Hibri	Chief Executive Officer
Ed Arcuri	Executive VP, Chief Operating Officer
Dan Abdun-Nabi	Senior VP, Corporate Affairs & General Counsel
Kyle Keese	Senior VP, Marketing & Communications
Thomas Zink	Senior VP, Medical Affairs & Chief Medical Officer
Don Elsey	VP, Chief Financial Officer
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

Emergent BioSolutions - BioDefense Operations - Lansing

Name of Participant	*Title of Participant*
Robert Kramer	President, BioDefense Operations — Lansing
[**]	[**]
[**]	[**]

Emergent BioSolutions - Product Development - Gaithersburg

Name of Participant	*Title of Participant*
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

Emergent BioSolutions - Product Development - Reading

Name of Participant	*Title of Participant*
Steven Chatfield	Chief Scientific Officer & President, Emergent Product Development — Reading
[**]	[**]

Emergent BioSolutions - Sales & Marketing - Germany

Name of Participant	*Title of Participant*
[**]	[**]

Total: 23 Participants

List of Participants

Termination Without Cause — No CIC

Name of Participant	*Applicable Percentage of Base Salary*	*Severance Payment and Continuation Benefit*
Fuad El-Hibri	150%	18 months
Edward Arcuri	100%	12 months
Robert Kramer	100%	12 months
Daniel Abdun-Nabi	100%	12 months
Kyle Keese	100%	12 months
*Steve Chatfield	75%	9 months
(Chatfield's current employment contract includes language re: the Severance Plan and Termination Protection Program)		
[**]	[**]%	[**]
Don Elsey	75%	9 months
Tom Zink	75%	9 months

Total: 9 Participants

List of Participants

Termination Without Cause — CIC

Name of Participant	*Applicable Percentage of Base Salary*	*Severance Payment and Continuation Benefit*
Fuad El-Hibri	250%	30 months
Edward Arcuri	200%	24 months
Robert Kramer	200%	24 months
Daniel Abdun-Nabi	150%	18 months
Kyle Keese	100%	12 months
Steve Chatfield	100%	12 months
[**]	[**]%	[**]
Don Elsey	75%	9 months
Tom Zink	75%	9 months

Total: 9 Participants

Confidential Materials omitted and filed separately with the
Securities and Exchange Commission. Asterisks denote omissions.

SOLICITATION, OFFER AND AWARD | 1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) | RATING: DO-C9 | PAGE 1 OF PAGES 26

2. CONTRACT NUMBER	3. SOLICITATION NUMBER	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NUMBER
W9113M-04-D-0002	W9113M-0R-4-0004	☐ SEALED BID (IFB) ☐ NEGOTIATED (RFP)	11/18/2003	W90GXK33010005

7. ISSUED BY CODE W9113M
US Army Space and Missile Defense Command,
64 Thomas Johnson Drive
Frederick, MD 21702

8. ADDRESS OFFER TO (*if other than Item 7*)
Same

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder".

SOLICITATION

Sealed offers in original and _____ copies for furnishing the supplies or services in the Schedule will be received at the place specified in item 8, or if handcarried, in the depository located in _____ until _____ (Hour) local time _____ (Date)

CAUTION – LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE (*NO COLLECT CALLS*) AREA CODE	NUMBER	EXT.	C. E-MAIL ADDRESS
	Lynn M. Selfridge	301	619-2707		Lynne.Selfridge@SMCC.A

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OFFER ***(Must be fully completed by offeror)***

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within 60 calendar days *(60 calendar days unless a different period is inserted by the offeror)* from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT *(See Section I, Clause No. 52.232-8)*	10 CALENDAR DAYS (%)	20 CALENDAR DAYS (%)	30 CALENDAR DAYS (%)	CALENDAR DAYS (%)

14. ACKNOWLEDGEMENT OF AMENDMENTS *(The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated)*:	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR: CODE 1H086 FACILITY
BioPort Corporation
3500 N. Martin Luther King JR., Blvd.
Lansing, Michigan 48906

16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER *(Type or print)*
Robert G. Kramer, President

15B. TELEPHONE NUMBER AREA CODE	NUMBER	EXT.	15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE – ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE
517	327 - 1579		☐	/s/ Robert G. Kramer	Jan. 3, 2004

AWARD ***(To be completed by Government)***

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION
0001-0003		To be cited on individual delivery orders

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	23. SUBMIT INVOICES TO ADDRESS SHOWN IN *(4 copies unless otherwise specified)*	ITEM
☒ 10 U.S.C. 2304(c) (1) ☐ 41 U.S.C. 253(c) ( )		

24. ADMINISTERED BY *(If other than Item 7)* CODE S2303A	25. PAYMENT WILL BE MADE BY CODE
DCMA Detroit-Grand Rapids 678 Front Avenue, NW Grand Rapids, MI 49504-5352	DFAS-Columbus ATTN: DFAS-CO/Chesapeake, PO Box 182264 Columbus, Ohio 43218-2264

26. NAME OF CONTRACTING OFFICER *(Type or print)*	27. UNITED STATES OF AMERICA	28. AWARD DATE
Lynn M. Selfridge	/s/ Lynn M. Selfridge *(Signature of Contracting Officer)*	Jan. 3, 2004

IMPORTANT – Award will be made on this Form, or on Standard Form 26, or by other authorized official written notice.

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is unusable

STANDARD FORM 33 (REV. 9-97)
Prohibited by GSA – FAR (48 CFR) 53.214(c)

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
	ACRN AA Funded Amount				

FOB: Origin

ITEM NO	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0002		[**]		$ [**]	$ 95,950,567.80
OPTION					
	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	SUPPLIES/SERVICES	MAX QUANTITY	UNIT	UNIT PRICE	MAX AMOUNT
0003		[**]		$ [**]	$ 78,340,433.60
OPTION					
	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:

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.

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	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0001	IAW Attachment No. 1 in Section J of the Contract	1,297,380	To be determined	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.

(l) 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 name.

(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.

(End of clause)

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).

_____ (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) (U.S.C. 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)).

_____ (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).

_____ (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.S.-Flag 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) (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 (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).

(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's performance 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.

(l) 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%

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*	Bu					
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	1,383.52
208	DAMD17-91-C-1139	P	Co	9/1/00	Compaq Deskpro En NT Workstation	1,878.91
263	DAMD17-91-C-1139	P	Co	9/1/00	Compaq Proliant ML530 Server and Parts	10,842.00
180	DAMD17-91-C-1139	P	Co	10/1/00	HP Brio BA410 Computer	1,019.35
220	DAMD17-91-C-1139	P	Co	10/1/00	Compaq Deskpro En Workstation	1,440.00
183	DAMD17-91-C-1139	P	Co	11/1/00	Viewsonic 17” Color Monitor	228.87
182	DAMD17-91-C-1139	P	Co	11/1/00	Compaq Deskpro EN Pen III 733 mhz	1,318.87
184	DAMD17-91-C-1139	P	Co	11/1/00	Compaq Deskpro EN Pen III 733 mhz and Viewsoni	1,318.87
186	DAMD17-91-C-1139	P	Co	11/1/00	Compaq Deskpro EN Pen III 733 mhz and Viewsonic	1,318.87
746	DAMD17-91-C-1139	P	Co	11/1/00	Datafile Diskette for VAERS	1,344.00
181	DAMD17-91-C-1139	P	Co	12/1/00	Elron Software Server	3,669.46
244	DAMD17-91-C-1139	P	Co	12/1/00	Security System Upgrade, Camera and wiring neces	128,502.20
273	DAMD17-91-C-1139	P	Co	1/1/01	Viewsonic 17” Color Monitor	189.99
274	DAMD17-91-C-1139	P	Co	1/1/01	Viewsonic 17” Color Monitor	189.99
275	DAMD17-91-C-1139	P	Co	1/1/01	Viewsonic 17” Color Monitor	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	Co	1/24/02	Dell P793 Monitor	274.54
533	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
534	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
535	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	274.54
536	DAMD17-91-C-1139	P	Co	1/24/02	Dell P793 Monitor	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
812	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
813	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
814	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
815	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
816	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
817	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
856	DAMD17-91-C-1139	P	Co	10/1/02	Dell P793 Monitor	350.26
857	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.94
858	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.94
859	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.94
860	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.94
861	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
862	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
863	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
864	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
865	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
866	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
867	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
868	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
869	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
870	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
871	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
872	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
873	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
874	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
875	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
876	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
877	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
878	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
879	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
880	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
881	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
882	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
883	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
884	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
885	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
886	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
887	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
888	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
889	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
890	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
891	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
892	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
893	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
894	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
895	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
896	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
897	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
898	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
899	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
900	DAMD17-91-C-1139	P	Co	10/1/02	Dell Optiplex GX 240 Small Mini Tower	1,250.95
901	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	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
961	DAMD17-91-C-1139	P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
962	DAMD17-91-C-1139	P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
963	DAMD17-91-C-1139	P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
964	DAMD17-91-C-1139	P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
965	DAMD17-91-C-1139	P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
966	DAMD17-91-C-1139	P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
967	DAMD17-91-C-1139	P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08
968	DAMD17-91-C-1139	P	Co	5/1/03	Dell Optiplex GX 240 Small Mini Tower	1,230.08

Contract Sys 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
146	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	3/1/00	Eppendorf Centrifuge 5417R w/rotor	5,357.00
260	DAMD17-91-C-1139	P	Eq	3/1/00	Eppendorf Centrifuge 5417R w/rotor	5,357.00
254	DAMD17-91-C-1139	P	Eq	3/1/00	96 Well Plate Washer	7,229.16
266	DAMD17-91-C-1139	P	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	Acquisition Class	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	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-SubTotal		Eq				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	1,953.00
233	DAMD17-91-C-1139	P	Fu	8/1/00	Office furniture	1,983.05
234	DAMD17-91-C-1139	P	Fu	8/1/00	Office furniture	2,077.00
239	DAMD17-91-C-1139	P	Fu	8/1/00	Office furniture	2,543.00
236	DAMD17-91-C-1139	P	Fu	8/1/00	Office furniture	4,302.20
228	DAMD17-91-C-1139	P	Fu	8/1/00	Furniture	7,341.31
227	DAMD17-91-C-1139	P	Fu	8/1/00	Furniture	21,390.75
243	DAMD17-91-C-1139	P	Fu	10/1/00	Management Chair	541.87
230	DAMD17-91-C-1139	P	Fu	10/1/00	Office Furniture	2,120.00
240	DAMD17-91-C-1139	P	Fu	10/1/00	Office Furniture	2,120.00
238	DAMD17-91-C-1139	P	Fu	10/1/00	(13) Task Chairs, Paint and Carpet Squares	2,535.58
241	DAMD17-91-C-1139	P	Fu	12/1/00	10 Chairs	2,039.99
242	DAMD17-91-C-1139	P	Fu	12/1/00	Office Furniture	2,231.50
715	DAMD17-91-C-1139	P	Fu	3/1/01	Heather Blue Chair	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	Fu	4/1/02	Stainless Steel Utility Cart	370.30
733	DAMD17-91-C-1139	P	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-SubTotal	Fu					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-Subtotal	Im					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
15	DAMD17-97-E-0004	P	Eq	9/1/91	10 Liter Fermenter, Train 3	102,900.00
16	DAMD17-97-E-0004	P	Eq	9/1/91	100 Liter Fermenter, Train 4	102,900.00
17	DAMD17-97-E-0004	P	Eq	9/1/91	10 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-		Eq				
Subtotal						1,252,478.00
77	DAMD17-97-E-0004	R	Im	9/1/94	Stairs	1,000.00
Class-		Im				
Subtotal						1,000.00
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-		Eq				
Subtotal						250,000.00
Contract #-	DAMD17-98-C-8052					
Subtotal						250,000.00
Grand Total:						13,965,861.67

	Jan	Feb	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec	Total
Jan 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
Jan 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
Jan 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

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
J	1		2

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00001	20-Jan-2004	W90GXK33010005	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
US ARMY SPACE & MISSILE DEFENSE COMMAND SMDC-CM-CB / MS. O'CONNELL 301-819-2895 64 THOMAS JOHNSON DRIVE FREDERICK, MD 21702	W9113M	DCMA GRAND RAPIDS RIVERVIEW CENTER BUILDING 678 FRONT STREET, NW GRAND RAPIDS, MI 49504-5352	S2303A

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and ZIP Code)		9A. AMENDMENT OF SOLICITATION NO.
BIOPORT CORPORATION 3400 N. MARTIN LUTHER KING JR. BLVD LANSING, MI 48906		9B. DATED (SEE ITEM 11)
	X	10A. MOD OF CONTRACT/ORDER NO. W9113M-04-D-0002
	X	10B. DATED (SEE ITEM 13) 08-Jan-2004
CODE 1H086	FACILITY CODE	

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 for receipt of Offers ☐ is extended, ☐ 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 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 your 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)

13. THIS ITEM ONLY APPLIES TO MODIFICATION 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.
X	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).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

See Attached

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) LYNN M. SELFRIDGE/CONTRACTING OFFICER TEL: 301-619-2707 EMAIL: lynn.selfridge@DET.AMEDD.ARMY.MIL	
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY /s/ Lynn M. Selfridge (Signature of Contracting Officer)	16C. DATE SIGNED 22-JAN-2004

EXCEPTION TO SF 30
APPROVED BY OIRM 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 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)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
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2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00002	2-Sep-2004	W90GXK33010005	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
US ARMY SPACE & MISSILE DEFENSE COMMAND SMDC-CM-CB / MS. SELFRIDGE 301-619-2707 64 THOMAS JOHNSON DRIVE FREDERICK, MD 21702	W9113M	DCM GRAND RAPIDS RIVERVIEW CENTER BUILDING 678 FRONT STREET, NW GRAND RAPIDS, MI 49504-5352	S2303A

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		9B. DATED (SEE ITEM 11)
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. W9113M-04-D-0002
	X	10B. DATED (SEE ITEM 13) 06-Jan-2004
CODE 1HDB6	FACILITY CODE	

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 for receipt of Offers ☐ is extended, ☐ 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 1 5, 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 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 your 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)

13. THIS ITEM ONLY APPLIES TO MODIFICATION 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.
	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 IT EM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER (Specify type of modification and authority) FAR52.217-9

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Exercise Option

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) LYNN SELFRIDGE, / CONTRACTING OFFICER TEL: 301-619-2707 EMAIL: lynn.selfridge@DET.AMEDD.ARMY.MIL	
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY /s/ Lynn M. Selfridge (Signature of Contracting Officer)	16C. DATE SIGNED 2-Sep-2004

EXCEPTION TO SF 30
APPROVED BY OIRM 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)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
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2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00003	09/28/04	N/A	N/A

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
U.S. Army Space and Missile Defense Command Attn: SMDC-CM-CB 64 Thomas Johnson Drive Fredrick, MD 21702	W9113M	DCMA Detroit-Grand Rapids 678 Front Avenue, NW Grand Rapids, MI 49504-5352	S2303A

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)	(X)	9A. AMENDMENT OF SOLICITATION NO.
BioPort Corporation, Inc. 3500 Martin Luther King Jr., Blvd. Lansing, MI 48906		9B. DATED (SEE ITEM 11)
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. W9113M-04-D-0002
CODE 1H0B6 FACILITY CODE		10B. DATED (SEE ITEM 11) 01/04/04

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 for receipt of Offers ☐ is extended, ☐ 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 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 RESULTINREJECTION OF YOUR OFFER. If by virtue of this amendment, your 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 ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE		
	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.
	B.	THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH INITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C.	THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D.	OTHER (Specify type of modification and authority) PL 85-804, Implemented byFAR 50.403-2(b) and MoD dated Sep. 28, 2004

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

See Attached.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
		LYNN M. SELFRIDGE	
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA /s/ Lynn M. Selfridge (Signature of Contracting Officer)	16C. DATE SIGNED 09/28/04

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.

52.250 — 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 —

(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 contract 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, 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 —

(1) 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

(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 Contactor 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 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)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
J	1		2

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00004	26-Oct-2004	W90GXK33010005	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
CHEMICAL-BIOLOGICAL-MEDICAL SYSTEMS PMO 64 THOMAS JOHNSON DRIVE FREDERICK MD 21702	W90GXK	DCM GRAND RAPIDS RIVERVIEW CENTER BUILDING 678 FRONT STREET, NW GRAND RAPIDS MI 49504-5352	S2303A

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and ZIP Code)		9A. AMENDMENT OF SOLICITATION NO.
BIOPORT CORPORATION 3500 N MARTINLUTHER KING JR BLVD LANSING MI 48906		9B. DATED (SEE ITEM 11)
	(X)	10A. MODIFICATION OF CONTRACT/ORDER NO. W9113M-04-D-0002
CODE 1HOB6 FACILITY CODE	(X)	10B. DATED (SEE ITEM 13) 06-Jan-2004

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 for receipt of Offers ☐ is extended, ☐ 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 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 your 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)

13. THIS ITEM ONLY APPLIES TO MODIFICATION 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.
	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).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Mutual Agreement
	D. OTHER (Specify type of modification 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 terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) LYNN M. SELFRIDGE / CONTRACTING OFFICER	
Robert Kramer, President & CEO		TEL: 301-619-2707 EMAIL: Lynn.Selfridge@DET.AMEDD.ARMY.MIL	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Robert Kramer (Signature of person authorized to sign)	11/12/04	BY /s/ Lynn M. Selfridge (Signature of Contracting Officer)	03-Nov-2004

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:

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
	Funded Amount				$ 0.00

FOB: Destination

SECTION E — INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0004:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	Government

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
J	1		5

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00005	Nov 16 2004	W90GXK33010005	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
CHEMICAL-BIOLOGICAL-MEDICAL SYSTEMS PMO 64 THOMAS JOHNSON DRIVE FREDERICK MD 21702	W90GXK	DCM GRAND RAPIDS RIVERVIEW CENTER BUILDING 678 FRONT STREET, NW GRAND RAPIDS MI 49504-5352	S2303A

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		9B. DATED (SEE ITEM 11)
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. W9113M-04-D-0002
CODE 1HOB6	X	10B. DATED (SEE ITEM 13) 06-Jan-2004
FACILITY CODE		

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 for receipt of Offers ☐ is extended, ☐ 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 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 your 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)

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

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X	C.	THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Mutual Agreement
	D.	OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Revise quantity of CLIN 0004 in P00004 dated November 3, 2004 from 1 test to 2 tests, and to increase the total value of CLIN 0004 to $104,648.

The Statement of Work Paragraph C.1.4.b. is revised to read: All testing "other than" Pentavalent Botulinum Vaccine.... as included on the attached SOW.

FAR 52.216-19 and FAR 52.232-32 of the contract are not applicable to CLIN 0004.

Funding will be provided on individual delivery orders.

All other terms and conditions of the contract remain unchanged and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Robert Kramer, President & CEO		LYNN M. SELFRIDGE TEL: EMAIL:	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
By /s/ Robert Kramer (Signature of person authorized to sign)	11/12/04	BY /s/ Lynn M. Selfridge (Signature of Contracting Officer)	Nov 16, 2004

EXCEPTION TO SF 30
APPROVED BY OIRM 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.				

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.

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

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.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
J	1		2

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00006	01/04/04	N/A	N/A

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
U.S. Army Space and Missile Defense Command ATTN: SMDC-CM-CB 64 Thomas Johnson Drive Frederick, MD 21702	W9113M	DCMA Detroit-Grand Rapids 678 Front Street, NW Grand Rapids, MI 49504	S2101A

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)	(X)	9A. AMENDMENT OF SOLICITATION NO.
BioPort Corporation 3500 N. Martin Luther King, Jr. Blvd Lansing, MI 48906		9B. DATED (SEE ITEM 11)
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. W9113M-04-D-0002
		10B. DATED (SEE ITEM 11) 01/02/04
CODE / FACILITY CODE		

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 for receipt of Offers ☐ is extended, ☐ 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 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 your 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)
Not applicable

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE		
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X	C.	THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.212-4 (c)
	D.	OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

See Page 2.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Robert G. Kramer, President & CEO		Lynn M. Selfridge	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Robert G. Kramer (Signature of person authorized to sign)	2/3/05	/s/ Lynn M. Selfridge (Signature of Contracting Officer)	2/8/05

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 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 Price/dose	Adjusted 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.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
J	1		2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
01	02/16/05	N/A	N/A

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
U.S. Army Space and Missile Defense Command ATTN: SMDC-CM-CB 64 Thomas Johnson Drive Frederick, MD 21702	W9113M	DCMA Grand Rapids Riverview Center Building 678 Front Street, NW Grand Rapids, MI 49504-5352	S2303A

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)	(X)	9A. AMENDMENT OF SOLICITATION NO.
3500 N.BioPort Corporation Martin Luther King Jr. Blvd Lansing, MI 48906		9B. DATED (SEE ITEM 11)
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. W9113M-04-D-0002-0001
		10B. DATED (SEE ITEM 11) 01/02/04
CODE 1HNOB6 FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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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 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 your 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)
See Block 14, below.

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

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X	C.	THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.212-4
	D.	OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return __1__ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

This instrument modifies delivery order number 0001 issued under the provisions of contract W9113M-04-D-0002, as a result of contract modification P00006 dated February 8, 2005.

The price per dose of the commercially available anthrax vaccine (the DoD's Anthrax Vaccine Adsorbed) is increased to cover the additional expense for labels, labeling, packaging for shipment, stability testing, potency testing, and the provision of security at the BioPort Lansing, MI facility. The revised dose price is $[**].

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Robert G. Kramer, President & CEO		Lynn M. Selfridge	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Robert G. Kramer (Signature of person authorized to sign)	2/17/05	/s/ Lynn M. Selfridge (Signature of Contracting Officer)	2/17/05

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. 0001 is revised as follows:

ITEM NO	SUPPLIES	MIN QTY	UNIT	UNIT PRICE	AMOUNT
0001	AVA Vaccine	[**]	Dose	$ [**]	$ 32,408,552.40

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.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
J	1		2

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
01	02/16/05	N/A	N/A

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
U.S. Army Space and Missile Defense Command ATTN: SMDC-CM-CB 64 Thomas Johnson Drive Frederick, MD 21702	W9113M	DCMA Grand Rapids Riverview Center Building 678 Front Street, NW Grand Rapids, MI 49504-5352	S2303A

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)	(X)	9A. AMENDMENT OF SOLICITATION NO.
BioPort Corporation 3500 N. Martin Luther King Jr. Blvd Lansing, MI 48906		9B. DATED (SEE ITEM 11)
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. W9113M-04-D-0002-0002
		10B. DATED (SEE ITEM 11) 01/02/04
CODE 1HOB6 FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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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 SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment your 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)
See Block 14, below.

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X	C.	THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.212-4
	D.	OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

This instrument modifies delivery order number 0002 issued under the provisions of contract W9113M-04-D-0002, as a result of contract modification P00006 dated February 8, 2005.

The price per dose of the commercially available anthrax vaccine (the DoD's Anthrax Vaccine Adsorbed) is increased to cover the additional expense for labels, labeling, packaging for shipment, stability testing, potency testing, and the provision of security at the BioPort Lansing, MI facility. The revised dose price is $[**].

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
Robert G. Kramer, President & CEO	Lynn M. Selfridge

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Robert G. Kramer (Signature of person authorized to sign)	2/17/05	/s/ Lynn M. Selfridge (Signature of Contracting Officer)	2/17/05

Section B of delivery order no. 0002 is revised as follow:

ITEM NO	SUPPLIES	MIN QTY	UNIT	UNIT PRICE	AMOUNT
0002	AVA Vaccine	[**]	Dose	$ [**]	$ 36,870,814.50

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.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
J	1		2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
04	01-Oct-2006	[Illegible]	

6. ISSUED BY CODE W9113M

US ARMY SPACE & MISSILE DEFENSE COMMAND
SMDC-RDCM
PO BOX 1500
HUNTSVILLE, AL 15807-3501

7. ADMINISTERED BY (If other than Item 6) CODE S2303A

DCM GRAND RAPIDS
RIVERVIEW CENTER BUILDING
678 FRONT STREET, NW
GRAND RAPIDS MI 49504-5352

8. NAME AND ADDRESS OF CONTRACTOR (No. Street, County, State and ZIP Code)

BIOPORT CORPORATION
3500 N MARTIN LUTHER KING BLVD
LANSING MI 48906

CODE 1HOB6 FACILITY CODE

	9A. AMENDMENT OF SOLICITATION NO.
	9B. DATED (SEE ITEM 11)
X	10A. MODIFICATION OF CONTRACT/ORDER NO. W9113M-04-D-0002-0001
X	10B. DATED (SEE ITEM 13) 06-Jan-2004

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

O The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers O is extended, O 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 amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT 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 your 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)

13. THIS ITEM ONLY APPLIES TO MODIFICATION 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.
	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).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Mutual Agreement of Both Parties
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor O is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: oconnels0767

See Attached

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Robert G. Kramer, President & CEO		Lynn M. Selfridge TEL:	EMAIL:
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Robert G. Kramer (Signature of person authorized to sign)	10/12/06	By /s/ Lynn M. Selfridge (Signature of Contracting Officer)	October 12, 2006

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

A. DELIVERY INFORMATION

The delivery schedule is revised as follows:

FROM:

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0001	30-SEP-2006	1,297,380	Contractor's Facility FOB: Origin	

TO:

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0001	30-SEP-2006	[**]	Contractor's Facility	
	31-DEC-2006	[**]	FOB: Origin	

Those doses delivered on 31 Dec 06 shall have at least 30 months remaining shelflife, determined by the date of submission of the DD250 to the Government.

B. The parties specifically agree that consideration for the extension of the delivery date shown above is the removal of the proprietary markings from the Pentavalent Botulinum Toxoid (PBT) documents submitted with the test reports, for USAMMDA use only.

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
J	1		2

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
	01-Oct-2006	[Illegible]	

6. ISSUED BY CODE W9113M

US ARMY SPACE & MISSILE DEFENSE COMMAND
SMDC-RDCM
PO BOX 1500
HUNTSVILLE, AL 15807-3501

7. ADMINISTERED BY (If other than Item 6) CODE S2303A

DCM GRAND RAPIDS
RIVERVIEW CENTER BUILDING
678 FRONT STREET, NW
GRAND RAPIDS MI 49504-5352

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and ZIP Code)

BIOPORT CORPORATION
3500 N MARTIN LUTHER KING BLVD
LANSING MI 48906

CODE 1HOB6 FACILITY CODE

	9A. AMENDMENT OF SOLICITATION NO.
	9B. DATED (SEE ITEM 11)
X	10A. MODIFICATION OF CONTRACT/ORDER NO. W9113M-04-D-0002-0004
X	10B. DATED (SEE ITEM 13) 01-Jan-2006

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

O The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers O is extended, O 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 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 your 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)

13. THIS ITEM ONLY APPLIES TO MODIFICATION 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.
	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).
û	C.	THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Mutual Agreement of Both Parties
	D.	OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor O is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: oconnels0768
See Attached

Except as provided herein, all terms and conditions of the document referenced in item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Robert G. Kramer, President & CEO		TEL:	EMAIL:
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Robert G. Kramer (Signature of person authorized to sign)	10/12/06	By /s/ Lynn M. Selfridge (Signature of Contracting Officer)	October 12, 2006

EXCEPTION TO SF 30
APPROVED BY OIRM 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

A. DELIVERY INFORMATION

The delivery schedule is revised as follows:

FROM: CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0003	30 SEP 06	1,034,930	BioPort Corporation 3500 N. Martin Luther King Jr., Blvd Lansing, MI 48906	
0004	30 SEP 06	[**]	Same as Above	

TO: CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0003	30 SEP 06	[**]	BioPort Corporation	
	31 DEC 06	[**]	3500 N. Martin Luther King Jr., Blvd Lansing, MI 48906	
0004	31 DEC 06	[**]	Same as Above	

Those doses delivered on 31 Dec 06 shall have at least 30 months remaining shelflife, determined by the date of submission of the DD250 to the Government.

B. The parties specifically agree that consideration for the extension of the delivery date shown above is the removal of the proprietary markings from the Pentavalent Botulinum Toxoid (PBT) documents submitted with the test reports, for USAMMDA use only.

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
J	1		2

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00009	30-Sep-2006	[Illegible]	

6. ISSUED BY	CODE	W9113M	7. ADMINISTERED BY (If other than Item 6)	CODE	S2303A
US ARMY SPACE & MISSILE DEFENSE COMMAND SMDC-RDCM PO BOX 1500 HUNTSVILLE, AL 15807-3501			DCM GRAND RAPIDS RIVERVIEW CENTER BUILDING 678 FRONT STREET, NW GRAND RAPIDS MI 49504-5352		

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 BLVD LANSING MI 48906		9B. DATED (SEE ITEM 11)
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. W9113M-04-D-0002
CODE 1H0B6	X	10B. DATED (SEE ITEM 13) 06-Jan-2004
FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

O The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers O is extended, O 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 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 your 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)

13. THIS ITEM ONLY APPLIES TO MODIFICATION 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.
	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).
X	C.	THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Mutual Agreement of both Parties
	D.	OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor O is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section heading, including solicitation/contract subject matter where feasible.)

Modification Control Number: oconnels082517

See Attached.

Except as provided herein, all terms and conditions of the document referenced in item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Robert G. Kramer, President & CEO		TEL:	EMAIL:
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Robert G. Kramer (Signature of person authorized to sign)	10/12/06	By /s/ Lynn M. Selfridge (Signature of Contracting Officer)	October 12, 2006

EXCEPTION TO SF 30 APPROVED BY OIRM 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

A. CLIN 0003 ordering period is changed to read from “January 1, 2006 through September 30, 2006” to “January 1, 2006 through February 16, 2007”.

B. Clauses in Section I. are revised as follows:

52.216-18 ORDERING, paragraph (a) is changed to read from “January 3, 2004 through September 30, 2006” to “January 3, 2004 through February 16, 2007”

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT, paragraph (c) is hereby changed from “33 months” to “38 months”.

C. By extending the dates for which the government may issue further delivery orders against this contract, the contractor agrees that it may also benefit from the contract extension and serves as the consideration due under any clause of this contract.

D. All other terms and conditions of this contract remain the same and in full force and effect.

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
J	1		2

2. AMENDMENT/MODIFICATION NO	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
02	01-Oct-2006	[Illegible]	

6. ISSUED BY CODE W9113M

US ARMY SPACE & MISSILE DEFENSE COMMAND
SMDC-RDCM
PO BOX 1500
HUNTSVILLE, AL 15807-3501

7. ADMINISTERED BY (If other than Item 6) CODE S2303A

DCM GRAND RAPIDS
RIVERVIEW CENTER BUILDING
678 FRONT STREET, NW
GRAND RAPIDS MI 49504-5352

8. NAME AND ADDRESS OF CONTRACTOR (No. Street, County State and ZIP Code)

BIOPORT CORPORATION
3500 N MARTIN LUTHER KING BLVD
LANSING MI 48906

CODE 1HOB6 FACILITY CODE

	9A. AMENDMENT OF SOLICITATION NO.
	9B. DATED (SEE ITEM 11)
X	10A. MODIFICATION OF CONTRACT/ORDER NO. W9113M-04-D-0002-0005
X	10B. DATED (SEE ITEM 13) 14-Jun-2006

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

O The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers O is extended, O 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 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 your 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)

13. THIS ITEM ONLY APPLIES TO MODIFICATION 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.
	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).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Mutual Agreement of Both parties
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor O is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: oconnels0770

See Attached

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Robert G. Kramer, President & CEO		Lyan M. selfridge	
		TEL:	EMAIL:
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Robert G. Kramer	10/12/06	By /s/ Lynn M. Selfridge	Oct 12, 2006
(Signature of person authorized to sign)		(Signature of Contracting Officer)	

EXCEPTION TO SF 30
APPROVED BY OIRM 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

A. DELIVERY INFORMATION

The delivery schedule is revised as follows:

FROM:

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0005	30-SEP-2006	[**]	Contractor's Facility FOB: Origin	

TO:

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0005	31-DEC-2006	[**]	Contractor's Facility FOB: Origin	

Those doses delivered on 31 Dec 06 shall have at least 30 months remaining shelflife, determined by the date of submission of the DD250 to the Government.

B. The parties specifically agree that consideration for the extension of the delivery date shown above is the removal of this proprietary markings from the Pentavalent Botulinum Toxoid (PBT) documents submitted with the test reports, for USAMMDA use only.

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE	OF	PAGES
J	1		2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
02	01-Oct-2006	SEE SCHEDULE	

6. ISSUED BY CODE W9113M

US ARMY SPACE & MISSILE DEFENSE COMMAND
SMDC-RDCM
PO BOX 1500
HUNTSVILLE, AL 15807-3501

7. ADMINISTERED BY (If other than Item 6) CODE S2303A

DCM GRAND RAPIDS
RIVERVIEW CENTER BUILDING
678 FRONT STREET, NW
GRAND RAPIDS MI 49504-5352

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County Sate and ZIP Code)

BIOPORT CORPORATION
3500 N MARTIN LUTHER KING BLVD
LANSING MI 48906

CODE 1HOB6 FACILITY CODE

	9A. AMENDMENT OF SOLICITATION NO.
	9B. DATED (SEE ITEM 11)
X	10A. MODIFICATION OF CONTRACT/ORDER NO. W9113M-04-D-0002-0006
X	10B. DATED (SEE ITEM 13) 22-Sep-2006

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

O The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers O is extended O 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 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 your 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)

13. THIS ITEM ONLY APPLIES TO MODIFICATION 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.
	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).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Mutual Agreement of Both Parties
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor O is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract, subject matter where feasible.)

Modification Control Number: oconnels076B

See Attached

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Robert G. Kramer, President & CEO		Lyan M. selfridge TEL:	EMAIL:
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Robert G. Kramer (Signature of person authorized to sign)	10/12/06	By /s/ Lynn M. Selfridge (Signature of Contracting Officer)	October 12, 2006

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

SECTION SF30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

A. DELIVERY INFORMATION

The delivery schedule is revised as follows:

FROM:

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0003	30 Jun 07	[**]	BioPort Corporation 3500 N. Martin Luther King Jr., Blvd Lansing, MI 48906	
	31 Jul 07	[**]	Same as above	
	31 Aug 07	[**]	Same as above	
0004	31 Aug 07	[**]	Same as above	
	30 Sep 07	[**]	Same as above	
	31 Oct 07	[**]	Same as above	
	30 Nov 07	[**]	Same as above	
	31 Dec 07	[**]	Same as above	

TO:

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0003	31 Mar 07	[**]	BioPort Corporation 3500 N. Martin Luther King Jr., Blvd Lansing, MI 48906	
	30 Apr 07	[**]	Same as above	
	31 May 07	[**]	Same as above	
0004	31 May 07	[**]	Same as above	
	30 Jun 07	[**]	Same as above	
	31 Jul 07	[**]	Same as above	
	31 Aug 07	[**]	Same as above	
	30 Sep 07	[**]	Same as above	

The above delivery schedule is subject to the ‘‘Early Delivery of Doses” clause found at section C.1.6 upon FDA approval of a supplement extending the shelf-life of BioThrax to four years.

B. The parties specifically agree that consideration for the early delivery of doses shown above is the contractors best efforts to obtain AVA shelf-life extension to four years.

(End of Summary of Changes)

Exhibit 10.25

AMENDED AND RESTATED
LOAN AGREEMENT

THIS AMENDED AND RESTATED LOAN AGREEMENT is made as of July 29th, 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 appointment by 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 or 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.

[The remainder of this page is intentionally left blank.]

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

Michael Debri

Its Vice President

Schedule 2.12

Plans

[Unavailable]

Schedule 2.16

Affiliates

[Unavailable]

April 25, 2006

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 Patrick D. Saam

Its Controller

FIFTH THIRD BANK

By /s/ Mark Conn

Its Vice President

AMENDMENT TO LOAN DOCUMENTS

AMENDMENT (this **"Agreement"**), dated as of August 25, 2006, by and among **FIFTH THIRD BANK**, a Michigan banking corporation (**"Lender"**) and **BIOPORT CORPORATION,** a Michigan corporation (**"Borrower"**).

RECITALS

A. 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 ("**Revolver Loan Agreement**") and to secure Borrower's obligations under the Revolver Loan Agreement, Borrower and Lender entered into an Amended and Restated Security Agreement, dated as of July 29, 2005 (the "**General Security Agreement**"), which security agreement is still in effect, and two mortgages, each dated as of July 30, 2004, granting Lender first priority liens against certain real estate owned by Borrower, which mortgages have been released by Lender pursuant to an Amendment, dated August 1, 2006, to the Revolver Loan Agreement and the related documents, by and between Lender and Borrower.

B. In addition, Borrower made an unrelated $2,400,000 Term Note on August 10, 2004 for the benefit of Lender (the "**Term Note**") and Borrower and Lender entered into a Security Agreement, dated as of August 10, 2004, securing Borrower's payment of the Term Note (the "**Term Note Security Agreement**").

C. HSBC Realty Credit Corporation (USA) ("HSBC") has agreed to make certain loans to the Borrower and in connection therewith, HSBC and Lender have agreed to enter into an Intercreditor Agreement, to be dated as of August 25, 2006 and acknowledged and consented to by the Borrower and Emergent BioSolutions Inc. (as Guarantor) (the "**Intercreditor Agreement**"), pursuant to which Lender and HSBC agree upon their various rights and remedies with respect to the assets of the Borrower securing their respective indebtedness.

D. In connection with the incurrence of the HSBC Indebtedness (as such term is defined in the Intercreditor Agreement), Borrower and Lender desire to amend certain provisions of the Revolver Loan Agreement and the Term Note, to terminate the Term Note Security Agreement and to update certain schedules delivered in connection with the Term Note.

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, the parties hereto agree as follows:

Article I. Revolver Loan Agreement

Section 1.01 The following definition shall be inserted in its entirety:

" "**Intercreditor Agreement**" means the Intercreditor Agreement, dated as of August 25, 2006, by and among HSBC Credit Realty Corporation

(USA) and the Lender, and acknowledged and consented to by the Borrower and Emergent BioSolutions Inc."

Section 1.02 The definition of "Collateral" shall be changed to read as follows:

" "**Collateral**" means all of Borrower's right, title and interest in, to and under (a) all accounts (as defined in the Uniform Commercial Code in effect as of the date hereof in the applicable state) that Borrower now owns and in the future acquires, including, without limitation, all Government Contracts, (b) the Enterprise Resource Planning System, together with all documents related to the installation and operation of it and (c) all proceeds of the foregoing and all books, records (including computer software) and documents that at any time evidence or relate to any of the foregoing or any proceeds of the foregoing."

Section 1.03 The following definition shall be inserted in its entirety:

" "**Enterprise Resource Planning System**" means a software system that integrates departments and functions across the organization and automates tasks involved in performing business processes. The ERP system was licensed from SAP and is supported with, and includes, specific hardware primarily purchased from Dell."

Section 1.04 The definition of "Government Contracts" shall be changed to read as follows:

" "**Government Contracts**" means (1) Contract No. W9113M-04-D-0002, dated January 3, 2004, between U.S. Army Space and Missile Defense Command ("**DOD**") and Borrower, which provides for Borrower to sell to DOD, and for DOD to purchase form Borrower, anthrax vaccine, as it has been and in the future is amended, (2) Contract No. 200-2005-11811 (amended to be designated Contract No. HHS0100200600019C), dated May 5, 2005, between the 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 it has been and in the future is amended, and (3) each other contract that Borrower at any time enters into with DOD or HHS or any other state or federal government agency or department and that provides for Borrower to sell goods and/or services to the government agency or department."

Section 1.05 The definition of "Permitted Lien**"** is hereby deleted in its entirety and the following language shall be inserted in its place:

" "**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, (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's books in accordance with GAAP and if the lien does not jeopardize any Collateral and does not have a Material Adverse Effect, and (5) the HSBC Liens (as such term is defined in the Intercreditor Agreement)."

Section 1.06 Section 5.3 of the Revolver Loan Agreement is hereby deleted in its entirety and the following language shall be inserted in its place:

"5.3 Borrower shall sign and deliver to Lender all financing statements, assignments, and other documents, agreements and instruments in connection with the perfection or priority of the security in the Collateral, and shall take all further actions that Lender reasonably requests in connection with the perfection or priority of the security in the Collateral."

Section 1.07 Section 6.5 of the Revolver Loan Agreement is hereby deleted in its entirety and the following language shall be inserted in its place:

"6.5 (1) Maintain insurance, including, but not limited to, fire, and extended coverage insurance, worker's 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 the manner consistent with Borrower's current practice; (2) furnish to Lender upon 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 to the extent their respective interests appear and shall include, where appropriate, lender's loss payable endorsement in favor of Lender to the extent its interests shall appear, in such form and substance reasonable satisfactory to Lender."

Section 1.08 Section 7.2 of the Revolver Loan Agreement is deleted in its entirety and the following language shall be inserted in its place:

"7.2 Sell, lease or otherwise dispose of any of the Collateral."

Section 1.09 Section 7.8 of the Revolver Loan Agreement is hereby deleted in its entirety and the following language shall be inserted in its place:

"7.8 Issue, incur, assume or permit to remain outstanding any Indebtedness that is not Subordinated Indebtedness, other than (1) Lender Indebtedness, (2) the HSBC Indebtedness (as such term is defined in the Intercreditor Agreement), and (3) other Indebtedness that does not exceed $500,000 in the aggregate at any time outstanding."

Capitalized terms used in this Article I, and not defined herein, shall have the meanings assigned to such term in the Revolver Loan Agreement.

Article II. Term Note

Section 2.01 Section 5(h) of the Term Note is deleted in its entirety and the following language shall be inserted in its place:

"(h) Subsidiaries and Partnerships. Borrower has no subsidiaries and is not a party to any partnership agreement or joint venture agreement."

Section 2.02 Section 6(c) of the Term Note is hereby deleted in its entirety and the following language shall be inserted in its place:

"(c) At its own cost, Borrower shall obtain and maintain insurance against (a) loss, destruction or damage to its properties and business in the kinds and 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) to the extent Lender's interests shall appear, name Lender as 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 cancelled. 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."

Section 2.03 Schedule B (Litigation), Schedule C (Permitted Liens) and Schedule D (Subsidiaries, Partnerships and Joint Ventures) to the Term Note are each hereby deleted and

replaced in their entirety with the Revised Schedule B, Revised Schedule C and Revised Schedule D, respectively, attached to this Agreement.

Capitalized terms used in this Article II, and not defined herein, shall have the meanings assigned to such term in the Term Note.

Article III. Security Agreement

Section 3.01 The Term Note Security Agreement is terminated in its entirety.

Section 3.02 Paragraph 1. of the General Security Agreement is amended to read as follows:

"1. **Grant of Security Interest**. Debtor grants to Secured Party a continuing security interest in all of Debtor's right, title and interest in, to and under (a) all accounts (as defined in the Uniform Commercial Code in effect as of the date hereof in the applicable state) that Debtor now owns and in the future acquires, including, without limitation, all Government Contracts and all amounts at any time owing to Debtor under a Government Contract, (b) the Enterprise Resource Planning System, together with all documents related to the installation and operation of it and (c) all proceeds of the foregoing and all books, records (including computer software) and documents that at any time evidence or relate to any of the foregoing or any proceeds of the foregoing, (collectively called "**Collateral**"). In this Agreement, "**Government Contracts**" means (1) Contract No. W9113M-04-D-0002, dated January 3, 2004, between U.S. Army Space and Missile Defense Command ("**DOD**") and Borrower, which provides for Borrower to sell to DOD, and for DOD to purchase from Borrower, anthrax vaccine, as it has been and in the future is amended, (2) Contract No. 200-2005-11811 (amended to be designated Contract No. HHSO100200600019C), 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 has been and is in the future amended and (3) each other contract that Debtor at any time enters into with DOD or HHS or any other state or federal government agency or department and that provides for Debtor to sell goods and/or services to government agency or department. In this agreement, "**Enterprise Resource Planning System**" means a software system that integrates departments and functions across the organization and automates tasks involved in performing business processes. The ERP system was licensed from SAP and is supported with, and includes, specific hardware primarily purchased from Dell."

Article IV. Miscellaneous

Section 4.01 Except as expressly provided in this Agreement, all of the provisions of the Term Loan Agreement, the Term Note and the General Security Agreement are ratified and confirmed, and the amendments contained herein shall only apply to the provisions specifically named herein.

Section 4.02 This Agreement when duly executed and delivered by the parties will constitute the valid and binding obligations of each of them.

Section 4.03 This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns.

Section 4.04 This Agreement, the Revolver Loan Agreement, the General Security Agreement, the Intercreditor Agreement, the Term Note, all the schedules and exhibits hereto and thereto, and all amendments and modifications to the same entered into prior to the date hereof constitute the entire agreement among the parties with respect to its subject matter.

Section 4.05 This Agreement may be executed in several counterparts, each of which shall be deemed an original, but all of which, when taken together, shall constitute one and the same document.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

Borrower and Lender have executed this Agreement as of the date stated in the first paragraph.

BIOPORT CORPORATION

By /s/ R. Don Elsey

Its Treasurer

And by /s/ Daniel J. Abdun-Nabi

Its Secretary

FIFTH THIRD BANK

By /s/ Mark D. Conn

Its Vice President

Revised Schedule B — Litigation (as of August 14, 2006)

Anthrax Vaccine Product Liability Matters

1. *Adamus v. BioPort Corp., Emergent BioSolutions, Inc., and Antex Corp.* (sic), No. 05-CV-6759 (N.D. Ill.) (filed October 14, 2005) (BioPort's MTD/to transfer pending.)
2. *Emery v. BioPort Corp.*, No. CV-06-0008-AAM (E.D. Wash.) (filed January 9, 2006) (BioPort's MTD/to transfer pending.)
3. *Savage v. BioPort, Inc.* (sic), No. 1:06CV00081 (D.D.C.) (filed January 17, 2006) (BioPort's MTD/to transfer pending.)

Thimerosal Product Liability Matters (BioPort is one of numerous defendants.)

California State Court (pending in Los Angeles)

1. *Allen v. Abbott Laboratories, et al.*, No. 02CC00108 (filed April 26, 2002) (BioPort has not been served.)
2. *Mays v. Abbott Laboratories, et. al. No. 266529 (BioPort has not been served.)*
3. *Schmuck v. Abbott Laboratories, et al., No. BC 2552268 (filed August 1, 2001)*
4. *Werley v. Abbott Laboratories, et al., No. 787422 (filed April 25, 2002) (BioPort has not been served.)*

Illinois State Court (*Reilly* in Cook County; all others in Madison County)

1. *Barkwell v. Abbott Laboratories, et al.*, No. 02-L-845 (filed June 13, 2002)
2. *Choate v. Abbott Laboratories, et al.*, No. 02-L-844 (filed June 13, 2002)
3. *Conrick v. Abbott Laboratories, et al.*, No. 02-L-843 (filed June 13, 2002)
4. *Curia v. Abbott Laboratories, et al.*, No. 02-L-842 (filed June 13, 2002)
5. *Curia (Christopher) v. Abbott Laboratories, et al.*, No. 02-L-1593 (filed December 2, 2002)
6. *Delghingaro v. Abbott Laboratories et al.*, No. 02-L-1344 (filed September 30, 2002)
7. *Fredericks v. Abbott Laboratories, et al.*, No. 03-L-1037 (filed July 23, 2003)
8. *Gabor v. Abbott Laboratories, et al.*, No. 02-L-1345 (filed September 30, 2002)
9. *Goodman v. Abbott Laboratories, et al.*, No. 02-L-641 (filed May 7, 2002)
10. *Guinn v. Abbott Laboratories, et al.*, No. 02-L-841 (filed June 13, 2002)
11. *Haderlein v. Abbott Laboratories, et al.*, No. 04-L-1253 (filed November 10, 2004)
12. *Hornstein v. Abbott Laboratories, et al.*, No. 02-L-642 (filed May 7, 2002)
13. *Howard v. Abbott Laboratories, et al.*, No. 02-L-1487 (filed November 4, 2002)
14. *Kramer v. Abbott Laboratories, et al.*, No. 03-L-670 (filed May 22, 2002)
15. *Livi v. Abbott Laboratories, et al.*, No. 02-L-643 (filed April 30, 2002)
16. *Mahnke v. Abbott Laboratories, et al.*, No. 02-L-1594 (filed December 12, 2002)
17. *Miller v. Abbott Laboratories, et, al.*, No 04-L-443 (filed May 25, 2004)
18. *Miller (II) v. Abbott Laboratories, et al.*, No. 04-L-650 (filed June 18, 2004)
19. *Owczarzak v. Abbott Laboratories, et al.*, No-L-840 (filed June 13, 2002)
20. *Panek (Nicholas) v. Abbott Laboratories*, et al., No. 05-L-624 (filed July 13, 2005)
21. *Panek (Brandon) v. Abbott Laboratories*, et al., No. 05-L-623 (filed July 13, 2005)

22. *Peterman v. Abbott Laboratories, et al.*, No. 04-L-0443 (filed April 1, 2004)
23. *Prohaska v. Abbott Laboratories, et al.*, No. 04-L-1065; (filed September 28, 2004)
24. *Robinson v. Abbott Laboratories, et al.*, No. 02-L-1346 (filed September 30, 2002)
25. *Sexton v. Abbott Laboratories, et al.*, No. 03-L-1971 (filed December 5, 2003)
26. *Spaetzel v. Abbott Laboratories, et al.*, No. 03-L-1972 (filed December 5, 2003)
27. *Strohbeck v. Abott Laboratories, et al.*, No. 03-L-93 (filed January 27, 2003)
28. *Sullivan v. Abbott Laboratories, et al*., No. 04-L-1393 (filed December 17, 2004)
29. *Sumner v. Abbott Laboratories, et al.*, No. 04-L-442 (filed May 25, 2004)
30. *Thomason v. Abbott Laboratories, et al.*, No. 02-L-896 (filed June 26, 2002)
31. *Trocke v. Abbott Laboratories, et al.*, No. 02-L-1486 (filed November 4, 2002)
32. *Vaselopulos v. Abbott Laboratories, et al.*, No. 03-L-1176 (filed August 25, 2003)
33. *Villareal v. Abbott Laboratories, et al.*, No. 04-L-180 (filed February 23, 2004)
34. *Weider v. Abbott Laboratories, et al.*, No. 03-L-1559 (filed November 19, 2003)
35. *Weider (II) v. Abbott Laboratories, et al*., No. 04-L-181 (filed February 23, 2004)
36. *Zezulak v. Abbott Laboratories, et al.*, No. 03-L-1175 (filed August 25, 2003)
37. *Reilly v. Laboratories*, et al., No. 02-L-14697 (Cook County) (filed November 20, 2002) (dismissed April 2006; appeal pending)

Miscellaneous Litigation

1. *Pandey v. Giri*, et al., United States District Court for the District of Massachusetts, Civil Case No. HDCV2006-00529 (Emergent BioSolutions named as a defendant in action where plaintiff alleges that employee of Emergent and his wife misled him in connection with potential marriage of individual defendants' niece to son of plaintiff.)

Revised Schedule C — Permitted Liens

HSBC Liens (as such term is defined in the Intercreditor Agreement) and the below:

BIOPORT CORPORATION
DEBT SUMMARY &
OPERATING LEASES
AS OF JULY 31, 2006

CREDITOR	DESCRIPTION	UNPAID PRINCIPAL & INTEREST AS OF JULY 31, 2006	COLLATERAL
GMAC	2002 CHEVROLET VENTURE MINIVAN	$6,741	2002 CHEVROLET VENTURE MINIVAN
LEXUS FINANCIAL SERVICES	2004 LEXUS E330	$24,990	2004 LEXUS E330
BOBCAT FINANCIAL SERVICES	INGERSOL BOBCAT	$546	INGERSOL BOBCAT
IMAGISTICS (rolled up of Pitney Bowes operating leases)	COPIERS & FAX MACHINES	$225,500	COPIERS & FAX MACHINES
	TOTAL DEBT	**$257,777**	

Revised Schedule D — (Subsidiaries, Partnerships and Joint Ventures)

None.

THIRD AMENDMENT TO AMENDED
AND RESTATED LOAN AGREEMENT

THIS THIRD AMENDMENT TO AMENDED AND RESTATED LOAN AGREEMENT is made as of October 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, as amended on August 1, 2006 and August 25, 2006, 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 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 Agreement.

3. 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 November 15, 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."

4. Except as expressly amended by this Amendment, all of the provisions of the Loan Agreement, as previously amended, 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 & CEO

And by /s/ Patrick D. Saam

Its Controller

FIFTH THIRD BANK

By /s/ Mark Conn

Its /s/ Vice President

Exhibit 10.34

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

PRODUCT SUPPLY AGREEMENT

BETWEEN

EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC.

AND

TALECRIS BIOTHERAPEUTICS, INC.

PRODUCT SUPPLY AGREEMENT

This Product Supply Agreement is made on June 12, 2006 (the "Effective Date") by and between

(1) Emergent Product Development Gaithersburg Inc., a Delaware corporation having offices at 300 Professional Drive, Gaithersburg, MD 20879 ("Emergent"); and

(2) Talecris Biotherapeutics, Inc., a Delaware corporation having offices at 4101 Research Commons, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 ("Talecris")

(hereinafter, each of Emergent and Talecris a "Party" and, collectively, the "Parties").

W I T N E S S E T H :

WHEREAS, Emergent is engaged in the development of certain pharmaceutical products, including, without limitation, vaccines and therapeutic products for the prevention and treatment of anthrax infection;

WHEREAS, Talecris possesses certain patented processes, technology, equipment and facilities to manufacture clinical and commercial supply of the Finished Product (as defined below) in a manner which complies with cGMP and Product Specifications (each as defined below);

WHEREAS, the Parties wish, therefore, that Talecris perform the manufacture of the Finished Product and that Talecris authorize Emergent to commercialize Finished Product without restriction; and

WHEREAS, Emergent is a wholly owned subsidiary of Emergent BioSolutions, Inc., a Delaware corporation ("Parent"), and Parent desires to guarantee certain indemnification and payment obligations of Emergent pursuant to this Agreement.

NOW THEREFORE, in consideration of the foregoing premises, which are incorporated into and made a part of this Agreement, and of the mutual covenants which are recited herein, the Parties agree as follows:

ARTICLE 1 — DEFINITIONS

When used in this Agreement, the capitalized terms listed in this Article 1 shall have the following meanings:

1.01 "Adverse Events" shall mean, with respect to the Finished Product, any adverse event associated with the use of the Finished Product in a patient or clinical investigation, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of the Finished Product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any significant and consistent failure of expected pharmacological action. Adverse Events shall include, without limitation, any unfavorable and unintended sign (including, without limitation, an abnormal laboratory finding), exacerbation of a pre-existing condition, intercurrent illness, drug interaction, significant worsening of a disease under investigation or treatment, significant failure of expected pharmacological or biological action, and/or symptom or disease temporally associated with the use of the Finished Product, whether or not considered related to the Finished Product. Notwithstanding anything foregoing to the contrary, with respect to the Territory in which the Finished Product is marketed, Adverse Events shall include any experience required to be reported to a relevant authority in any such country.

1.02 "Affiliate" shall mean, with respect to a Party, any business entity which directly or indirectly controls, is controlled by, or is under common control with such Party. A business entity shall be deemed to "control" another business entity if (a) it owns, directly or indirectly, at least fifty percent (50%) of the issued and outstanding voting securities, capital stock, or other comparable equity or ownership interest of such business entity, or (b) it has the de facto ability to control or direct the management of such business entity. If the laws of the jurisdiction in which such entity operates prohibit ownership by a Party of fifty percent (50%) or more, "control" shall be deemed to exist at the maximum level

of ownership allowed by such jurisdiction, provided, however, that there is a de facto ability to direct or control its management.

1.03 "Agreement" shall mean this Product Supply Agreement, including any exhibits or schedules hereto, as such may be amended from time to time, in writing, by mutual agreement of the Parties.

1.04 "AIG" shall mean Anthrax Immune Globulin derived from AIG Source Plasma.

1.05 "AIG specific IgG Yield" shall mean the total volume of AIG contained in AIG Source Plasma or Processed Product (as applicable) expressed in grams per liter.

1.06 "AIG specific IgG Target Yield" shall have the meaning set forth in Section 4.01(c)(i).

1.07 "AIG Source Plasma" shall mean anthrax immune human plasma, as defined under Applicable Law, collected by or on behalf of Emergent. AIG Source Plasma shall exclude By-Products.

1.08 "AIG Source Plasma Specifications" shall mean the quality and other specifications for Source Plasma, as set forth on Exhibit C attached hereto, which specifications may be amended from time to time by mutual agreement of the Parties.

1.09 "Applicable Law" shall mean any statute, law, treaty, rule, code, ordinance, regulation, permit, interpretation, certificate or order of a government authority, or any judgment, decision, decree, injunction, writ, order, subpoena, or like action of any court, arbitrator or other government entity (including without limitation, requirements of the FDA and cGMP) to the extent applicable and in each case as amended from time to time.

1.10 "Batch Production Record" shall mean a copy of the Master Batch Record for AIG and Finished Product, which shall include, without limitation, instructions for manufacturing, packaging, in-process testing and release testing for the AIG and Finished Product, as well as the actual record of the performance of such work.

1.11 "BLA" shall mean a Biologics License Application filed with the FDA and/or any other application required for the purpose of marketing or selling or using a therapeutic or prophylactic product to be filed with a governmental agency in a non-U.S. country or group of countries, including, without limitation, a Product License Application or Marketing Authorization in the European Union.

1.12 "Business Day" shall mean Monday, Tuesday, Wednesday, Thursday or Friday of any week other than such days on which banking institutions located in Washington, D.C. and/or Raleigh, North Carolina are permitted or required by law, executive order or governmental decree to remain closed.

1.13 "By-Products" shall mean products or materials, other than the Finished Product, that are processed from derivative materials resulting from Talecris' Processing of the AIG Source Plasma into Finished Product at the Facilities hereunder.

1.14 “Certificate of Analysis” shall mean a document or documents provided by Talecris to Emergent for a batch of the Finished Product, that (a) bears the results of in-process or release analytical testing and their respective specifications, and (b) states whether such Finished Product was Processed in accordance with cGMP.

1.15 “Certificate of Conformance” shall mean a document or documents provided by Talecris to Emergent that attests that a specific Lot of Finished Product was Processed in accordance with cGMP.

1.16 “cGMP” shall mean current good manufacturing practices as set forth in Title 21, Parts 210 and 211 of the C.F.R. and 21 C.F.R. Part 312 (IND), and 21 C.F.R. Part 600, 606, 610, 630 and 640 (Biologics and Blood Products), as established and amended by the FDA, and any comparable requirement of law in a country or group of countries other than the United States.

1.17 “Claim” shall mean any charge, complaint, action, suit, proceeding, hearing, investigation, claim, controversy, dispute, demand, judgment, order, decree, stipulation, injunction, or similar matters.

1.18 “Commercial Product” shall mean Finished Product for commercial use or use other than for Pre-Commercial Product.

1.19 “Commercial Target Yield” shall have the meaning set forth in Section 4.01(d).

1.20 “Commercial Term” shall have the meaning set forth in Section 10.01(b).

1.21 “Commercial Volume Commitment” shall have the meaning set forth in Section 4.02(a).

1.22 “Commercially Reasonable Efforts” shall mean that degree of skill, effort, expertise, and resources which a Person of ordinary skill, ability, and experience, under similar circumstances, in the matters addressed herein would reasonably utilize and otherwise apply with respect to fulfilling the obligations assumed hereunder.

1.23 “Conforming AIG Source Plasma” shall have the meaning set forth in Section 11.02(a).

1.24 “Contract Year” shall mean each twelve (12) month period during the Commercial Term or any Extension Period hereunder, commencing on the effective date of the Commercial Term.

1.25 “Dedicated Equipment” shall consist of the equipment and associated fixtures which are used by Talecris during the Term of this Agreement for the purpose of manufacturing the Finished Product for Emergent hereunder.

1.26 “Dollar” shall mean the United States dollar.

1.27 “Emergent Indemnitee” shall mean Emergent, its Affiliates, its Sublicensees, and their respective directors, officers, employees and agents.

1.28 “Emergent Specifications” shall mean the specifications concerning [**] Product hereunder, established by Emergent in its sole discretion from time to time pursuant to Section 5.04. The initial Emergent Specifications shall be completed by Emergent as soon as practicable following the Effective Date and attached hereto as Exhibit A-1.

1.29 “Evaluation Lot” shall have the meaning set forth in Section 4.01(a).

1.30 “Exclusivity Agreement” shall mean the exclusivity agreement between the Parties dated as of the Effective Date, in the form attached hereto as Exhibit G.

1.31 “Extension Period” shall have the meaning set forth in Section 10.01(c).

1.32 “Facilities” shall mean the Melville, New York Precision Pharma or Clayton, North Carolina location where fractionation shall take place, and the manufacturing facility in Clayton, North Carolina where purification shall take place, and the real property underlying such manufacturing facilities used by Talecris to practice the Process, together with all of the Dedicated Equipment, but not including equipment which is not used in the Process.

1.33 “Facility Goods” shall mean any products manufactured at the Facilities other than the Finished Product, including without limitation Gamunex.

1.34 “FDA” shall mean the United States Food and Drug Administration.

1.35 “Field” shall mean the prevention, treatment or therapy of anthrax infection in humans.

1.36 “Fill/Finish Specifications” shall mean such manufacturing specifications concerning the [**], as the Parties may mutually agree.

1.37 “Finished Product” shall mean any [**] as an active ingredient.

1.38 “Firm Commitment” shall have the meaning set forth in Section 4.02(d).

1.39 “Force Majeure” shall have the meaning set forth in Section 15.11.

1.40 “Foreign Currency Sales” shall mean Sales which are invoiced by Emergent in a currency other than the Dollar.

1.41 “Gamunex” shall mean Talecris’ immunology product marketed as Gamunex®.

1.42 “Gamunex Specifications” shall mean the specifications for Gamunex attached hereto as Exhibit A, as amended by Talecris from time to time in accordance with Section 5.01.

1.43 “Generally Accepted Accounting Principles” shall mean generally accepted accounting principles as set forth in opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board as consistently applied per usual accounting practices.

1.44 “Gross Price” shall mean, with respect to a Finished Product, the unit price, without deduction, actually invoiced by Emergent, its Affiliates and Sublicensees for the Sale of such Finished Product.

1.45 “IgG Yields” shall have the meaning set forth in Section 4.01(c)(iv).

1.46 “INCOTERMS 2000” shall mean the specifications of the obligations for delivering goods in international contracts, as issued by the International Chamber of Commerce.

1.47 “IND” shall mean an investigational new drug application filed with the FDA and/or any other similar application to be filed with a governmental agency in a country or group of countries other than the United States.

1.48 “Initial AIG Source Plasma” shall have the meaning set forth in Section 3.01(a).

1.49 “Insolvency Event” shall mean the commencement of any action, whether voluntarily or involuntarily (provided, that such involuntary action is not dismissed within ninety (90) days of commencement thereof), seeking any relief by liquidation, reorganization (other than for corporate reorganization), dissolution or similar act under any bankruptcy, insolvency or similar law or otherwise any action seeking any arrangement between or with its creditors or any commencement of a proceeding or receipt of an order, judgment or decree seeking the liquidation, reorganization or dissolution of a Party or any other relief under any bankruptcy, insolvency or similar law or an arrangement is made with respect to such Party’s debts or business by its creditors.

1.50 “Losses” shall mean losses, deficiencies, defaults, assessments, dues, penalties, fines, amounts paid in settlement, liabilities, obligations, taxes, liens, damages, costs and actual out-of-pocket expenses (including interest, penalties, court costs, attorneys’ fees, accountants and other experts, or other expenses of any Claim), including all damages awardable pursuant to statute and treble damages.

1.51 “Lot” shall mean a lot of between [**] liters to [**] liters of AIG Source Plasma to be Processed by Talecris in accordance with Product Specifications and cGMP (or as otherwise may be mutually agreed by the Parties).

1.52 “Major Markets” shall mean the United States and Canada.

1.53 “Master Batch Record” shall mean the master batch record for AIG and Finished Product, which shall include, without limitation, instructions for manufacturing, packaging, and in-process testing and release testing for the AIG and Finished Product.

1.54 “Minimum Commitment Fee” shall have the meaning set forth in Section 7.05(a).

1.55 “Negotiation Period” shall have the meaning set forth in Section 2.03.

1.56 “Net Sales” shall mean the Gross Price of Finished Products multiplied by the quantity of Finished Products Sold in the Territory, less (a) trade and quantity discounts actually allowed and taken, (b) sales, value added, or other excise taxes paid, absorbed or allowed,

(c) import and export taxes and such other amounts paid by Emergent, its Affiliates or Sublicensees to a governmental entity as a result of the importing or exporting of Finished Product, (d) amounts repaid or credited by reason of purchase chargebacks, rebates (including rebates in kind), rejections, defects or returns (including, without limitation, rebates pursuant to governmental and managed care programs), and (e) charges actually incurred for insurance, handling, distribution, freight and transportation, provided that the aggregate amount of such charges shall not exceed two percent (2%) of the total invoiced price. All of the items set forth in (a) through (e) above shall be calculated according to Emergent's standard method of accounting consistently applied in accordance with Generally Accepted Accounting Principles, and shall not in aggregate exceed fifteen percent (15%) of the aggregate Gross Price of any Finished Product.

If a Finished Product is Sold in the form of a Combination Product (as defined below), Net Sales for such Combination Product will be calculated by multiplying actual Net Sales of such Combination Product by the fraction A/(A+B) where: A is the Gross Price of the Finished Product contained in the Combination Product if Sold separately by Emergent, its Affiliates or Sublicensees, and B is the Gross Price of any other active component or components in the Combination Product if sold separately by Emergent, its Affiliates or Sublicensees. If the Finished Product is Sold in the form of a Combination Product containing one or more active ingredients other than the Finished Product, and one or more active ingredients of the Combination Product are not Sold separately by Emergent, its Affiliates or Sublicensees, then the Parties shall meet and mutually agree upon a commercially reasonable portion of such Net Sales to allocate to the Finished Product. In no event shall less than seventy-five percent (75%) of the Net Sales for any Combination Product be allocated to the Gross Price of the Finished Product. "Combination Product" shall mean any pharmaceutical product, in any formulation, which comprises two (2) or more active ingredients, at least one (1) of which is AIG (an "active ingredient" being a biologically active ingredient which causes one (1) or more direct clinical therapeutic effects, and excluding diluents, vehicles, drug delivery systems, adjuvants or other ingredients which do not by themselves have such therapeutic effects).

Upon the Sale of the Finished Product other than in a bona fide arm's length transaction exclusively for money or upon any use, transfer or disposal of Finished Product for purposes which do not result in sales revenue which would be expected in an arm's length transaction exclusively for money in the relevant country, that Sale, use, transfer or disposal shall be deemed to constitute a Sale at the relevant open market price in the country in which the Sale, use, transfer or disposal occurs, or if that price is not ascertainable, a reasonable price assessed on an arm's length basis.

1.57 "Non-Conforming" or "Non-Conforming Product" shall mean Finished Product which at the time of delivery does not (and/or could not) meet the Product Specifications and cGMP. For purposes of Section 5.02 (Quality Assurance), Section 11.04 (Remedies for Delivery of Non-Conforming Product or Spoiled AIG Source Plasma) and Section 12.03 (Product Liability Claims), Finished Product shall not be deemed Non-Conforming if the non-conformance results from the use of Non-Conforming AIG Source Plasma.

1.58 “Non-Conforming AIG Source Plasma” shall mean AIG Source Plasma which does not comply with the AIG Source Plasma Specifications as of the time of delivery of such AIG Source Plasma to Talecris.

1.59 “Nonspecific IgG Target Yield” shall have the meaning set forth in Section 4.01(c)(i).

1.60 “Nonspecific IgG Yield” shall mean the total volume of all immune globulins present in AIG Source Plasma or Processed Product (as applicable) expressed in grams per liter.

1.61 “Notice” shall have the meaning set forth in Section 15.01 of this Agreement; “Notify” or any variation thereof shall mean to provide Notice or other corresponding meaning.

1.62 “Order” shall mean a written order for either Pre-Commercial Product or Commercial Product.

1.63 “Person” shall mean any natural person or any corporation, company, sole proprietorship, partnership, joint venture, firm or other business entity.

1.64 “Pre-Commercial Product” shall mean Finished Product (a) for pre-clinical or animal studies, (b) for clinical use or for non-clinical testing required for clinical trials in preparation for submission, approval or maintenance of a regulatory filing, including without limitation any INDs and/or BLAs, and/or (c) necessary for Emergent to secure the first contractual commitment for Finished Product from a Third Party and/or to obtain government funding for Finished Product.

1.65 “Pre-Commercial Target Yield” shall have the meaning set forth in Section 4.01(c)(iv).

1.66 “Pre-Commercial Term” shall have the meaning set forth in Section 10.01(a).

1.67 “Process,” “Processed,” or “Processing” shall mean the act of fractionation, purification, sterilization, virus inactivation/removal, testing, filling, finishing and any other pharmaceutical manufacturing procedures, or any part thereof, for manufacturing the Finished Product hereunder, consisting of activities which are required to meet the Gamunex Specifications and, with respect to Finished Product, such other activities required to meet the Fill/Finish Specifications.

1.68 “Processing Fee” shall have the meaning set forth in Section 7.03(a).

1.69 “Processed Product” shall mean AIG Source Plasma that has been Processed in compliance with Gamunex Specifications but has not yet met Fill/Finish Specifications.

1.70 “Product Liability Claim” shall mean, with respect to any Finished Product or By-Product, as applicable, a Claim of a Third Party (other than a Claim arising out of use of Finished Product in a clinical trial) that (a) arises as a result of the use of such product that results in personal injury or death or (b) is in anticipation of or intended to prevent or forestall personal injury or death as a result of the use of such product.

1.71 “Product Specifications” shall mean the (a) Gamunex Specifications, and (b) the Fill/Finish Specifications.

1.72 “Quality Agreement” shall mean the agreement attached hereto as Exhibit F.

1.73 “Regulatory Authority” shall mean, with respect to the United States, the FDA or, in the case of a country in the Territory other than the United States, such other appropriate regulatory authority with similar responsibilities.

1.74 “Rolling Forecast” shall have the meaning specified in Section 4.02(c).

1.75 “Sale(s)”, “Sold” and “Sell” shall mean the sale, transfer or disposition of the Finished Product for commercial purposes for value to a Third Party (whether an end user, wholesaler or otherwise), whether by Emergent, its Affiliates or Sublicensees, but excluding the sale, transfer or disposition of any Validation Lots or Pre-Commercial Product.

1.76 “Sublicensee” shall mean any third party (including Affiliates) to whom a sublicense has been granted pursuant to this Agreement.

1.77 “Supply Failure” shall be deemed to exist with respect to any Lot of AIG Source Plasma Processed under this Agreement to provide Finished Product to Emergent if either of the following has occurred:

(a) a Lot of AIG Source Plasma Processed hereunder has a Yield of less than [**] percent ([**]%) of the Commercial Target Yield on [**] occasions within any given rolling twelve (12) month period.

(b) over any given rolling (12) month period, the Lots of AIG Source Plasma Processed hereunder have an average Yield of less than the Commercial Target Yield, provided that any Lot described in clause (a) shall be excluded from the computation of average Yield.

1.78 “Talecris BLA sections” shall have the meaning set forth in Section 8.01(a).

1.79 “Talecris Gamunex Activities” shall mean those activities as defined in Section 8.01(a), as such activities are related to Finished Product hereunder. The list of such activities under Section 8.01 is provided for illustrative purposes only and is not intended to be a comprehensive list.

1.80 “Talecris Patent Rights” shall mean Talecris’s rights in inventions and discoveries which are related to AIG or the Finished Product and/or the Process and covered by a patent or patent application listed on Exhibit B, all provisionals, divisions, continuations, continuations-in-part, reissues, reexaminations or extensions thereof, and any corresponding foreign counterparts and equivalents thereof.

1.81 “Term” shall have the meaning set forth in Section 10.01(c).

1.82 “Territory” shall mean each country in the world.

1.83 “Third Party” shall mean any Person which is not a Party, an Affiliate or a Sublicensee under this Agreement.

1.84 “Third Party Customer” shall mean a Third Party that is a customer of Talecris for Facility Goods.

1.85 “US CPI” shall mean the U.S. consumer price index medical care commodities index for similar goods and services published by the United States Department of Labor, Bureau of Labor Statistics, as reported by the Wall Street Journal (Eastern Edition), or such other index as may be mutually agreed upon by the Parties.

1.86 “Validation” shall mean successful validation of the Facilities, Dedicated Equipment and critical Process steps in compliance with cGMP, including (a) the successful completion of all validation protocols established by the Parties for the Facility and Designated Equipment, and (b) ensuring and providing documentary evidence that the Process used by Talecris to manufacture Finished Product is capable of consistently producing Finished Product of the required quality as determined by the Product Specifications.

1.87 “Validation Lot(s)” shall mean the consistency Lot(s) necessary to obtain Validation hereunder and that meets the Pre-Commercial Target Yield.

1.88 “Yield” shall mean, with respect to any Lot of AIG Source Plasma Processed under this Agreement to provide Finished Product to Emergent, in the case of AIG specific IgG, (i) the quantity of AIG specific IgG from Processed Product exhibited following Processing divided by (ii) the quantity of AIG specific IgG from Source Plasma exhibited prior to Processing (“AIG specific IgG Yield”), and, in the case of Nonspecific IgG, (i) the quantity of Nonspecific IgG from Processed Product exhibited following Processing divided by (ii) the quantity of Nonspecific IgG from Source Plasma exhibited prior to Processing (“Nonspecific IgG Yield”); provided, however, that Non-Conforming Product shall not be included in the computation of Yield.

ARTICLE 2 — SCOPE OF SERVICES AND GENERAL ARRANGEMENT

2.01 Emergent Obligations. Emergent shall provide AIG Source Plasma meeting the AIG Source Plasma Specifications to Talecris for Processing. Emergent shall pursue all necessary regulatory approvals with regard to Finished Products with the assistance of Talecris as each is further described in Article 8 below.

2.02 Scope of Talecris Services. Talecris shall, in accordance with the terms of this Agreement:

(a) perform Processing services at the Facilities in accordance with the Product Specifications and cGMP, provided, however, that during the Pre-Commercial Term the purification and fill and finish shall be performed at the Facility in Clayton, North Carolina;

(b) perform quality assurance review of the Finished Product and of the Processing in accordance with the Product Specifications and cGMP; and

(c) permit Emergent to perform quality assurance review of the Finished Product and of the Processing in accordance with the Product Specifications and cGMP.

2.03 Emergent [**]. If at any time during the Term Talecris [**] Centers for Disease Control ("CDC") category A, B and/or C bioterrorism agents which are listed on Exhibit J attached hereto (the "Proposal"), then Talecris [**] Emergent [**]. If Emergent [**] Talecris [**], the Parties shall [**] in good faith for up to [**] days (or longer, upon mutual agreement of the Parties) ("Negotiation Period") [**]. If the Parties are [**] Negotiation Period, Talecris shall be [**].

2.04 Exclusivity. Each Party's noncompete and/or exclusivity obligations under this Agreement with respect to Finished Product shall be governed by the terms of the Exclusivity Agreement.

ARTICLE 3 — SUPPLY OF AIG SOURCE PLASMA; BY-PRODUCTS

3.01 Supply and Use.

(a) Delivery of AIG Source Plasma; Use of AIG Source Plasma. Emergent shall (or shall cause one of its Affiliates or a designee to) deliver to Talecris (by or on a date mutually scheduled by Talecris and Emergent) such quantity of AIG Source Plasma which meets the AIG Source Plasma Specifications as is reasonably necessary for Talecris to manufacture Finished Product hereunder, including without limitation an initial pool of [**] liters (or such other amount as the Parties may mutually agree) of AIG Source Plasma ("Initial AIG Source Plasma"). Talecris shall not procure human plasma from sources other than Emergent, its designee(s) or Affiliates for use in Finished Product. Talecris shall not use AIG Source Plasma, except as set forth in Section 2.02, Section 3.04 and 4.01(e) below, for any purpose other than to supply Finished Product to Emergent. Except as specifically set forth in Article 4 below, Talecris shall handle, store, use and dispose of all such AIG Source Plasma at the Facilities in compliance with Applicable Law in the Major Markets.

(b) Processing of AIG Source Plasma. Talecris shall Process the AIG Source Plasma in compliance with the Product Specifications and, except as set forth in Section 4.01(e) below (Macrobench-Scale Purification), cGMP.

3.02 Delivery. Within fifteen (15) Business Days following Talecris' receipt from Emergent of each Order for Finished Product pursuant to Article 4, Talecris shall Notify Emergent of the scheduled date(s) for commencement of the Processing of the Finished Product covered by such Order. Emergent shall use Commercially Reasonable Efforts to deliver or have delivered to Talecris a sufficient quantity of AIG Source Plasma to meet Processing of the Finished Product covered by such Order at least [**] days prior to each of Talecris' scheduled run date(s) for Processing of such Finished Product. Emergent acknowledges and agrees that its failure to provide sufficient quantity of AIG Source Plasma meeting the AIG Source Plasma Specifications on a timely basis may negatively affect Talecris' ability to Process and deliver the Finished Product by the delivery dates requested by Emergent.

3.03 Ownership of AIG Source Plasma. Emergent shall retain ownership of all right, title and interest in and to any AIG Source Plasma.

3.04 By-Products. Subject to the terms and conditions of this Agreement, Talecris shall have the right to dispose of, further manufacture, or sell any By-Products, provided that Talecris shall not, by itself or in collaboration with or on behalf of a Third Party, develop, manufacture, produce, promote, market, offer to sell, sell or otherwise dispose of any By-Product for use in the Field, and By-Products shall not be generated from any unprocessed Lot of AIG Source Plasma or portion thereof nor from any II/III paste generated therefrom. Furthermore, Talecris shall not undertake any changes to the Process with the purpose of increasing the quantity of By-Products at the expense of the Finished Product.

ARTICLE 4 — PRE-COMMERCIAL AND COMMERCIAL PRODUCT; FORECASTS AND ORDERS

4.01 Pre-Commercial Product.

(a) Evaluation Lot.

During the Pre-Commercial Term, Emergent shall submit to Talecris an Order for [**] ("Evaluation Lot"). Emergent shall pay Talecris the Processing Fee for such Evaluation Lot.

(b) Validation Lots.

For purposes of calculating the Commercial Target Yield in order to determine whether a Supply Failure has arisen pursuant to Section 4.04(a) below, Emergent shall order at least [**] Validation Lots. The Evaluation Lot may constitute a Validation Lot for the purposes of this Section 4.01(b). Emergent shall pay Talecris the Processing Fee for each Validation Lot provided by Talecris.

(c) Pre-Commercial Target Yield.

(i) During the Pre-Commercial Term, Talecris shall provide a Nonspecific IgG Yield of no less than [**] percent ([**]%) ("Nonspecific IgG Target

Yield") and a AIG specific IgG Yield of no less than [**] percent ([**]%) ("AIG specific IgG Target Yield").

(ii) In conjunction with the Processing of each Lot of Pre-Commercial Product, Talecris shall determine the Nonspecific IgG Yield in a manner consistent with Talecris' customary practices.

(iii) In conjunction with the Processing of each Lot of Pre-Commercial Product, Emergent shall determine the AIG specific IgG Yield, with the use of testing procedures reviewed and approved by Talecris, which approval shall not be unreasonably withheld, delayed or conditioned.

(iv) The Nonspecific IgG Yield and the AIG specific IgG Yield shall collectively be referred to as the "IgG Yields." The Nonspecific IgG Target Yield and the AIG specific IgG Target Yields shall collectively be referred to as the "Pre-Commercial Target Yield."

(v) In the event that Talecris determines that the Nonspecific IgG Yield is less than the Nonspecific IgG Target Yield, Talecris shall Notify Emergent of such determination and provide reasonable documentation supporting such determination, which shall be reflective of its usual manufacturing process and procedures. In the event that Emergent determines that the AIG specific IgG Yield is less than the AIG specific IgG Target Yield, Emergent shall Notify Talecris of such determination and provide reasonable documentation supporting such determination, which shall be reflective of its usual process and procedures.

(A) If the Parties agree with the determination that either the Nonspecific IgG Yield or the AIG specific IgG Yield is less than the respective Pre-Commercial Target Yield, Emergent shall have the right, but not the obligation, to utilize the services of a Third Party to process another Evaluation Lot.

(1) In the event that such Third Party achieves an AIG IgG specific Yield of at least [**] percent ([**]%) greater than Talecris' AIG specific IgG Yield, Emergent may terminate this Agreement pursuant to Section 10.02(i) and the Exclusivity Agreement shall terminate in accordance with the terms set forth therein.

(2) In the event that such Third Party does not achieve an AIG IgG specific Yield of at least [**] percent ([**]%) greater than Talecris' AIG IgG specific Yield, Emergent may not sell any pharmaceutical product processed on its behalf that contains AIG as an active ingredient from any Third Party in accordance with the terms of the Exclusivity Agreement, and the terms and conditions of the Exclusivity Agreement shall remain in full force and effect.

(B) If either Party disagrees with the determination of the other Party whether or not the IgG Yield is less than the Pre-Commercial Target Yield, such Party shall Notify the other Party of such disagreement and the Parties shall engage a mutually selected independent laboratory to make such determination.

(d) Commercial Target Yield.

If the Parties mutually determine that the IgG Yields are equal to or greater than the Pre-Commercial Target Yield for the Evaluation Lot (if applicable) and each of the [**] Validation Lots, the "Commercial Target Yield" for the Commercial Term shall be computed and determined as follows:

With respect to Nonspecific IgG:

(i) the average final quantity of Nonspecific IgG exhibited after Processing all of the Validation Lots ordered pursuant to Section 4.01(b), divided by

(ii) the average initial quantity of Nonspecific IgG from the AIG Source Plasma exhibited prior to Processing all of the Validation Lots ordered pursuant to Section 4.01(b); and

(iii) the quotient of which is multiplied by [**] percent ([**]%).

With respect to AIG specific IgG:

(i) the average final quantity of AIG specific IgG exhibited after Processing all of the Validation Lots ordered pursuant to Section 4.01(b), divided by

(ii) the average initial quantity of AIG specific IgG from the AIG Source Plasma exhibited prior to Processing all of the Validation Lots ordered pursuant to Section 4.01(b); and

(iii) the quotient of which is multiplied by [**] percent ([**]%).

Upon the completion of the Pre-Commercial Term and at the completion of each twelve (12) month period during the Commercial Term, the Parties shall recompute the Commercial Target Yield to include the additional Processed Lots which were not included in the original computation set forth above. Such computation shall be based on Yield results provided by each respective Party to the other at the end of each period. In the event that the recomputed Commercial Target Yield more closely resembles the historical average yields experienced by Talecris in processing Gamunex, the Parties agree to negotiate in good faith an adjustment to the Commercial Target Yield to reflect the processing information provided by the additional Lots.

(e) Macrobench-Scale Purification. Talecris shall Process a non-cGMP macrobench-scale purification of [**] liters (or such other amount as the Parties may mutually

agree) of the Initial AIG Source Plasma Processed by Talecris hereunder, which may be used by Emergent for proof-of-concept studies, validation of the potency release assay for Finished Product, development activities, pre-clinical studies, and otherwise in support of Emergent's development efforts in connection with Finished Product. For purposes of clarity, such macrobench-scale purification process shall be sterile and endotoxin-free and otherwise be the same as the purification process used in the Process, except that Talecris shall not be required to conduct such purification under cGMP conditions.

(f) Additional Lots of Pre-Commercial Product. During the Pre-Commercial Term, Emergent shall have the right, in its sole discretion, to submit to Talecris Orders for additional Lots of Pre-Commercial Product in excess of those Ordered pursuant to Sections 4.01(a) through 4.01(c), including without limitation Validation Lots. Talecris shall conduct the Processing of any Lots of Pre-Commercial Product ordered by Emergent pursuant to Sections 4.01(a) through 4.01(c) at such times as the Parties may mutually agree; provided, however, that Talecris shall use Commercially Reasonable Efforts to schedule the Processing of such Lots on dates which are as close as practicable to the dates requested by Emergent in the Order(s) for such Lots. Emergent shall pay the Processing Fee for any additional Lots of Pre-Commercial Product ordered pursuant to this Section 4.01(f).

(g) Non-Binding Forecast for Pre-Commercial Product. As soon as practicable following the Effective Date of this Agreement and from time to time thereafter during the Pre-Commercial Term, Emergent shall submit to Talecris a non-binding, good faith forecast that sets forth the total quantity of Pre-Commercial Product which Emergent expects to order from Talecris within the time period set forth in such forecast. Emergent shall update such forecast from time to time but not less frequently than annually, unless otherwise agreed by the Parties in writing, based on its reasonable expectations and/or need for Pre-Commercial Product.

(h) Orders for Pre-Commercial Product. Each Order for Pre-Commercial Product shall specify the Pre-Commercial Product ordered, the quantities of the Pre-Commercial Product ordered, the requested manner and address of delivery, and the requested delivery date, which shall be no earlier than [**] days from the date of the Order (unless otherwise agreed to by Talecris in writing), all of which shall be subject to Article 6. Emergent shall submit its initial Order for Pre-Commercial Product on the Effective Date and may submit additional Orders for Pre-Commercial Product at any time thereafter during the Pre-Commercial Term.

4.02 Commercial Product.

(a) Commercial Volume Commitment. Unless otherwise mutually agreed by the Parties, the minimum annual volume commitment by Emergent ("Commercial Volume Commitment") for each Contract Year shall be (a) [**] liters of AIG Source Plasma per annum to be Processed into Finished Product during the

Commercial Term, and (b) [**] liters of AIG Source Plasma per annum to be Processed into Finished Product during any Extension Period. The Commercial Volume Commitment shall be reduced, upon the occurrence of a Supply Failure, on a prorated basis with respect to each month in which Emergent is able to use an alternative supplier pursuant to Section 4.04(a) below and Emergent has elected to use such an alternative supplier.

(b) Process Initiation. Subject to the provisions of Section 3.02 above, Talecris shall use Commercially Reasonable Efforts to initiate the Processing of the Commercial Product on the date which is as close as practicable to the initial fill date set forth in the initial Rolling Forecast submitted by Emergent under Section 4.02(c) below, but in no event later than twelve (12) months from the date of Emergent's Notice of its intent to initiate the Commercial Term as set forth in Section 10.01(b).

(c) Rolling Forecast for Commercial Product. No later than thirty (30) days following the commencement of the Commercial Term, Emergent shall submit to Talecris an initial twelve (12) month rolling forecast ("Rolling Forecast") that sets forth the total quantity of Finished Product which Emergent expects to order from Talecris within such twelve (12) month period ("Annual Forecast Amount"), with a breakdown of the total quantity of Finished Product by month and the delivery schedule for such Finished Product. Without Talecris' prior written approval, the initial Annual Forecast Amount for the first Contract Year shall not exceed [**] liters of Finished Product, and the Annual Forecast Amount for any other given Contract Year shall not exceed [**] liters. The initial Annual Forecast Amount shall include an initial delivery date for Finished Product which is not earlier than [**] days from Emergent's submission of the initial Rolling Forecast to Talecris. Following Emergent's submission of the initial Rolling Forecast, Emergent shall submit to Talecris on a monthly basis on or before the first Business Day of each month, an updated Rolling Forecast, provided that (i) the monthly forecast amount shall not exceed [**] Lots for any given month without Talecris' prior written approval, and (ii) the Annual Forecast Amount shall be updated on an annual basis only.

(d) Firm Commitments for Commercial Product. The Rolling Forecast shall be binding on Emergent for the first [**] months (i.e., months [**]) (each, a "Firm Commitment"), each of which Firm Commitment shall be the subject of an Order delivered in accordance with Section 4.02(e).

(e) Orders for Commercial Product. Emergent shall, together with its monthly Rolling Forecast, deliver to Talecris an Order for each new Firm Commitment that was only a forecasted amount in the previous month's Rolling Forecast. Each Order shall specify the Commercial Product ordered, the quantities of the Commercial Product ordered, the requested manner and address of delivery, and the requested delivery date, which shall be no earlier than [**] days from the date of the Order (unless otherwise agreed to by Talecris), all of which shall be subject

to Article 6. Emergent may submit its initial Order for Commercial Product at any time on or after the commencement of the Commercial Term.

(f) Amending Forecasts for Commercial Product. Any Rolling Forecast that is not a Firm Commitment is to be considered an estimated forecast to be used for planning purposes, shall not be construed as a Firm Commitment by Emergent to Talecris, and may be increased or reduced by Emergent from time to time. Notwithstanding anything in the foregoing to the contrary, in the event of a Supply Failure as set forth in Section 4.04(a) below, the Rolling Forecast for each month during which the Supply Failure persists shall not be considered a Firm Commitment until such time that Talecris is capable of resuming the Processing of Finished Products under this Agreement.

(g) Fulfillment of Orders for Commercial Product. Talecris shall diligently fulfill Emergent's Orders in accordance with their terms and the terms of this Agreement, provided that Talecris shall not be obligated to fulfill any Orders during any Contract Year to the extent that the quantity of Commercial Product covered by such Orders exceeds in the aggregate [**] percent ([**]%) of the Annual Forecast Amount for such Contract Year. Talecris shall promptly Notify Emergent if it becomes aware or believes that it will not be able to fulfill a particular Order that was included in a Firm Commitment on time, in full or at all, which Notice shall include an explanation in reasonable detail of the reason for Talecris' failure to comply with a particular Order and its proposed course of action for remedying such failure.

4.03 Bona Fide Forecasts. Emergent shall make its Rolling Forecasts under Section 4.02(c) acting reasonably, in good faith, based on its reasonable expectations for Sales of the Finished Product (having due regard to any sales over the previous twelve (12) months). Emergent shall use Commercially Reasonable Efforts to give accurate Rolling Forecasts.

4.04 Alternative Supplier. Emergent shall be required to obtain all of its Finished Product requirements from Talecris, provided, however, that:

(a) Supply Failure. In the event of a Supply Failure, Emergent shall have the right to purchase from one or more alternative suppliers its Finished Product requirements, to the extent necessary to replace Finished Product not provided by Talecris due to the Supply Failure, until Talecris reasonably demonstrates that Talecris is able to resume Processing of Finished Product, provided that Emergent shall [**] Finished Product [**] of the Supply Failure. In any case, Emergent shall [**] to the Supply Failure. Emergent shall purchase all other Finished Product requirements from Talecris as soon as Emergent has fulfilled all obligations or commitments, if any, undertaken by Emergent in connection with Emergent's arrangement(s) with the alternative supplier(s).

(b) Redundant Supply. Emergent shall have the right to purchase from one or more alternative suppliers such portion of its Finished Product requirements as Emergent may reasonably establish, if, and for so long as, any Regulatory Authority, governmental agency or Applicable Law (relevant to the Major Markets) requires Emergent to obtain and/or maintain a redundant supply of Finished Product from one or more alternative suppliers. In such event, to the extent not otherwise prohibited by any Regulatory Authority, governmental agency or Applicable Law (in the Major Markets), Emergent shall give priority to selling Finished Product provided by Talecris and Emergent shall not sell products supplied by a Third Party until the inventory of Finished Product Processed by Talecris has been exhausted. Emergent shall notify the appropriate Regulatory Authority or governmental agency in the United States that Talecris shall act as Emergent's sole commercial supplier with respect to Finished Product pursuant to the terms of this Agreement. Emergent shall promptly Notify Talecris in the event that any Regulatory Authority, governmental agency or Applicable Law (relevant to the Major Markets) requires Emergent to obtain and/or maintain a redundant supply of Finished Product from one or more alternative suppliers. Emergent shall not advocate to any Regulatory Authority that a redundant supply from alternate suppliers should be required with respect to the Finished Product.

ARTICLE 5 — PROCESS CHANGES; QUALITY ASSURANCE; PRODUCT SPECIFICATIONS; PROCESSING

5.01 Process Changes.

(a) Prior Approval of Emergent Required. Talecris shall have the right to make any change to the manufacturing process for Gamunex or other Facility Goods, or to the Facilities, as such change applies to Gamunex or other Facility Goods, provided, however, that Talecris shall not make any change to the Process or any Facility (other than routine maintenance, reconditioning and/or replacement of the equipment) that would reasonably be expected to have a material negative impact on the AIG or the Finished Product or require submissions to or approvals from any Regulatory Authority specific to the Finished Product, except by prior written approval of Emergent for such change, which approval shall not be unreasonably conditioned, withheld or delayed, and, in any event, which costs shall be borne by Talecris.

(b) Process Changes Based on cGMP. Talecris shall make such changes to the Process or any Facility as may be required pursuant to cGMP, provided that (i) changes to the Process or any Facility which affect the Finished Product, but do not affect Gamunex or another Facility Good, shall be at Emergent's cost, and (ii) the cost of any changes to the Process or any Facility which affect both the Finished Product and Gamunex or another Facility Good shall be shared between the Parties, taking into consideration various factors, including without limitation, improvements in Yields for Finished Product, historical volumes, and other measures mutually agreed upon by the Parties. If the Parties are not able to reach

consensus on the allocation of such costs, such allocation shall be determined in accordance with the dispute resolution mechanism set forth in Article 14.

(c) Changes Made at the Request of Emergent. From time to time, Emergent may request that Talecris make certain changes (other than those required pursuant to Section 5.01(b) above) to the Process; provided, however, that (i) Emergent shall seek to minimize such changes, (ii) Talecris shall not be required to make any changes which may have a negative impact on any Facility Good, on Talecris' ability to manufacture such Facility Good at the Facilities, or on Talecris' business, including without limitation the production of Gamunex, or which require submissions to or approvals from any Regulatory Authority specific to Gamunex or any other Facility Goods, (iii) Emergent and Talecris shall enter into good faith negotiations with each other regarding the assessment of the implications and costs arising from a change to the Process, and (iv) after the Parties have agreed upon the implications and costs related to a change to the Process, Talecris may, at its sole discretion, implement such change. Costs incurred by Talecris in connection with such changes shall be fully reimbursed by Emergent.

5.02 Quality Assurance.

(a) Testing by Talecris. Talecris shall perform quality testing using assays proposed by Emergent and acceptable to Talecris (which acceptance shall not be unreasonably withheld, conditioned or delayed), in order to assure that the Finished Product complies with the Product Specifications and cGMP, and shall retain samples of the Finished Product produced and records of the tests made on each such batch of Finished Product. In addition, no Finished Product shall be delivered until such Finished Product has been released in accordance with the tests, inspections and controls required under the Product Specifications and cGMP, and such other tests as the Parties may mutually agree upon; provided, however, that the foregoing shall not relieve Talecris of its obligations under Section 4.02(g). Talecris shall maintain records with respect to the quality testing and shall make such records available to Emergent during normal business hours, upon prior written request. Without limiting Talecris' obligations under Sections 4.01 and 4.02, Talecris shall run, complete and record such number of qualification batches of the Finished Product as are required by Regulatory Authorities in the Major Markets pursuant to the BLA submission and ordered by Emergent pursuant to Sections 4.01(a)-(b), at Emergent's expense.

(b) Notice of Non-Conforming Products. Talecris shall promptly Notify Emergent of any Non-Conforming Product of which it becomes aware, specifying the Finished Product's release testing and Batch Production Record for the completed Lot.

(c) Testing by Emergent. At Emergent's election, the Finished Product may be subjected to testing by Emergent at Emergent's facilities in order to verify conformance of the Finished Product with the Product Specifications, Emergent Specifications and Applicable Law in the Major Markets. Such testing

procedures shall be reviewed by Talecris in advance of their implementation. Emergent shall maintain records with respect to the scope and nature of any such testing and shall disclose such records to Talecris in a timely fashion.

(d) Notice of Delivery of Non-Conforming Products. Emergent shall Notify Talecris of any Non-Conforming Product within (i) [**] days of Emergent's receipt of such Non-Conforming Product if a defect is discovered by Emergent through the use of reasonable testing methods and procedures or (ii) in the event of a defect (hidden or otherwise) which was not discovered through the use of such testing methods and procedures, the earlier of (A) [**] Business Days following Emergent's confirmation of the Non-Conforming status of the Finished Product, and (B) [**] months after delivery of the Non-Conforming Product. Talecris shall have the right to examine and test any Finished Product in Emergent's possession that Emergent claims is Non-Conforming, provided that such re-testing is conducted in accordance with applicable regulatory guidelines and other Applicable Law in the Major Markets. The Parties shall cooperate to determine the point at which the Finished Product became Non-Conforming. In the event that the Parties cannot agree as to whether any Finished Product is Non-Conforming, the Parties shall engage a mutually selected independent laboratory to make such determination in accordance with applicable regulatory guidelines and other Applicable Law in the Major Markets. If the dispute between the Parties relates to Talecris's ability to manufacture and deliver Finished Product that is not Non-Conforming, which is not attributable to any negligence or willful misconduct of Emergent, the Parties shall resolve their dispute in accordance with the procedures in Article 14. This Section shall not relieve Talecris of its obligations to deliver Finished Products in accordance with Sections 4.02(g) and 6.01.

(e) Responsibilities of the Quality Units. A summary of the responsibilities of the quality units of each Party related to the Process shall be set forth on Exhibit E, which responsibilities shall be further described in Exhibit F. Such responsibilities shall include, without limitation, (i) the specific content of the Certificate of Analysis, (ii) the specific content of the Certificate of Conformance, (iii) the nature of the Batch Production Record and/or Master Batch Record review process, including notification of deviations associated with the Process, and (iv) a table of key contacts associated with the manufacturing, regulatory, quality control and quality assurance functions; (v) establishing the process by which it can be determined whether a particular Lot of Finished Product is Non-Conforming.

(f) Quality Assurance Audits by Emergent. During the Term, Emergent shall have the right, at Emergent's sole cost and expense, during normal business hours and upon reasonable Notice, to (i) have an Emergent employee present at the Facility(ies) during Processing and (ii) inspect the Facility(ies) in order to ensure that the Processing complies with the Product Specifications and cGMP. Such inspections shall not interfere with Talecris's operations and shall not exceed one (1) occurrence in any year; provided, however, that if any such inspection reveals

any noncompliance with the Product Specifications or cGMP, Emergent shall have the right to conduct a reasonable number of follow-on inspections as necessary in order to confirm that compliance with such Product Specifications and cGMP has been re-established.

(g) Recalls and Voluntary Withdrawals. If either Party becomes aware of information about [**] indicating that they may be Non-Conforming or that there is potential adulteration, misbranding and/or any potential issues regarding safety or effectiveness, it shall promptly serve Notice to that effect on the other Party. The Party initiating an investigation and assessment of such circumstances shall promptly Notify the other Party of its findings and any proposed course of action. The Parties shall meet to discuss such circumstances and to consider appropriate courses of action; provided, however, that if Emergent determines that a recall or withdrawal of the [**] is necessary or advisable, Emergent shall have final decision-making authority concerning the course of action to be taken with respect to the affected [**]. Emergent shall bear all costs associated with such a recall or withdrawal of the [**], unless such recall or withdrawal is caused by Talecris' gross negligence or willful misconduct.

5.03 Labeling and Packaging. Talecris shall be responsible for labeling and packaging the Finished Product for shipment to Emergent or to its designee(s), in accordance with Emergent's directions, provided that Emergent shall be responsible for developing the design and content for the final label and package inserts. Upon Emergent's request, Talecris shall assist Emergent in developing the design and content for such final label and package inserts at Emergent's cost and Talecris' standard consulting rates set forth in Exhibit D, and shall provide regulatory support pursuant to Section 8.09.

5.04 Emergent Specifications; Fill/Finish Specifications. Emergent shall have the right, from time to time, at its cost, to amend the (a) Emergent Specifications, but only to the extent such revisions do not affect the Product Specifications, and (b) the Fill/Finish Specifications, but only to the extent that such revisions are agreed to in writing by Talecris, provided, that Emergent shall use Commercially Reasonable Efforts to minimize the frequency of such changes and shall provide Talecris with reasonable advance Notice of any changes to such portions of the Fill/Finish Specifications. Without limiting the foregoing, any modifications to the Fill/Finish Specifications required by any Regulatory Authority with jurisdiction to require such modifications shall be made in accordance therewith. Emergent shall reimburse Talecris for any additional charges incurred by Talecris as a result of changes made by Emergent to the Emergent Specifications or the Fill/Finish Specifications.

ARTICLE 6 — DELIVERY

6.01 Delivery. Subject to the provisions of Sections 3.01 and 3.02, Talecris shall use Commercially Reasonable Efforts to deliver Finished Product in accordance with the delivery dates specified in the Orders. All shipments shall be made by Talecris (FCA) in accordance with INCOTERMS 2000 at a Talecris Facility (NY or NC as Talecris may

designate during the Commercial Term from time to time). The delivery of any Finished Product to Emergent hereunder shall be deemed to occur when such Finished Product is delivered into the custody of Emergent's carrier at such designated location. Talecris shall bear all expense and risk of shipping the AIG, Finished Product, AIG Source Plasma and/or other materials between its Facilities.

6.02 Certificates of Analysis. Each Finished Product batch delivered to Emergent shall be accompanied by an appropriate Certificate of Analysis and Certificate of Conformance. Talecris shall, for customs purposes, upon delivery of Finished Product, provide Emergent with a valid declaration of origin, in a form reasonably acceptable to Emergent, in respect of all Finished Products supplied to Emergent under this Agreement, together with such other supporting documents relating to the origin of such Finished Product as Emergent may reasonably require.

ARTICLE 7 — FEES; ROYALTY; PAYMENT TERMS

7.01 Deposit. Within thirty (30) days following the Effective Date, Emergent shall pay Talecris a deposit of [**] Dollars (US$[**]), which shall be fully creditable against the cost of Lot(s) of Finished Product manufactured by Talecris hereunder and any other amounts payable by Emergent to Talecris hereunder, including without limitation, the amount payable by Emergent under Section 7.02 for Start-Up Preparations (as defined below).

7.02 Fees Associated With Certain Pre-Commercial Activities.

(a) Start-Up Preparations. Within thirty (30) days following the Effective Date, Emergent shall pay Talecris a one-time fee of [**] Dollars (US$[**]) for Talecris' performance of reasonable start-up preparations related to the Processing of Finished Product hereunder, including without limitation preparation of SOP's, Master Batch Production Records, assay transfers, equipment validation, and product-specific cleaning validation ("Start-Up Preparations"). Talecris shall provide Emergent with documentation of such Start-Up Preparations in form and substance reasonably satisfactory to Emergent within thirty (30) days following the Effective Date (or such other time as may be mutually agreed by the Parties) and upon completion thereof. If, within one-hundred eighty (180) days of the Effective Date, Talecris has failed to complete the preparation of SOP's, Batch Production Records and assay transfers and/or to use Commercially Reasonable Efforts to conduct equipment validation and product-specific cleaning validation, and such failure can not be attributed in any way to the acts or omissions of Emergent, and Talecris has not provided to Emergent a reasonable plan of action for completing such Start-Up Preparations in a reasonable time period, Emergent shall have the right to terminate this Agreement pursuant to Section 10.02(i).

(b) Stability Testing. Emergent shall pay Talecris a one-time fee of [**] Dollars (US$[**]) following Talecris' performance of the stability testing and related activities set forth in Section 9.07 hereof.

(c) Container Closure Study. [**], Talecris shall conduct a container closure study, as further described on Exhibit K attached hereto.

(d) Process Validation Study. Emergent shall pay Talecris a one-time fee not to exceed [**] Dollars (US$[**]) for Talecris' conduct of the process validation study, as further described on Exhibit K attached hereto.

7.03 Processing Fee.

(a) Processing Fee. Subject to any price adjustments set forth in this Article 7 and the method of payment set forth in Section 7.07, the Parties agree that the price of the Finished Product to be charged to Emergent (the "Processing Fee") shall be at a rate equal to [**] Dollars ($[**]) per liter. Such Processing Fee shall include final fill and finish, but shall not include the cost of labels or packaging.

(b) Annual Price Adjustments. During the Commercial Term, upon commencement of each Contract Year following the first Contract Year, the Processing Fee and any relevant hourly billable rates of Talecris personnel shall be adjusted prospectively by a percentage equal to the percentage increase in the US CPI reported from the commencement of the prior Contract Year, beginning with the calendar quarter following the publication of the US CPI. For clarity, such adjustment shall take place only once per Contract Year on a calendar-year basis.

7.04 Royalty.

(a) Commercialization License. Talecris hereby grants to Emergent, under the Talecris Patent Rights, the rights, which shall be exclusive within the Field, to commercialize Finished Product, including to use, have used, offer for sale, sell, have sold, import, and have imported the Finished Product in the Territory .

(b) Royalty Rate. In addition to the Processing Fee set forth in Section 7.03(a), Emergent shall pay Talecris a royalty equal to [**] percent ([**]%) of Net Sales on a country-by-country basis for Commercial Product manufactured by Talecris hereunder.

(c) Royalty Term. The royalty payable under Section 7.04(b) shall be paid on a country-by-country basis on Finished Product Processed by Talecris hereunder (the "Royalty Term").

(d) Obligation to Pay. The obligation to pay royalties hereunder is imposed only once with respect to the same unit of Finished Product.

(e) Royalty Report. Emergent shall deliver to Talecris, within sixty (60) days after the end of each calendar quarter during the Royalty Term reasonably detailed written accountings of Net Sales of Finished Product that are subject to royalty payments due to Talecris for such calendar quarter. When Emergent delivers such accountings to Talecris, Emergent shall also deliver any royalty payments due under this Section 7.04 to Talecris for the calendar quarter.

7.05 Minimum Commitment Fee.

(a) Minimum Commitment Fee. If, during the Commercial Term or any Extension Period, Emergent fails to submit Orders (other than as a result of any Supply Failure) for the greater of (i) the total quantity of the [**] or (ii) the total quantity of [**], Emergent shall be responsible for an amount which is equal to the difference between the [**] and [**], as applicable ("Minimum Commitment Fee"). Emergent shall make a payment in cash of the Minimum Commitment Fee within [**] days of the end of the Contract Year or month, as applicable, during which the failure occurs.

(b) Exclusive Remedy. Emergent's payment of fees or submission of Orders, as applicable, as set forth under this Section 7.05, shall be Talecris' exclusive remedy and Emergent's sole liability, solely with respect to any failure to submit Orders as set forth herein.

7.06 Method of Invoicing for Orders. All Orders under this Agreement shall be invoiced at the time of Finished Product release by Talecris.

7.07 Remittance of Payments. Payments due by Emergent under this Article 7 shall be payable by Emergent no later than thirty (30) days after the invoice date; provided, however, that the Finished Product associated with such payment was actually delivered in compliance with Section 6.01. Emergent shall make payment by wire transfer of Dollars to a bank account designated by Talecris or by such other payment method as the Parties may agree upon from time to time.

7.08 Foreign Currency. Payments made under this Agreement shall be payable in United States Dollars. With respect to foreign exchange rate conversion, Net Sales calculated under this Agreement shall be computed for each quarter with Foreign Currency Sales converted into United States Dollars using the average exchange rate for such period, which average exchange rate shall be the actual rate as utilized by Emergent for its standard financial reporting, provided that such rate shall be consistent with other generally available, publicly reported exchange rates.

7.09 Talecris' Right to Audit. Emergent shall maintain and keep (and shall cause its Affiliates and Sublicensees to maintain and keep) for three (3) years after payment is made or should have been made by Emergent under this Agreement complete and accurate books and records in sufficient detail to calculate all sums falling due or which should fall due for payment by Emergent under this Agreement. No more than once during each calendar year during the Term, Emergent shall permit Talecris' independent auditors, to

whom Emergent has no reasonable objection and with reasonable Notice at any time during Emergent's normal business hours, to inspect, audit and copy relevant accounts and records of Emergent, its Affiliates and Sublicensees, for the sole purpose of verifying the accuracy of the calculation of payments to Talecris based on Net Sales and the reports which accompanied them. Talecris' independent auditors shall not disclose to Talecris any information other than information relating solely to the accuracy of the accounting and payments made by Emergent. If such audit determines that payments are due to Talecris, Emergent shall pay to Talecris any such additional amounts within thirty (30) days of the date on which such auditor's written report is delivered to Emergent, unless such audit report is disputed, in which case the dispute shall be resolved in accordance with Article 14. If the auditor determines that Emergent's payments are in excess of those required under this Agreement, Talecris shall credit the amount of such overpayment towards any amounts payable by Emergent to Talecris under this Agreement within ninety (90) days following the date of the auditor's determination of such overpayment, and shall promptly remit to Emergent any portion of such overpayment which has not been credited within such ninety (90) day period, unless such audit report is disputed, in which case the dispute shall be resolved in accordance with Article 14. Any such inspection of records shall be at Talecris's expense unless such audit discloses a deficiency in the payments made by Emergent of more than five percent (5%), in which case Emergent shall bear the cost of such audit.

7.10 Deductions from Payments. Any income or other taxes which Emergent is required by Applicable Law to pay or withhold on behalf of Talecris with respect to payments and any other monies payable to Talecris under this Agreement shall be deducted from the amount of such payments and other monies due and paid to the relevant competent taxing authority. Emergent shall furnish Talecris with proof of such payments. Any such tax required to be paid or withheld shall be an expense of and borne solely by Talecris. Emergent shall promptly provide Talecris with a certificate or other documentary evidence and provide reasonable assistance to enable Talecris to support a claim for a refund or a foreign tax credit with respect to any such tax so withheld or deducted by Emergent. Emergent and Talecris will reasonably cooperate in completing and filing documents required under the provisions of any applicable tax treaty or under any other Applicable Law, in order to enable Emergent to make such payments to Talecris without any deduction or withholding, if possible.

ARTICLE 8 — IND/BLA; REGULATORY MATTERS

8.01 Preparation of INDs and BLAs.

(a) Drafting. Emergent shall prepare and submit all necessary regulatory approvals for the AIG and/or Finished Product other than the Talecris BLA sections (as defined below), including without limitation INDs and the BLAs in the United States for the production of Initial AIG Source Plasma and for the Processing of Finished Product (including, without limitation, the filling and finishing of Finished Product, but excluding those activities set forth on Exhibit I attached hereto ("Talecris Gamunex Activities"), including any amendments or supplements thereto ("Emergent BLAs"). Emergent shall reasonably determine,

upon consultation with Talecris and taking into account in good faith Talecris' concerns and proposed timetable for submission of the Talecris BLA sections, the timing of the submission of the Emergent BLAs to the Regulatory Authorities. Talecris shall, at Talecris' expense, diligently and timely prepare and submit in compliance with Applicable Law in the Major Markets the portions of the BLA that cover the Talecris Gamunex Activities, including any amendments or supplements thereto ("Talecris BLA sections"), in the United States and in any other country or group of countries where such separate submission by Talecris is required, in accordance with the submission date(s) established by Emergent, which shall take into account in good faith Talecris's concerns and proposed timetable for submission of the Talecris BLA sections.

(b) Assistance by Talecris. Talecris hereby agrees to provide (i) to Emergent all information and regulatory support which is reasonably necessary in the preparation of comprehensive and complete INDs for Finished Product and the Emergent BLAs, and any amendments and supplements thereto, including, without limitation, the Talecris BLA sections (including without limitation the Chemistry Manufacturing and Controls (CMC) section), and (ii) access to the Facilities and pertinent information to Emergent and to FDA inspectors conducting the pre-approval inspection. Talecris shall provide such regulatory support pursuant to the provisions of Section 8.09.

(c) Changes. Subject to Section 5.01 and Section 8.06, each Party shall be responsible for timely notifying the applicable Regulatory Authority regarding proposed changes to the portion of the Process or Product Specifications or Emergent Specifications, as the case may be, covered by such Party's relevant sections of the Emergent BLAs in accordance with Applicable Law in the Major Markets.

8.02 Ownership. The Parties agree that all INDs arising under this Agreement related to AIG and/or Finished Product will be owned solely by Emergent, that Emergent BLAs arising under this Agreement, except for the Talecris BLA sections, will be owned solely by Emergent and held in the name of Emergent, in compliance with Applicable Law in the Major Markets.

8.03 Right of Cross-Reference. Emergent shall have the right to cross-reference all Talecris regulatory documents related to the Finished Product and/or the Process which are on file with applicable Regulatory Authorities as necessary in order to obtain all applicable regulatory approvals for Finished Product. During the term of the Agreement (excluding any suspensions of performance thereunder), Talecris shall have the right to cross-reference all Emergent regulatory documents related to the Finished Product and/or the Process which are on file with applicable Regulatory Authorities, solely as necessary for Talecris to Process Finished Product for Emergent under this Agreement or to exercise the rights granted to Talecris with respect to By-Products pursuant to Section 3.04 above. Talecris shall provide Emergent with regulatory support as reasonably necessary for each Party to obtain and maintain all necessary regulatory approvals for Finished Product

hereunder. Talecris shall provide such regulatory support pursuant to the provisions of Section 8.09.

8.04 Subsequent Filings or Applications. Talecris hereby agrees to provide to Emergent, regulatory support, data and other information which is reasonably necessary for the preparation of IND annual reports and/or any subsequent filings or applications Emergent may submit to the FDA pursuant to the provisions of Section 8.09.

8.05 Record and Files. Talecris shall maintain those documents required by applicable cGMP regulations. Emergent shall have the right to audit such Talecris documents and records related to the Processing of Finished Product upon reasonable advance Notice to Talecris and at reasonable intervals during the Term (but not more frequently than once every twelve (12) month period) to verify Talecris' compliance with such requirements.

8.06 Communications with Regulatory Authorities. Talecris shall not, without the consent of Emergent or unless so required by Applicable Law in the Major Markets, correspond or communicate with any Regulatory Authority specifically regarding the Finished Product. Furthermore, Talecris shall, as soon as practicable after any contact with or receipt of any communication from any Regulatory Authority relating to the Finished Product, forward a copy or description of the same to Emergent and respond to all inquiries by Emergent relating thereto. If Talecris is advised by its counsel that it must communicate with any Regulatory Authority specifically regarding the Finished Product, then Talecris shall so advise Emergent as soon as practicable and, unless prohibited by Applicable Law in the Major Markets, provide Emergent in advance with a copy of any proposed written communication with any Regulatory Authority and comply with any and all reasonable direction of Emergent concerning any meeting or written or oral communication with any Regulatory Authority. To the extent permitted by the Regulatory Authority, Emergent shall have the right to participate in any planned oral communications or meetings between Talecris and any Regulatory Authority relating to Finished Product, including without limitation periodic reporting sessions. For purposes of clarification, the obligations imposed on Talecris pursuant to this Section 8.06 shall not apply with respect to communications with Regulatory Authorities that are focused primarily on Gamunex and not on the Finished Product.

8.07 Governmental Inspections. Talecris shall immediately Notify Emergent in the event that any Regulatory Authority carries out or gives notice of its intention to carry out any inspection or investigation in connection with the Finished Product. To the extent permitted by the Regulatory Authority, Emergent shall have the right to be present at and observe any such inspection.

8.08 Post-Approval Obligations. Unless otherwise set forth in this Agreement, Emergent shall be responsible, at its own cost, for post-approval regulatory obligations associated with the Finished Product, including without limitation post-marketing clinical trials, additional product stability studies, drug safety monitoring, complaint handling, recalls, error and accident reporting, and adverse experience reporting, as each may be further described in Article 9. Emergent may procure regulatory support services from Talecris pursuant to the provisions of Section 8.09.

8.09 Regulatory Support; Investigations; Reports; Data. Talecris shall provide regulatory support, investigative support and reports or data to Emergent in support of filings to the Regulatory Authorities of the Major Markets only up to a maximum of [**] hours at no cost to Emergent, and, subject to Talecris' agreement, at Talecris' standard consulting rates set forth on Exhibit D for Talecris' personnel time in excess of the cap set forth herein. For other markets, Talecris shall use Commercially Reasonable Efforts to support Emergent at the consulting rates set forth on Exhibit D. Talecris shall use diligent efforts to provide the regulatory, advisory and related services under this Agreement in a professional manner; provided, however, that in no event does Talecris guarantee the outcome of such services.

ARTICLE 9 — REPORTING OF EVENTS

9.01 Exchange of Drug Safety Information. Each Party shall, and shall require that its Affiliates, (a) adhere to all Applicable Laws in the Major Markets which relate to the reporting and investigation of Adverse Events and biological product deviations as defined in 21 C.F.R. Part 600.14, and (b) keep the other Party informed of such experiences related to the Finished Product.

9.02 Adverse Events and Biological Product Deviations.

(a) Regulatory Reporting. Emergent shall have sole and exclusive responsibility for worldwide regulatory reporting of all Adverse Events and biological product deviations with respect to the Finished Product. In order that Emergent may be fully informed, Talecris shall, and shall require that its Affiliates and Sublicensees, provide Notice to Emergent of all Adverse Events and biological product deviations with respect to the Finished Product anywhere in the world in accordance with the timelines specified herein. Notwithstanding the foregoing, all Adverse Events and biological product deviations with respect to the Finished Product shall be reported by Talecris to Emergent promptly enough to allow Emergent sufficient time to evaluate, process and comply with worldwide regulatory reporting. Talecris shall have sole and exclusive responsibility for worldwide regulatory reporting of all Adverse Events and biological product deviations with respect to Gamunex, activities required to meet the Gamunex Specifications, or By-Products. In order that Talecris may be fully informed, Emergent shall, and shall require that its Affiliates, provide Notice to Talecris of all Adverse Events and biological product deviations with respect to the Finished Product anywhere in the world that may affect Gamunex, activities required to meet the Gamunex Specifications or By-Products, in accordance with the timelines specified herein. Notwithstanding the foregoing, to the extent practicable, all such Adverse Events and biological product deviations with respect to the Finished Product shall be reported by Emergent to Talecris promptly enough to allow Talecris sufficient time to evaluate, process and comply with worldwide regulatory reporting.

(b) Complaints. [**] all complaints, as defined in 21 C.F.R. Part 211.198 or any analogous

regulations or requirements in jurisdictions outside the United States, regarding the Finished Product. [**] shall Notify [**] within [**] hours of becoming aware of a complaint, including [**]. Talecris shall timely cooperate in [**], including providing information applicable to each, and shall timely initiate and complete corrective and preventive actions related to such investigations and identified product and quality system nonconformities that are the responsibility of Talecris under this Agreement. Talecris shall make [**] accessible to Emergent for purposes of FDA inspection in accordance with FDA regulations or pursuant to applicable regulations and requirements in jurisdictions outside the United States. [**] shall Notify [**] within [**] hours of becoming aware of a complaint pertaining to the [**] which may affect Gamunex or the Process, and shall timely share information pertaining to the investigation of such complaint with Talecris.

(c) Reports. Talecris shall provide to Emergent, within [**] hours of becoming aware thereof, information from any source that suggests an Adverse Event related to the [**] occurred. Emergent shall provide to Talecris, within [**] hours of becoming aware thereof, information from any source that suggests an Adverse Event related to the [**] occurred. This information shall include any adverse drug experience or reaction reports or any other reports or information, from whatever source derived, indicating that the [**] has any toxicity, sensitivity reactions, or is otherwise alleged to cause illness or injury of any kind due to a possible product quality problem, or is adulterated or misbranded.

(d) Investigations and Inquiries. With respect to information received regarding [**] complaints, Adverse Events and biological product deviations, Talecris shall thereafter reasonably cooperate with Emergent and the Regulatory Authority regarding an investigation or inquiry directed at the [**] that may be initiated by a Regulatory Authority or otherwise required in response to a [**] with respect thereto (which investigation or inquiry [**] shall have the right to direct and control) and shall further provide Emergent with all data or other information related solely to the [**] and excluding data or other information related to Gamunex that Emergent may reasonably require in connection with any reports or correspondence that Emergent provides to the Regulatory Authority, the [**] relative to any such adverse drug reaction [**] complaint.

9.03 Exchange of Drug Safety Requests. The Parties shall immediately provide each other with copies of all drug safety requests from all governmental agencies and Regulatory Authorities directed solely toward the Finished Product. Proposed answers materially affecting the Finished Product will be exchanged between the Parties before submission and the Parties shall cooperate with respect to such answers; provided, however, that

Emergent shall have ultimate decision-making authority with respect to answers relating solely to the Finished Product, unless Applicable Law in the Major Markets requires otherwise. The Parties shall exchange decisions from applicable health authorities immediately.

9.04 Regulatory Actions. Each Party shall advise the other Party of any regulatory action of which it is aware, which would affect the Finished Product in any country in the Major Markets.

9.05 Events Affecting Integrity or Reputation. During the Term, the Parties shall Notify each other immediately of any circumstances of which they are aware which arise whereby the integrity and reputation of the Finished Product or of the Parties are threatened by the unlawful activity of any Third Party in relation to the Finished Product.

9.06 Retention of Product Samples. Talecris shall, or shall cause one of its Affiliates to, retain all records and samples with respect to the Finished Product supplied by Talecris in accordance with Applicable Law in the Major Markets.

9.07 Stability. Talecris will perform stability testing, data interpretation, reporting and updating of stability information to regulatory documents for the Finished Product. Talecris shall perform such stability testing and related activities in accordance with the stability protocols, Talecris procedures, timing and other terms as set forth on Exhibit H, from the date of commencement of Processing of Finished Product from each Lot.

9.08 Annual Product Reviews. On a calendar-year basis, Talecris will prepare summary data for Finished Product Processed within the prior calendar year. Such data will be prepared and sent to Emergent within one calendar month (unless otherwise agreed by Talecris and Emergent) of the end of the applicable calendar year during which the Finished Product was Processed hereunder. This data will include [**]. Such data shall be prepared pursuant to the provisions of Section 8.09.

9.09 Quality Assurance Investigations. Upon Notice to Talecris that Emergent has received an Adverse Event, product complaint or inquiry regarding Finished Product supplied by Talecris to Emergent hereunder, Talecris shall (or shall cause one of its Affiliates to) within a reasonable period, conduct a quality assurance investigation to determine if any process or testing deviations or events may have contributed to such Adverse Event, complaint or inquiry. Quality assurance investigations may include a review of Batch Production Records and the evaluation of returned or retained samples of Finished Product. Talecris shall, or shall cause one of its Affiliates to, supply Emergent with the outcome of the investigation within thirty (30) days of Emergent’s notice. In cases where a more comprehensive investigation might be required, the Parties will jointly develop an investigational plan. Talecris shall conduct such quality assurance investigations pursuant to the provisions of Section 8.09.

ARTICLE 10 — TERM AND TERMINATION

10.01 Pre-Commercial Term; Commercial Term; Term.

(a) Pre-Commercial Term. "Pre-Commercial Term" shall mean the period commencing on the Effective Date and ending on the earlier of (i) January 1, 2009, or January 1, 2010 if Emergent gives Notice to Talecris by at least December 31, 2008 that it desires to extend the Pre-Commercial Term until January 1, 2010 and (A) the aggregate amount paid by Emergent to Talecris under this Agreement prior to December 31, 2008 plus the aggregate amount committed to be paid by Emergent during the first six (6) months of 2009 for (1) Pre-Commercial Product based on the forecasts and orders for such period and (2) other services to be provided hereunder during such period, equals or exceeds [**] Dollars (US$[**]), or (B) Emergent pays Talecris on or before December 31, 2008 a non-refundable deposit of [**] Dollars (US$[**]) less all amounts already paid or committed to be paid as described in the immediately preceding clause (i) (the "Extension Deposit"); and (ii) such date that is twelve (12) months following the date on which Emergent provides Notice to Talecris of its desire to commence the Commercial Term. The Extension Deposit, if any, shall be fully creditable against any amounts payable thereafter by Emergent to Talecris hereunder.

(b) Commercial Term. "Commercial Term" shall mean a five (5) year period commencing on the earlier of (i) either January 1, 2009 or, if the Pre-Commercial Term was extended pursuant to the terms of Section 10.01(a) above, January 1, 2010, or (ii) such earlier date that is twelve (12) months following the date on which Emergent provides Notice to Talecris of its desire to commence the Commercial Term.

(c) Term. Unless earlier terminated as set forth below, this Agreement shall be in effect from the Effective Date until the end of the Commercial Term (the "Initial Term"), which Commercial Term may be extended by Emergent for an additional five (5) year period ("Extension Period") upon Notice to Talecris at least twelve (12) months prior the expiration of such Initial Term; provided, however, that Emergent shall have no right to extend the Commercial Term if Talecris has provided to Emergent a Notice of termination pursuant to Section 10.02(b) (Elective Termination by Talecris). The "Term" shall consist of the Initial Term and any Extension Period.

10.02 Termination. This Agreement may be terminated in accordance with the following sections.

(a) Elective Termination by Emergent. Emergent may terminate this Agreement by giving at least two (2) years' advance Notice ("Emergent Elective Termination Notice") to Talecris, which Emergent Elective Termination Notice may not be given prior to the completion of the third (3rd) Contract Year during the Commercial Term but may be given at any time thereafter (including without

limitation during any Extension Period). Upon the second (2nd) anniversary of the Emergent Elective Termination Notice, this Agreement shall terminate.

(b) Elective Termination by Talecris. Talecris may terminate this Agreement by giving at least two (2) years' advance Notice ("Talecris Elective Termination Notice") to Emergent, which Talecris Elective Termination Notice may not be given prior to the completion of the third (3rd) Contract Year during the Commercial Term but may be given at any time thereafter (including without limitation during any Extension Period). If, despite good faith efforts, Emergent is unable to obtain regulatory approval for the manufacture and sale of any alternative Finished Product during the two (2) year notice period commencing upon the date of the Talecris Elective Termination Notice ("Termination Notice Period"), Emergent may Notify Talecris that Emergent desires for Talecris to continue to Process Finished Product for Emergent. Upon receipt of such Notice, Talecris shall continue to Process Finished Product for Emergent at a price per liter equal to [**] percent ([**]%) of the then-current Processing Fee until such time as Emergent obtains regulatory approval for such alternative Finished Product, provided that (a) Emergent shall continue to use good faith efforts to obtain such regulatory approval during such period of extension of the Termination Notice Period ("Termination Extension Period"), and (b) the Termination Extension Period shall be no longer than an additional twelve (12) months following the end of the Termination Notice Period. This Agreement shall terminate upon the later of the end of the Termination Notice Period or any Termination Extension Period.

(c) Mutual Agreement. This Agreement may be terminated by mutual written agreement of the Parties.

(d) Force Majeure. In the event a Party ("Affected Party") continues to experience a Force Majeure condition for a period of at least twelve (12) consecutive months after Notice of the Force Majeure was given pursuant to Section 15.11, the other Party shall be entitled to terminate this Agreement by giving a Notice of termination to the Affected Party at any time while such Force Majeure persists thereafter.

(e) Supply Failure. Upon the occurrence of a Supply Failure that has not been corrected within [**] from the triggering of the Supply Failure, Emergent shall have the right to terminate this Agreement by giving a Notice of termination to Talecris, such termination to take effect upon delivery of the Notice of termination.

(f) Material Breach by Emergent. In the event Emergent commits a material breach of this Agreement, Talecris shall be entitled to terminate this Agreement if such breach is not cured within sixty (60) days of Notice from Talecris, in which case the termination shall be effective sixty (60) days after receipt of the Notice; provided, however, that if such breach is incapable of cure within such sixty (60)

day period, the termination shall be effective upon delivery of the Notice of material breach.

(g) Material Breach by Talecris. In the event Talecris commits a material breach of this Agreement, Emergent shall be entitled to terminate this Agreement if such breach is not cured within sixty (60) days of Notice from Emergent, in which case the termination shall be effective sixty (60) days after receipt of the Notice; provided, however, that if such breach is incapable of cure within such sixty (60) day period, the termination shall be effective upon delivery of the Notice of material breach.

(h) Insolvency. Either Party shall be entitled to terminate this Agreement, by giving Notice to the other Party ("Insolvent Party"), in the event of an Insolvency Event occurring in relation to the Insolvent Party, such termination to take effect upon delivery of the Notice of termination to the Insolvent Party.

(i) Pre-Commercial Failure. During the Pre-Commercial Term, Emergent shall have the right to terminate this Agreement by Notice to Talecris if Talecris has failed to meet its obligations (i) to perform Start-Up Preparations as set forth in Section 7.02 above; or, (ii) pursuant to Pre-Commercial Target Yield provisions as set forth in Section 4.01(c). Such Notice of termination shall take effect upon delivery of such Notice to Talecris.

(j) Termination of AIG Program. Emergent shall have the right to terminate this Agreement by Notice to Talecris if (i) Emergent's production of AIG Source Plasma or development of AIG or Finished Product is discontinued or terminated for any reason other than for safety concerns, or (ii) Emergent determines in good faith not to file an IND for Finished Product, or the FDA rejects an IND or BLA for Finished Product. Such Notice of termination shall take effect upon delivery of such Notice to Talecris.

(k) Safety Concerns. Emergent shall have the right to terminate this Agreement by Notice to Talecris if Emergent determines in good faith that the development or commercialization of AIG or Finished Product should be discontinued for safety reasons and the safety problem cannot be resolved by modification of the Product Specifications. Such Notice of termination shall be accompanied by a written statement explaining in reasonable detail such safety concerns, and the basis thereof, and shall take effect upon delivery of such Notice to Talecris.

10.03 [Section Intentionally Left Blank]

10.04 Talecris' Rights Upon Termination of AIG Program.

(a) Termination During Pre-Commercial Term. In the event Emergent terminates this Agreement pursuant to Section 10.02(j) (Termination of AIG Program) or Section 10.02(k) (Safety Concerns) during the Pre-Commercial Term, within thirty (30) days following such termination, Emergent shall pay Talecris the aggregate Processing Fees which would have been payable to Talecris for the

total amount of Finished Product covered by all Orders that are submitted to Talecris prior to such termination had such termination not occurred.

(b) Termination During Commercial Term. In the event Emergent terminates this Agreement pursuant to Section 10.02(j) (Termination of AIG Program) or Section 10.02(k) (Safety Concerns) during the Commercial Term, within thirty (30) days following such termination, Emergent shall pay Talecris twice (X2) the aggregate Processing Fees for the Commercial Volume Commitment in effect for the current Contract Year.

10.05 Effect of Termination. Except as specifically set forth in this Agreement, all rights and obligations of the Parties shall terminate upon the expiration or termination of this Agreement, provided that such expiration or termination is without prejudice to any accrued rights of the Parties and shall not be construed to release either Party of any obligation matured prior to the effective date of such termination or expiration.

10.06 Survival. Sections 2.04, 3.03, 3.04, 7.09 (and the remainder of Article 7 to the extent any amounts are owed but unpaid), 8.02 and 10.04-10.06, and Articles 1, 11, 12, 13, 14, and 15 shall survive the expiration or termination of this Agreement in accordance with their terms.

ARTICLE 11 — REPRESENTATIONS AND WARRANTIES

11.01 Warranty by Talecris. Talecris hereby represents and warrants to Emergent the following:

(a) Compliance with Product Specifications. The Finished Product shall have been Processed in accordance with the Product Specifications and cGMP, shall comply with the Product Specifications and cGMP, and shall not be adulterated or misbranded within the meaning of any applicable food and/or drug law or regulation in the Major Markets, all at time of delivery.

(b) Rights. Talecris has all rights necessary to undertake the activities contemplated under this Agreement.

(c) Ownership of Talecris Patent Rights. Talecris holds good title to and is the legal and beneficial owner of the Talecris Patent Rights, free and clear of all liens, security interests and other recorded encumbrances of any kind.

(d) Validity and Enforceability; Non-Infringement. To Talecris' knowledge, (i) the Talecris Patent Rights are valid and enforceable, (ii) the Processing of Gamunex to the extent that such Processing is applicable to the Finished Product would not infringe the patent rights or misappropriate the trade secrets of any Third Party, and (iii) no Third Party is infringing any Talecris Patent Rights.

(e) Investigations. There are no inquiries, actions, investigations or other proceedings pending before or, to the best of Talecris' knowledge, threatened by any Regulatory Authority or other governmental agency with respect to any

Facility or with respect to Gamunex, and Talecris has not received written notice threatening any such inquiry, action or other proceeding.

11.02 Warranty by Emergent. Emergent hereby represents and warrants to Talecris the following:

(a) AIG Source Plasma. As of the time of delivery of AIG Source Plasma to Talecris hereunder, such AIG Source Plasma shall comply with the AIG Source Plasma Specifications and Applicable Laws ("Conforming AIG Source Plasma") and shall not be adulterated or misbranded within the meaning of any applicable food and/or drug law or regulation. If any Non-Conforming AIG Source Plasma is delivered to Talecris hereunder, Emergent shall replace or have replaced such Non-Conforming AIG Source Plasma with Conforming AIG Source Plasma, as reasonably necessary for Talecris to manufacture Finished Product hereunder. For the avoidance of doubt, if any Non-Conforming AIG Source Plasma is delivered to Talecris hereunder and Talecris Processes or has Processed such Non-Conforming AIG Source Plasma in accordance with the terms of this Agreement prior to Talecris becoming aware of such non-conformity, Emergent shall pay for the Processing of such Lot(s) of Non-Conforming AIG Source Plasma. Talecris shall, at Emergent's option and cost, either destroy or return to Emergent any unprocessed Non-Conforming AIG Source Plasma.

(b) Rights. Emergent has all rights to undertake the activities contemplated under this Agreement.

(c) Investigations. There are no inquiries, actions, investigations or other proceedings pending before or, to the best of Emergent's knowledge, threatened by any Regulatory Authority or other governmental agency with respect to Finished Product, and Emergent has not received written notice threatening any such inquiry, action or other proceeding.

11.03 Disclaimer of Warranties. The warranties set forth in Sections 11.01 and 11.02 are exclusive and are in lieu of all other warranties, whether written or oral express, implied or statutory. EXCEPT WITH RESPECT TO THE FOREGOING WARRANTY, THERE IS NO WARRANTY OF MERCHANTABILITY, SATISFACTORY QUALITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE GIVEN BY TALECRIS WITH RESPECT TO THE FINISHED PRODUCT OR BY EMERGENT WITH RESPECT TO THE AIG SOURCE PLASMA.

11.04 Remedies for Delivery of Non-Conforming Products or Spoiled AIG Source Plasma.

(a) General. In the event that Talecris Processes Non-Conforming Products it shall refund or credit any Processing Fees associated with such Non-Conforming Product resulting from the failure to follow the Process, negligence or willful misconduct in Processing the AIG Source Plasma. For the purpose of this Agreement, failure to follow the Process shall deemed to be negligence. In addition, Emergent shall, at Talecris's option and cost, either return or destroy any

Non-Conforming Products. Any Non-Conforming Products returned by Emergent pursuant to this Section shall be delivered to Talecris at its Facility.

(b) Damages for Spoiled AIG Source Plasma. Talecris shall pay Emergent an amount equal to (i) [**] Dollars ($[**]) for each liter of Spoiled AIG Source Plasma resulting from the [**] of Talecris, and (ii) [**] Dollars ($[**]) for each liter of Spoiled AIG Source Plasma resulting from the [**] of Talecris. "Spoiled AIG Source Plasma" shall mean Conforming AIG Source Plasma which (i) has been Processed but results in Non-Conforming Product, (ii) cannot reasonably be Processed in accordance with Product Specifications and cGMP to produce Finished Product which conforms to the Product Specifications and cGMP, or (iii) is otherwise lost or destroyed.

(c) Non-Conformance with Emergent Specifications. Notwithstanding anything in the foregoing to the contrary, if Finished Product does not meet the Emergent Specifications, upon receipt of Notification by Emergent of such variance or non-conformance, Talecris shall use Commercially Reasonable Efforts (i) to assist Emergent in investigating the cause of any such variance or non-conformance and (ii) to cure such variance or non-conformance, pursuant to the provisions of Section 8.09. For the avoidance of doubt, in no event shall Talecris be obligated to effect, or undertake efforts to effect a cure under this Section 11.04(c) that would adversely affect the Gamunex Specifications or require the implementation of any changes to Talecris' production of Gamunex.

(d) Remedies Exclusive. Except for Product Liability claims for Finished Product governed by Section 12.03(a), the payments provided for under this Section 11.04 shall be Emergent's exclusive remedy, and Talecris' sole liability, in connection with Talecris' delivery of Non-Conforming Products.

ARTICLE 12 — INDEMNIFICATION

12.01 Indemnification In Favor of Emergent. Subject to Section 12.02, Talecris shall defend, indemnify and hold harmless each Emergent Indemnitee from and against any and all Losses for (a) any Claims of Third Parties that arise as a result of a material breach of any covenant, agreement, warranty or representation made by Talecris or any of its Affiliates under this Agreement which causes the Finished Product to not be Processed in accordance with Product Specifications, (b) any Third Party Claims of patent infringement or trade secret misappropriation involving the Processing of the Finished Product, but only to the extent such Third Party Claim is specifically directed to the activities required to meet the Gamunex Specifications, (c) any Claims of Third Parties (including, without limitation, any Product Liability Claims) that arise as a result of the development, manufacture, marketing, promotion, sale, disposition, distribution or other use of By-Products, (d) any Product Liability Claims, or such portion of Product Liability Claims, with respect to Finished Product as are allocated to Talecris pursuant to Section 12.03(a), and (e) any Claims arising from the regulatory, advisory and related services provided by Talecris in connection with this Agreement. Talecris shall not be obligated under this Section 12.01 to the extent it is shown that the Loss was the direct result of a

material breach of any covenant, warranty or representation made by Emergent under this Agreement. Except with respect to the indemnification of any Claim covered by clause (b) or (c) above, the indemnity in this Section 12.01 shall be limited to the greater of the (i) Processing Fees paid by Emergent during the twelve (12) months prior to the date the Claim arose, (ii) the Commercial Volume Commitment for the Contract Year during which such Claim arose, or (iii) the Firm Commitment for the Contract Year during which such Claim arose.

12.02 Indemnification In Favor of Talecris. Emergent shall defend, indemnify and hold harmless each Talecris Indemnitee from and against any and all Losses for (a) any Claims of Third Parties that arise as a result of a material breach of any covenant, agreement, warranty or representation made by Emergent under this Agreement, (b) any Claims of Third Parties of patent infringement or trade secret misappropriation involving the Processing or Sale of the Finished Product and which is not specifically directed to the activities required to meet the Gamunex Specifications, and (c) any Product Liability Claims, or such portion of Product Liability Claims, with respect to Finished Product as are allocated to Emergent pursuant to Section 12.03(b). Emergent shall not be obligated under this Section 12.02 to the extent it is shown that the Loss was the direct result of a material breach of any covenant, warranty or representation made by Talecris under this Agreement.

12.03 Product Liability Claims. Notwithstanding the foregoing Sections 12.01 and 12.02, the Parties' responsibilities with respect to Product Liability Claims for Finished Product shall be governed by this Section 12.03.

(a) Talecris' Liability. Talecris shall be solely responsible for all Product Liability Claims that arise out of Non-Conforming Product where such nonconformance (i) arose from Talecris' failure to Process Finished Product in accordance with Product Specifications or cGMP, and (ii) existed at the time the Finished Product was delivered by Talecris; provided, however, that Talecris' liability for such Product Liability Claims shall be limited to the greater of the (A) Processing Fees paid by Emergent during the twelve (12) months prior to the date the Claim arose, (B) the Commercial Volume Commitment for the Contract Year during which such Claim arose, or (C) the Firm Commitment for the Contract Year during which such Claim arose.

(b) Emergent's Liability. Emergent shall be solely responsible for all Product Liability Claims other than those for which responsibility was allocated to Talecris pursuant to Section 12.03(a).

(c) Responsibility for Settlement and Defense. The Parties shall jointly defend and settle any Product Liability Claim with respect to the Finished Product. Notwithstanding the foregoing, at such time that Talecris reasonably determines in good faith that there is a reasonable likelihood that a Product Liability Claim could have a material negative affect on Gamunex, then Talecris, shall have the right, but not the obligation, to assume the sole defense of such Product Liability Claim.

(d) Procedure. Each Party shall consult with the other Party on all material aspects of the defense, including without limitation settlement, of such Product Liability Claim, and the Parties shall cooperate fully with each other in connection therewith. To facilitate the defense of any Product Liability Claim, the Parties shall mutually select a law firm to represent them in the joint defense of such claim as soon as practicable following the Effective Date of this Agreement. In furtherance of the Parties' cooperation, the Parties will consult with each other regarding strategic decisions, including without limitation the changing of counsel and defense of each Product Liability Claim. Any settlement of a Product Liability Claim that would admit liability on the part of any Party or its Affiliates or Agents, or that would involve any relief other than the payment of money damages, shall be subject to the prior written approval of both Parties, such approval not to be unreasonably conditioned, withheld or delayed. All damages and expenses (including attorney's fees) incurred in connection with the defense of a Product Liability Claim shall be allocated between the Parties in accordance with Sections 12.03(a) and 12.03(b).

12.04 Notice. Should any claim arise which could reasonably be expected to lead to a claim for indemnification, the Party seeking indemnification (the "Indemnified Party") shall promptly Notify the other Party (the "Indemnifying Party") of the claim and the facts constituting the basis for such claim. The omission of such Notice shall not relieve either Party from its indemnification obligations under this Article 12, except to the extent the other Party can establish actual prejudice and direct damages as a result thereof.

12.05 Indemnification Not Sole Remedy. Each Party hereby acknowledges that the indemnification provided for under this Article 12 shall in no manner limit, restrict or prohibit (unless liability is otherwise expressly limited by the terms of this Agreement) either Party from seeking any recovery or remedy provided at law or in equity from the other Party in connection with any breach or default by such other Party of any representation, warranty or covenant hereunder.

12.06 Guarantor. Parent agrees to act as a third party guarantor ("Guarantor") of Emergent for the indemnities provided by Emergent to Talecris under this Article 12 and the payment obligations of Emergent set forth in Section 7.05(a). Upon Emergent's default of its indemnity obligations hereunder or its payment obligations set forth in Section 7.05(a), Guarantor agrees to guarantee such obligation as its own. Guarantor agrees that no amendment, termination or other release, other than Talecris expressly releasing Guarantor in writing, shall in any way alleviate its obligations under this Section 12.06 and Guarantor hereby waives any notice of any such amendment, termination or other release. Guarantor hereby agrees to give written notice to Talecris within ten (10) days of: (i) any notice received or action filed alleging the insolvency or bankruptcy of Guarantor; (ii) any notice received or action filed alleging the insolvency or bankruptcy of Emergent; or (iii) any other event which would otherwise reasonably prevent Guarantor from fulfilling its obligations under this Section 12.06.

ARTICLE 13 — CONFIDENTIALITY

Confidentiality. From the Effective Date through the seventh (7th) anniversary of the termination or expiration of this Agreement, each Party shall keep confidential and use solely for purposes of performing its obligations under this Agreement, and shall cause its respective Affiliates, Sublicensees and their respective officers, directors, employees and agents to keep confidential and to so use, all information proprietary or confidential to the other Party that has been acquired by it through its participation in the negotiation and performance of this Agreement. The foregoing restriction shall not apply to information that (a) is or hereafter becomes generally available to the public other than by reason of any default with respect to confidentiality under this Agreement, (b) is hereafter disclosed to such Party by a Third Party who is not in default of any confidentiality obligation to the other Party, (c) is hereafter developed by or on behalf of such Party, without reliance on confidential information acquired prior to the date hereof, (d) is required to be disclosed in compliance with Applicable Law or order by a court or other governmental or Regulatory Authority or body having competent jurisdiction, provided that reasonable measures shall be taken to assure confidential treatment of such information, or (e) is provided by such Party under appropriate terms and conditions, including confidentiality provisions equivalent to those in this Agreement, to Third Parties for consulting, accounting, legal and similar purposes, or to any permitted assignee of this Agreement, to the extent considered reasonably necessary to facilitate the assignment. For purposes of clarity, any information related to the composition and/or utility of Finished Product, the Emergent Specifications, and Fill/Finish Specifications shall be deemed confidential information of Emergent hereunder. The content of the Talecris BLA sections and the Gamunex Specifications shall be deemed confidential information of Talecris hereunder. Each Party recognizes that any violation of this confidentiality provision may cause the other Party irreparable harm and agrees that the other Party may be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction without the posting of any bond or other security, enjoining the disclosing Party, its Affiliates, Sublicensees and their respective officers, directors, employees and agents from any violation or potential violation of this Article.

ARTICLE 14 — DISPUTE RESOLUTION AND LITIGATION

14.01 Dispute Resolution Procedures. Except for matters to be resolved pursuant to Sections 4.01(c)(v)(B), 5.02(d) or 9.03, any dispute arising out of, relating to, or having any connection with this Agreement (including any question relating to its existence, validity, interpretation, performance, or termination) ("Dispute") shall be resolved pursuant to the procedures set forth in this Article. If either Party fails to observe the procedures of this Article, as may be modified by the written agreement of the Parties, the other Party may bring an action for specific performance.

(a) Negotiation. In the event of a Dispute, the affected Party shall notify the other Party of the Dispute in writing, and the Parties shall negotiate in good faith, for a period of thirty (30) days (or such longer period as may be agreed by the Parties) from the issuance of the Notice (the "Notice Date"), to resolve the Dispute without the intervention of a neutral party or a court.

(b) Mediation. If the Dispute remains unresolved within sixty (60) days after the Notice Date, either Party may request that the Parties submit the Dispute to non-binding mediation before a mutually acceptable neutral mediator by sending written Notice to the other Party. If the other Party agrees to mediate, the Parties shall attempt to resolve the Dispute through mediation until one of the following occurs: (i) the Parties reach a written settlement; (ii) the mediator notifies the Parties in writing that they have reached an impasse; (iii) the Parties agree in writing that they have reached an impasse; or (iv) the Parties have not reached a settlement within one hundred twenty (120) days after the Notice Date.

(c) Litigation. If the Parties fail to resolve the Dispute through mediation, or if the Dispute is, in any event, not resolved within one hundred eighty (180) days after the Notice Date, each Party shall have the right to pursue any other remedies legally available to resolve the Dispute.

(d) Statute of Limitations. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) shall be tolled while the procedures set forth in Sections 14.01(a) and 14.01(b) are pending. The Parties shall take any actions necessary to effectuate this result.

14.02 Other Rights.

(a) Exception for Additional Disputes. In the event that the Parties are involved in ongoing litigation of one or more Disputes that already have been through the dispute resolution process set forth in Sections 14.01(a)—(c), the Parties are not required to submit additional Disputes to negotiations pursuant to Section 14.01(b), as long as that litigation remains pending.

(b) Provisional Remedies. Notwithstanding the dispute resolution procedures described above, either Party may seek a preliminary injunction or other provisional equitable relief if, in its reasonable judgment, such action is necessary to avoid irreparable harm.

(c) Termination. For the avoidance of doubt, nothing in this Article shall preclude, interfere with or modify either Party's rights under Article 10 with respect to the termination of this Agreement.

14.03 Governing Law. This Agreement and any and all matters arising directly or indirectly herefrom shall be governed by and construed and enforced in accordance with the laws of the United States and the internal laws of the State of New York, without regard to conflicts of law principles.

ARTICLE 15 — GENERAL PROVISIONS

15.01 Notice. Notices and other communications (each, a "Notice") provided herein shall be in writing and shall be delivered by hand or overnight courier service, mailed or sent by facsimile (with receipt confirmed) as follows:

If to Emergent, to:

Emergent Product Development Gaithersburg Inc.
300 Professional Drive
Gaithersburg, MD 20879

Attn: General Counsel
or
Attn: Accounts Payable (for invoices only)

with copies (except as to invoices), which shall not constitute notice hereunder, sent to:

Wilmer Cutler Pickering Hale and Dorr LLP
1899 Pennsylvania Avenue, NW
Washington, DC 20006
Facsimile: (202) 663-6363

Attn: Van W. Ellis

If to Talecris, to:

Talecris BioTherapeutics, Inc.
79 T.W. Alexander Drive
4101 Research Commons
PO Box 13887
Research Triangle Park
North Carolina 27709

Attn: VP of Law, General Counsel

All Notices and other communications given to any Party in accordance with the provisions of this Agreement shall be deemed to have been given on the date of receipt if delivered by hand or overnight courier services or sent by facsimile (with receipt confirmed by telephone or by facsimile machine), or on the date five (5) Business Days after dispatch by certified or registered mail (postage prepaid) if mailed, in each case delivered, sent or mailed (property addressed) to such Party at its address as set forth in this Section 15.01, or to such other address that such Party may have Notified to the other Party from time to time.

15.02 Entire Agreement. This Agreement and the Exclusivity Agreement (including all attachments hereto and thereto) constitute the entire agreement among the Parties with respect to the matters set forth herein, and supersede all prior agreements and understandings, both written and oral, among the Parties with respect thereto, including without limitation the Letter of Intent, dated as of April 5, 2006 (as amended), between the Parties. In the event of any conflict or discrepancy between the terms of the Quality Agreement or the Exclusivity Agreement and this Agreement, the terms of this Agreement shall control.

15.03 Covenant of Further Assurances. The Parties covenant and agree that, subsequent to the execution and delivery of this Agreement and without any additional consideration, each of the Parties shall execute and deliver any further legal instruments and perform such acts which are or may become reasonably necessary to effectuate the purposes of this Agreement.

15.04 Waivers; Amendment. The failure of either Party to insist, in any one or more instances, upon the performance of any of the terms, covenants or conditions of this Agreement or to exercise any right hereunder, shall not be construed as a waiver or relinquishment of the future performance of any such term, covenant or conditions or the future exercise of such right, and the obligation of the other Party with respect to such future performance shall continue in full force and effect. No item or provision of this Agreement may be altered, amended or waived except by a writing signed by both Parties.

15.05 Relationship. Talecris is an independent contractor engaged by Emergent for the provision of the Finished Product. Nothing in this Agreement shall constitute Talecris as an employee, agent or general representative of Emergent. This Agreement shall not constitute either Party as the legal representative or agent of the other, nor shall either Party have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against, or in the name of or on behalf of, the other Party. This Agreement shall not constitute, create or in any way be interpreted as a joint venture, partnership or formal business organization of any kind.

15.06 Publicity. Except as otherwise required by Applicable Law, neither Party shall use the other's name or refer to it directly or indirectly in an advertisement, news release or release to any professional or trade publication or issue any news release relating to this Agreement, without the prior written approval from such Party for such use or release, which approval shall not be unreasonably withheld, conditioned or delayed. The Parties agree that a news release with respect to the consummation of this transaction and the details thereof will be made, the content, form and timing of which shall be reasonably agreed between the Parties.

15.07 Severability. If, under Applicable Law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement (such invalid or unenforceable provision, a "Severed Clause"), this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use Commercially Reasonable Efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of this Agreement.

15.08 Assignment. This Agreement may not be assigned by either Party without the prior written consent of the other Party; provided, however, that either Party may assign its right to receive payment hereunder without prior consent of the other Party, but provided it Notifies such other Party of such assignment within three (3) Business Days. In addition, either Party may assign this Agreement, without the other Party's prior written consent, to any Affiliate or in connection with an acquisition, merger or sale of all or substantially all of the stock, assets or business to which this Agreement pertains.

15.09 Subcontracting. Talecris shall not subcontract or otherwise delegate any of its obligations under this Agreement, either to an Affiliate or a Third Party, if such subcontracting or delegation would require the manufacturing of additional Validation Lots for Finished Product. If such subcontracting or delegation would not require the manufacturing of additional Validation Lots of Finished Product, Talecris may subcontract or delegate any of its obligations hereunder to an Affiliate or Third Party, provided, that (a) Talecris Notifies Emergent of such proposed subcontracting arrangement, including without limitation the identity of the proposed subcontractor, the location of such proposed subcontractor's facilities, and a reasonably detailed description of the terms of such proposed subcontracting arrangement as it relates to the Finished Product, (b) Talecris procures for Emergent a reasonable opportunity to conduct a quality audit of the facilities proposed to be used by such proposed subcontractor in performing its obligations with respect to Finished Product, at a time reasonably satisfactory to Emergent, (c) Talecris guarantees to Emergent the performance of any of its obligations which it fulfills through such subcontracting and remains primarily liable for the performance of such obligations, and (d) Talecris obtains Emergent's prior written consent, which shall not be unreasonably withheld, conditioned or delayed. Talecris shall bear all costs associated with or arising as a result of any such permitted subcontracting by Talecris (including, without limitation, costs associated with any regulatory filings which may be required to be submitted to any Regulatory Authorities with respect to Finished Product), and shall reimburse Emergent for such costs to the extent incurred by Emergent.

15.10 Headings. The headings used in this Agreement are included for convenience only and are not to be used in construing or interpreting this Agreement.

15.11 Force Majeure. Subject to Section 10.02(d), if either Party is impeded in fulfilling its undertakings in accordance with this Agreement by circumstances beyond its reasonable control, such as, but not limited to, labor conflict, lightening striking, acts of God, fire, war, mobilization or unforeseen military call-up of a large magnitude, requisition, confiscation, commandeering, public decrees, riots, insurrections, terrorism, general shortage of transport, goods or energy, and faults or delays in deliveries from subcontractor or suppliers caused by any circumstances referred to in this Section 15.11, the impediment shall be considered a "Force Majeure" condition and the Party shall be exempted from liability for delays due to such reasons; provided, however, that it Notifies the other Party thereof without undue delay after such a circumstance has occurred. Upon such Notice, the Parties shall agree upon a reasonable extension of the time for performance, not to exceed an extension equal to the period the Force Majeure condition continues to exist.

15.12 Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and same instrument.

15.13 LIMITATION OF DAMAGES. EXCEPT WITH RESPECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 12 HEREUNDER OR A BREACH OF A PARTY'S CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE

13, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY, AND EACH PARTY SHALL PROCURE THAT NONE OF ITS AFFILIATES SHALL MAKE ANY CLAIM AGAINST THE OTHER PARTY (OR ITS AFFILIATES) FOR ANY LOST PROFITS, LOSS OF BUSINESS, LOSS OF CONTRACTS, DIMINISHED GOODWILL, DIMINISHED REPUTATION, OR CONSEQUENTIAL, INCIDENTAL, SPECIAL, PUNITIVE OR OTHER INDIRECT DAMAGES ARISING UNDER OR IN CONNECTION WITH THIS AGREEMENT, THE AIG, THE FINISHED PRODUCT AND/OR THE PROCESSING OF FINISHED PRODUCT.

15.14 Talecris Limitation on Liability. To the fullest extent permitted by law, and except as otherwise expressly provided in this Agreement in Section 12.01 (b) and (c) and Third Party Claims relating to Gamunex® Products, Talecris' aggregate liability for any and all Claims, losses, costs or damages whatsoever arising out of or resulting from or in any way related to the Processing or this Agreement from any cause or causes, including but not limited to the negligence, strict liability, breach of contract or warranty (express or implied) of Talecris or Talecris' officers, directors, employees, agents or consultants shall be limited to the greater of the (i) Processing Fees paid by Emergent during the twelve (12) months prior to the date the Claim, loss, cost, or damage arose, (ii) the Commercial Volume Commitment for the Contract Year during which such Claim, loss, cost or damage arose, or (iii) the Firm Commitment for the Contract Year during which such Claim, loss, cost or damage arose.

15.15 Exhibits. In the event that an Exhibit referenced herein is not completed by the Effective Date, such Exhibit shall be completed as soon as practicable following the Effective Date, but no later than forty-five (45) days thereafter, and upon approval in writing by both Parties, shall be attached hereto.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective officers hereunto duly authorized as of the Effective Date.

EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC.

By: /s/ R. Don Elsey
Name: R. Don Elsey
Title: Treasurer

TALECRIS BIOTHERAPEUTICS, INC.

By: /s/ Alberto Martinez
Name: Alberto Martinez
Title: President and CEO

With respect to the Guarantor obligations set forth in Section 12.06 only, with the consent of the other Parties as evidenced by their signatures above, the following party joins as a signatory to this Agreement.

EMERGENT BIOSOLUTIONS INC.

By: /s/ Daniel J. Abdun-Nabi
Name: Daniel J. Abdun-Nabi
Title: Sr. V.P. and General Counsel

EXHIBIT A

Gamunex Specifications

Test	Specification
Protein concentration	[**]
Appearance: color	[**]
Appearance: clarity	[**]
Caprylate concentration	[**]
Anticomplement Activity	[**]
Anti-A	[**]
Anti-B	[**]
pH (1% protein solution)	[**]
Glycine concentration	[**]
Protein composition (CZE)	[**]
MW Distribution: Aggregate	[**]
MW Distribution: Monomer + Dimer	[**]
MW Distribution: Fragment	[**]
Prekallikrein activator	[**]
Sterility USP	[**]
Pyrogen USP	[**]
General Safety Testing	[**]
[**]	

EXHIBIT A-1

Emergent Specifications

Test	Specification
Post Packaging Identity: [**]	[**]
Potency: [**]	[**]

EXHIBIT B

Talecris Patent Rights

1. United States Patent No. 6,955,917, issued on October 18, 2005, entitled “Chromatographic method for high-yield purification and viral inactivation of antibodies”.

Inventors:	**Alred; Patricia** (Fredrick, MD); **Cook; Scott A.** (Apex, NC); **Lebing; Wytold R.** (Clayton, NC); **Lee; Douglas C.** (Raleigh, NC); **Paul; Hanns-Ingolf** (Leverkusen, DE); **Radtke; Klaus-Peter** (Apex, NC)
Assignee:	**Bayer Healthcare LLC** (Tarrytown, NY)
Appl. No.:	**270918**
Filed:	**October 15, 2002**

2. United States Patent No. 6,307,028, issued on October 23, 2001, entitled “Chromatographic method for high-yield purification and viral inactivation of antibodies”.

Inventors:	**Lebing; Wytold** (Clayton, NC); **Alred; Patricia** (New Market, MD); **Lee; Douglas C.** (Apex, NC); **Paul; Hanns-Ingolf** (Cary, NC)
Assignee:	**Bayer Corporation Incorporated** (Indiana, PA)
Appl. No.:	**270724**
Filed:	**March 17, 1999**

3. United States Patent No. 5,886,154, issued on March 23, 1999, entitled “Chromatographic method for high-yield purification and viral inactivation of antibodies”.

Inventors:	**Lebing; Wytold R.** (1304 Pine Trail, Clayton, NC 27520-9324); **Alred; Patricia** (9890 Washington Blvd. Apt. 404, Gaithersberg, MD 20878); **Lee; Doug C.** (116 Altair Cir., Apex, NC 27502); **Paul; Hanns-Ingolf** (1107 Queenferry Rd., Cary, NC 27511)
Assignee:	**[_____]**
Appl. No.:	**879362**
Filed:	**June 20, 1997**

Exhibit C

Talecris
BIOTHERAPEUTICS

8368 U.S. 70 West
Clayton, NC 27520

David Sorrell
Senior Contract Manager
Tel: 919.359.7094
Fax: 919.359.7174
david.sorrell@talecris.com

June 14, 2006

Emergent BioSolutions
Nili Leffers
300 Professional Dr, Suite 250
Gaithersburg, MD 20879

Dear Nili,

The purpose of this data packet is to provide three documents that govern the receipt of AIG Anthrax Plasma. The documents are:

1. Purchase Specification — Source Plasma — Anthrax (AX), Revision New, SAP # 08937351, Effective Date: 6/14/2006
2. SOP — Plasma Supplier Supplemental Directions, Revision 12, SOP # CS-000-BE-053, Effective Date: 03/31/2006
3. Purchase Specification — General Specification — Source Plasma, Revision 23, Effective Date: 03/31/2006

These are the documents that govern the shipment of AIG plasma to the Clayton Talecris facility.

Please distribute as needed.

Sincerely,

/s/ David M. Sorrell

David Sorrell, 6/14/06
Contract Manager

/s/ Amy W. Durham	6-12-06	/s/ John W. Parrish	6-12-2006
Document Owner	Date	Quality Approver	Date

Supercedes: N/A Date Effective: **JUN 14 2006**

1. PURPOSE

1.1. To describe specific requirements, in addition to those described in the Source Plasma, General Specification, for Source Plasma – Anthrax.

2. REFERENCE(S)

2.1. Source Plasma – General Specification

2.2. CS-000-BE-053, Plasma Supplier Supplemental Directions

2.3. CS-000-BH-010, Supplier Quality – Notification, Evaluation and Approval of Plasma Suppliers and Service Providers

3. DEFINITIONS

3.1. **Source Plasma Type – Anthrax (AX)** - Refers to plasma collected by approved plasmapheresis method from donors with naturally occurring or artificially stimulated antibody levels for Anthrax.

3.2. **SQID – Supplier Quality Information Database** - Database maintained by Talecris Supplier Quality that contains pertinent information and current status of each collection facility, test laboratory, and plasma transportation carriers.

4. GENERAL REQUIREMENTS

4.1. Plasma collection must be in approved bottles only.

4.2. Plasma collection is non-EU approved only.

5. SPECIAL REQUIREMENTS

5.1. Emergent BioSolutions is the purchaser of the [**] Anthrax (AX) plasma. Emergent is responsible for contracts with the individual plasma suppliers of the AX plasma and ensuring that these plasma centers and product meet the requirements listed in this specification and in the Source Plasma, General Specification for Source Plasma. Moreover, Emergent is responsible for the transport of the plasma to Talecris receiving dock.

5.2. The plasma donor centers supplying the AX plasma must also be on the Talecris approved centers listing in the SQID, as well as the testing labs associated with the plasma testing.

5.3. The AX plasma under this material number will be processed together to form a manufacturing pool, as modeled by Talecris. Only [**] will be further processed from an AX pool. The [**] will be further manufactured into IGIV-C product.

5.4. Plasma from donors identified with [**] Anthrax or AX antibodies (as judged by Emergent) may be designated as AX plasma.

6. NAT TESTING REQUIREMENTS

6.1. The following chart lists the required NAT testing and the material numbers for Anthrax high titer plasma. **Note:** Only plasma tested for HCV, HIV-1, HBV and Parvo B19 by NAT is acceptable to ship to Talecris.

SAP (Required) Material Numbers	EU ELIGIBLE	HCV by NAT	HIV-1 by NAT	HBV by NAT	Parvo B-19 by NAT	Bottles
08937351		**X**	**X**	**X**	**X**	**Bottles**

/s/ Amy W. Durham	2-28-06	/s/ John W. Parrish	2-28-2006
Document Owner	Date	Quality Approver	Date

Supercedes: CS-000-AR-107 Effective Date: **MAR 31 2006**

1. PURPOSE

1.1. This document outlines specific directions that supplement the minimum requirements listed in the Talecris General Specification — Source Plasma.

2. SCOPE

2.1. These directions are applicable to all plasma that is procured and designated for shipment to Talecris.

2.2. This document is to be used by plasma suppliers that sell plasma to Talecris.

2.3. This SOP is distributed by Clayton QO-Plasma to all Talecris Plasma Operations Account Managers.

2.4. This SOP contains Talecris-required NDP and Packing List Summary forms that are completed by plasma centers for shipments to Talecris. Changes to these forms must be documented through a revision of this SOP.

3. RESPONSIBILITY

3.1. Talecris QO-Plasma:

3.1.1. Communicates to plasma suppliers and appropriate Talecris departments (e.g., Plasma Ops, QO Compliance) any quality issues (discrepancies) with received product.

3.2. Talecris Plasma Operations Account Manager monitors plasma suppliers' compliance and adherence to regulatory agency requirements and to the Talecris General Specification — Source Plasma.

3.2.1. Provides supplier with most current revisions of this document, associated forms, and other SOPs/specifications.

3.2.2. May initiate changes to this SOP and other plasma supplier documents and participates in the review process of revisions.

3.3. Plasma Supplier assures that all conditions of the General Specification - Source Plasma and supply contract are met.

3.4. Talecris Plasma Operations Technical Services Manager approves the use of specific plasma collection materials and supplies, all packaging and shipping materials, samples tubes, labels and bar code systems used by suppliers. Successful completion of materials clearance testing is required prior to approval for all specific plasma collection and supply materials. These functions may be performed by the Talecris Plasma Operations Account Managers in the absence of the Technical Services Manager.

3.5. Talecris QO Manager, Supplier Quality determines and communicates all changes in plasma supplier status and/or services to Talecris, and maintains the appropriate documentation files for status of suppliers, collection and testing facilities.

3.6. Talecris, Regulatory Affairs coordinates implementation of any new regulatory requirements.

3.7. Talecris Plasma Receiving receives all incoming plasma shipments and handles all correspondence related to inventory control.

3.8. QO Document Management, Clayton, maintains and revises the NDP and PLS forms as requested.

4. REFERENCES

4.1. CS-000-BE-057 — Supplier Quality — Method For Evaluating The Suitability Of Source Plasma Collection Facilities And Test Laboratories

4.2. Talecris General Specification — Source Plasma

5. DEFINITIONS

5.1. ITS: Incident Tracking System. Used by Talecris to track discrepancy reports for plasma not yet processed (RMRs) and only impacting processed material (ITS).

5.2. NDP: Notification for Destruction of Plasma form. Submitted to Talecris in the event plasma unit removal or disposition is required.

5.3. NDDR: National Donor Deferral Registry

5.4. QO-Plasma: Quality Operations Plasma Business Unit

5.5. PPL: Plasma Packing List for individual plasma cases

5.6. PLS: Packing List Summary form. Separate PLS forms are submitted for each vendor batch number.

5.7. RMR: Raw Material Report. A report used to document discrepancies against plasma not yet processed (pooled).

5.8. RTL: Talecris Raleigh Test Lab

5.9. SAP Material Number: The SAP material number replaces the plasma item number. The SAP material number (referred to as plasma material number) identifies the plasma type, collection in bottles, level of testing, and whether or not the plasma is EU eligible.

5.10. Vendor Batch Number: Identifies the shipment, to Talecris. The vendor batch number is a unique identifier that is NEVER duplicated at the same center. Whenever a shipment comprises more than one plasma type, a unique vendor batch number must be assigned to each plasma type within the shipment. The first four (4) characters of the Vendor Batch Number must be the donor center’s NDDR number.

5.11. Working Day: Any scheduled workday.

6. REQUIREMENTS

6.1. Materials/Reagents — Refer to Talecris General Specification

6.2. Equipment — Refer to Talecris General Specification

6.3. Frequency

6.3.1. This procedure is to be used to verify each shipment of plasma sent to Talecris complies with all applicable regulatory requirements, Talecris General Specification — Source Plasma, and any plasma material-number-specific Talecris plasma specifications.

6.3.2. Copies of this SOP are sent to Plasma Operations Account Managers each time this SOP is revised. From the date this SOP is approved, the effective date will be stamped one month in advance and sent to plasma suppliers to conduct training.

6.3.3. Master copies of NDP and PLS forms are sent to Plasma Operations Account Managers each time the forms are modified.

7. PROCEDURE

7.1. Vendor Approval

7.1.1. Talecris must approve each plasma collection, testing, storage and transport establishment prior to shipment of plasma. This approval is documented internally at Talecris in accordance with CS-000-BE-057 and externally in written correspondence to the plasma supplier.

7.2. Plasma Identification

7.2.1. A Talecris-approved bar code labeling system must be used to generate all labels used for plasma donor, unit, sample, and case identification. Talecris provides appropriate scan sheets for use with the Sigma Bar Code Printer System. Alternate bar-coding systems are acceptable for use if approved, in writing, by Talecris Plasma Operations Technical Services Manager.

7.2.2. Correct plasma material number assignment is critical to Talecris receipt and manufacturing operations. Usage decisions and traceability of plasma is dependent on plasma material numbers. The plasma material number identifies the plasma type, that the plasma is collected in bottles, the testing level of the plasma, and EU approval status. Refer to Talecris' General Specification - Source Plasma for required plasma material number legend.

7.2.3. A unique vendor batch number must be assigned to each plasma type within the shipment.

a. The unique vendor batch number for the shipment must be for only one center (combining plasma units from different centers in one case is unacceptable).

7.3. Plasma Unit Documentation and Error Correction of PPL

7.3.1. Record Keeping

Adhere to the following instructions when making entries or correcting errors on packing lists and other records that are sent to Talecris:

a. Make all entries on all documents in permanent, indelible black or blue ink.

b. It is unacceptable to use felt-tipped or gel pens on documents sent to Talecris.

c. All entries on all documents and photocopies must be legible.

d. If a space is inappropriate for a given step, enter N/A (Not Applicable). If a space becomes inappropriate due to special circumstances, enter N/A and a brief explanation. A diagonal line may be used across unused spaces. All entries must be initialed and dated.

e. When a copy is sent as documentation, it must bear the statement, “This is a true and accurate copy of the original.” The statement must be initialed and dated by center management.

NOTE: If the entire packing list is a copy, one stamp on the PLS is adequate. If subsequent changes are made on plasma units or cases, the affected pages must be stamped, initialed, and dated.

f. Use of liquid paper, white out, or any similar material that obliterates errors is unacceptable.

g. Application of one plasma unit control number label over another is unacceptable.

7.3.2. Removal of a Plasma Unit

a. When a plasma unit is removed from a case, two initials and the date of action are required on the PPL to verify that the unit has been removed. Talecris QO Plasma may approve, in writing, an alternate documentation method for unit removal.

7.3.3. Error Correction

a. Draw a single line through the error so that the words (or figures, etc.) can still be read. Initial and date line out. Rewrite correct information.

b. If a plasma unit is lined out in error, it is not acceptable to Talecris. For Talecris to accept such a plasma unit, all correct unit information must be re-entered on the PPL with a detailed explanation of why the line out occurred. Comment must also be initialed and dated.

7.4. Unacceptable Plasma Units

7.4.1. Plasma units that test positive, reactive, or elevated for any of the required tests must not be shipped to Talecris. Actions to be taken and lookback requirements must be followed as outlined in Talecris General Specification — Source Plasma, Appendix A, Table of Actions.

7.4.2. If in error, a viral marker reactive or NAT reactive unit is shipped to Talecris or unit from a donor diagnosed with CJD/vCJD is shipped to Talecris, immediately forward the NDP by fax to 919-359-4428. Additionally, phone the Talecris QO Plasma Supervisor at 919-359-4581 to initiate unit trace.

7.4.3. Plasma units with unacceptably high hemoglobin concentrations must not be shipped to Talecris. Evaluate hemoglobin concentration at time of collection using the Talecris Hemoglobin Comparator by following the instructions for use printed on the card. Note that the color comparison must be performed against the well-mixed, liquid contents of the plasma collection bottle prior to freezing.

7.5. Notification for Destruction of Plasma (NDP)

7.5.1. As detailed in the Talecris General Specification- Source Plasma, Appendix A — Table of Actions, following receipt of a repeat reactive test result or valid post-donation information, complete the plasma center entries on the NDP form for notification to Talecris of needed unit destruction. It is critical for unit traceability at Talecris that all Plasma Item or SAP material numbers reported on the NDP form reflect the actual Plasma Item or SAP material numbers under which the plasma was shipped. Due to added NAT level testing, Plasma Item and SAP material numbers have changed over time.

7.5.2. Concerning instances of owner transfer of plasma centers, the NDDR and Talecris center code reported on the NDP sent to Talecris must reflect the NDDR/center code at the time of unit collection (not at time of reporting).

7.5.3. The NDP must be faxed to Clayton Plasma Receiving within 3 working days upon receipt of a reactive or positive test result for a donor from whom prior or subsequent units have been shipped to Talecris (lookbacks). Reference the Talecris fax number on the NDP form.

7.5.4. The NDP must be faxed to Clayton Plasma Receiving within 1 working day of notification of Post Donation Information resulting in product recalls or seizure concerning units shipped to Talecris. Reference the Talecris fax number on the NDP form.

7.5.5. The NDP must be faxed to Clayton Plasma Receiving within a timely manner for Post Donation Information (PDI) not resulting in a seizure or recall (example: tattoo, body piercing, high risk). Reference the Talecris fax number on the NDP form.

7.5.6. For any reason other than viral marker lookback, record reason as “Other” status in Section 3 of the NDP form and provide a detailed explanation. An example of “Other” unacceptable plasma is plasma from donors with valid post-donation information that would make them unacceptable donors; Public Health Notifications; plasma involved in plasma shipping errors, etc. Complete information is needed by Talecris to evaluate the status of plasma pools that contain units with any post-donation information except lookback plasma units. If necessary, use an additional sheet of paper identified by Center Code/NDDR and Donor Number.

7.5.7. Enter date the reactive test result, or other information, was received by the plasma center in Section 4 of the NDP form.

7.5.8. Complete only one NDP per donor, even if the donor is reactive for more than one test. Use the longest lookback period as defined in the Table of Actions.

7.5.9. Within one working day of receipt of a NDP, Clayton will fax a partially completed copy of the NDP, confirming receipt of NDP, to the fax number (plasma center or corporate office) entered in Step 6 of the form. If the fax is not received, contact Plasma Receiving, Talecris, Clayton (919-359-4444).

Clayton will only fax a completed dispositioned copy of the NDP for notifications marked “Recall.” It may take several months for plasma suppliers to receive the completed, dispositioned copy of the NDP from Talecris due to the plasma inventory hold periods.

7.5.10. In the event that a change has to be made to an original NDP that has already been sent to Clayton Lookback, the plasma supplier must stamp or write **Revision** and clearly indicate by circling the change(s) and/or addition(s) made that differ from the data reported on the original NDP before re-sending to Clayton Lookback. A date and initials must accompany these changes, additions, and/or comments. Any alternative method for error correction to original NDP’s must be pre-approved by Talecris (example: brackets).

7.6. Plasma Packaging

7.6.1. Talecris requires all U.S. source plasma to be collected and shipped in approved bottles for receipt.

a. Remove all rubber bands or tape prior to placing unfrozen plasma units in freezer.

b. Store filled cases in a freezer operating at - -20°C or colder until time of shipment.

c. The plasma case must be pre-approved, in writing, by Talecris Manager of Technical Services or designated Talecris Plasma Operations Account Managers with input from Talecris QO and Supply Chain groups.

d. The plasma case must have any softgoods labeling information either crossed out or only the plasma case label visible.

e. Line the case with a polyethylene liner of at least 1.3 mil thickness that has been inspected for tears prior to placing into the case. The liner selected must permit closure of the filled case without bulging or tearing. Do not use twist ties to close the liner.

f. The maximum acceptable volume of Normal plasma to be shipped to Talecris in a vendor batch number is 3,700 Liters.

g. Targeted volume of plasma to be shipped to Talecris in a vendor batch number is 1,840 Liters.

h. Targeted minimum volume of plasma to be shipped to Talecris in a vendor batch number is 90 liters. Talecris Plasma Operations Account Manager must be notified for any vendor batch number less than 90 liters prior to shipment.

i. Plasma units with less than 200 mL are unacceptable to Talecris.

j. Plasma units from individual donors must not be shipped to Talecris out of collection sequence.

7.6.2. Two plasma supplier employees must participate in packing plasma units into the case, one employee performing the task and the other verifying the correct units are being packed and the correct labels have been applied. Each participating employee's initials are required on the Plasma Packing List.

a. Alternatively, automated electronic verification may be used; in which case one person's initials must appear on the Plasma Packing List verifying correct packing and labeling.

b. Only if a Plasma Center has one employee can packing and manual verification be performed and initialed by one person.

7.6.3. When using the Sigma Bar Code Printer System apply a vendor batch number sticker and a SAP case number sticker on the plasma shipper label, in spaces adjacent to each hand-written entry.

7.6.4. Prior to use each day, verify the Sigma label printer/scanner against the Daily Start up Label Set. Create all three donation labels from the Daily Start up Label Set scan menu, and compare to the sample labels provided on the menu. Document results on a Daily Start up Scanner/Printer Test Record or equivalent. Deface and discard test labels.

a. Alignment of the label stock should be monitored throughout the day to ensure that the white spaces (quiet zones) on each side of the barcode are no less than 1/8."

7.7. Storage Temperature Certification

7.7.1. Using the Packing List Summary (PLS) form, the plasma supplier will record the temperature status of the plasma shipment while it has been in storage.

7.7.2. There are three options for plasma temperature storage disposition:

a. The first option for temperature storage certification is applicable if all storage temperature recordings for associated plasma have been -20°C or colder.

b. The second option for temperature storage certification is applicable if only one temperature storage excursion has occurred for associated plasma and it still meets the maximum temperature requirements for Source Plasma in 21 CFR 640.76. Option 2 requires copies of all applicable temperature records (freezer graph(s), freezer logs and any associated investigation and/or CAPA documents) to be attached to Page 2 of the PLS forms.

c. The third option for temperature storage certification is applicable if all storage temperature recordings for associated plasma meet the requirements for Source Plasma, Salvaged as defined in 21 CFR 640.76. Option 3 also requires copies of all applicable temperature records to be attached to Page 2 of the PLS forms. Additionally, since pre-approval from Talecris is required for shipment, the Request/Approval Form for Source Plasma, Salvaged must be initiated and forwarded to the Talecris Account Manager. Full instructions for shipment of Source Plasma, Salvaged is listed in Section 7.8.

7.8. Source Plasma, Salvaged

7.8.1. Because Talecris is limited in the timeframe in which plasma must be processed (greater than 60 days but less than 3 years from date of collection) and because of the limited markets that will accept product manufactured from source plasma, salvaged, receipt of this material is not desirable.

7.8.2. Source Plasma, Salvaged is defined in 21 CFR 640.76.

7.8.3. Prior to shipment of any Source Plasma, Salvaged, written approval must be received from Talecris Plasma Operations Account Manager with Clayton QO Plasma concurrence.

a. Complete Talecris Shipment Request/Approval Form for Salvaged Plasma.

b. Submit completed form with required documentation to Talecris Account Manager for approval.

7.8.4. Each case of plasma, the Packing List Summary Sheet and Bill of Lading must be clearly marked: “Source Plasma — Salvaged.”

7.8.5. Source plasma, salvaged, is not used for products going to EU and, therefore, cannot be labeled with German/EU plasma material numbers.

7.8.6. Talecris will not accept any salvaged hyperimmune plasma. If hyperimmune plasma, other than Anti-D plasma, is re-classified as Source Plasma Salvaged, it must be relabeled as Normal X plasma. ***Anti-D plasma may not be re-labeled as Normal X plasma nor shipped as salvaged.***

7.8.7. A copy of the freezer temperature chart(s) and a report containing the following information must accompany any shipment of source plasma, salvaged:

a. The vendor batch number

b. Prior written Talecris approval to ship source plasma, salvaged

c. The maximum temperature reached by the freezer

d. The time span during which the temperature was warmer than -20°C

e. The number of times the plasma was exposed to temperatures warmer than -20°C during the entire freezing and storage period of the product.

f. The cause of the incident and corrective action taken

7.9. Shipment Documentation Requirements

7.9.1. A documentation packet must accompany each shipment of plasma, and must include the plasma packing list(s), the Packing List Summary Sheet(s), and the Bill of Lading(s). This packet must be given to the driver of the Talecris designated-carrier when plasma is shipped.

a. The plasma center address provided on the plasma packing list(s), the Packing List Summary Sheet(s), and the Bill of Lading(s) must match the address listed on the Form FDA 2830, Blood Establishment Registration and Product Listing. The Form FDA 2830 is updated annually and validated by FDA. Any and all changes in plasma center address regardless of reason must be noted in the annual update of the Form FDA 2830. The most current Form 2830 must be provided immediately to the Talecris Plasma Operations Account Manager following validation by FDA and receipt by plasma supplier. This applies to the initial registration and each annual registration for every plasma center.

1.) A letter from the corporate office of the plasma supplier on company letterhead must be provided to the appropriate Plasma Operations Account Manager immediately for each address change. The letter must include the following information:

1.a) The reason for the address changes (e.g., Zip code change, street extension, correction, etc.)

1.b) Verification that the plasma center has not relocated.

1.c) Commitment to include the change in the Form FDA 2830 annual registration to FDA and provide the validated form to the Talecris Plasma Operations Account Manager immediately after receipt.

b. Any address changes which have not been previously communicated to Talecris that are discovered by upon receipt of plasma at the Clayton facility will be addressed with the plasma supplier corporate office by the Plasma Operations Account Manager.

c. The volume entries must be carried out to three decimal places for all manual entries. It is permissible to carry out to two decimal places when a document is system generated and the ending zero is dropped.

d. The plasma packing lists must be the original documents or, if copies, stamped with “This is a true and accurate copy of the original” or similar verbiage. Any copies must be signed and dated by the responsible individual at the collection facility. If the entire packing list is a copy, one stamp, initialed and dated is adequate with total number of pages of PPL indicated at stamp site.

NOTE: If the entire packing list is a copy, one stamp, initialed and dated is adequate.

7.9.2. The plasma packing list and Packing List Summary Sheet information may be alternatively sent to Talecris via electronic data interchange (EDI) with prior written approval by Talecris. The same information is required.

7.9.3. The plasma packing list must contain the following information:

a. Name, address, and Talecris assigned center code of the collection facility or, minimally, the corporate office address of the plasma supplier

b. Name and address of each testing facility used for all required tests

c. Individual test results per plasma unit. Only with prior written approval by Talecris QO Plasma may the supplier certify that all Source Plasma units are negative by approved tests for all required tests as detailed in the Talecris General Specification.

d. A statement that all donors have tested negative for syphilis as required by the Code of Federal Regulations. This statement may be documented on the Packing List Summary form.

e. Plasma material number

f. Case numbers

g. Unique bleed number/control number for each unit

h. Unique donor number for each unit or unique traceability system of units to donors

i. Plasma volume (mL) for each unit

j. Total number of units in each case

k. Total volume of plasma in each case

l. Vendor batch number

m. Initials and dates as required

7.9.4. The Packing List Summary must contain the following identifying information:

a. Plasma center name and address

b. Talecris-assigned center code

c. NDDR number

d. Vendor batch number

e. Talecris P.O. number

f. Talecris plasma material number

g. Number of shippers

h. List of case numbers

i. Liters

j. Earliest bleed date

k. Latest bleed date

l. Certifications as appropriate

7.9.5. The Bill of Lading must contain the following information:

a. Carrier's Name

b. Center name and address

c. Addressed to:

Talecris Biotherapeutics
c/o Nordic Warehouse
2400 Hodges Chapel Road
Benson, NC 27504

d. Number of cases of plasma per vendor batch

e. Plasma type

f. Plasma material number

g. Vendor batch number

NOTE: Each vendor batch must be on a separate line with required heading information.

h. Total cases shipped

i. The statement “Maintain -20°C or colder in transit”

j. The statement “Load at -25°C or colder”

k. Truck loading temperature

l. Shipper’s signature

m. Date and time (military or AM/PM designation). Indicate time zone.

n. Driver’s signature and date

o. Trailer Number

7.9.6. Plasma cases to be shipped should not be removed from the freezer until the transport truck is at the center and the trailer temperature has been checked and found to be at -25°C or colder.

7.9.7. The Sipper Label must, minimally, contain the following information:

a. “Ship from” and “ship to” addresses

b. The complete vendor batch number

c. The case number

d. The product description

Reference Appendix G, Example Of Talecris Shipper Label, for preferred format and other preferred label information.

8. DATA/INFORMATION MANAGEMENT, NOTIFICATION REQUIREMENTS

8.1. Detail all plasma shipment information on the accompanying plasma packing lists, Packing List Summary (PLS) form, and Bill of Lading (BOL).

8.2. Plasma suppliers must notify Talecris by the Notification for Destruction of Plasma (NDP) form of any lookback, recall, or other situations in which plasma would be deemed unacceptable to process.

8.3. During the normal course of business operations, Talecris RTL preferred method of test result data reporting will be an electronic method (Electronic Data Interface). An alternate method of test result data reporting will be by printed, hard copy data result sent by the most expedient method.

8.4. Revision numbers or revised date listed in Section 9 to track individual revisions to forms.

9. ATTACHMENTS

9.1. Appendix A, Example Of Notification For Destruction Of Plasma Form, 2 pages, Rev. 12

9.2. Appendix B, Example Of Packing List Summary Form, 2 pages, Rev. 11

9.3. Appendix C, Example Of Bill Of Lading, 1 page, Rev. 12

9.4. Appendix D, Example Of Daily Startup Scanner/Printer Test Record, 1 page, Rev. 10

9.5. Appendix E, Example Of Talecris Hemoglobin Comparator, 1 page, Revised 4/1/05, Rev. 11

9.6. Appendix F, Example Of Talecris Shipment Request/Approval Form For Source Plasma, Salvaged, 2 pages, Rev. 11

9.7. Appendix G, Example Of Talecris Shipper Label, 1 page, Rev. 00

Example Of Notification For Destruction Of Plasma Form

NOTIFICATION FOR DESTRUCTION OF PLASMA

CS-000-BE-053, NDP Form; Revision 12, March 2006
(Supercedes CS-000-AR-107, NDP Form; Revision 00)
Page 1 of ___

This side to be completed by plasma supplier:

1. Plasma Supplier Reference # (optional):

2. Center Code: | NDDR #: | Donor #

3. Center name and address:

4. (Circle as appropriate)
Lookback for: HBsAg anti-HCV anti-HIV 1/2 HIV-1 Ag HCV by NAT HIV-1 by NAT HBV by NAT **"Other" (explain below)**

Date test result or other information received:

Collection Date	Control Number	Plasma Item or Material Number	Ship Doc # or Vendor Batch #	Case Number	Disp. Code
		Reactive Unit for Viral or by NAT	N/A	N/A	N/A

Explanation for "Other": Collection date of last negative Unit:

5. Information verified:
Date: _____ Initials (2) _____ / _____

Phone Clayton of intent to fax (919) 359-4444 Initials: _____

6. Plasma Supplier fax:

7. Fax this form to Clayton: (919) 359-4428

Date faxed: _____ Initials: _____

This side to be completed by Talecris Biotherapeutics, Clayton:

1. Record receipt of fax from plasma supplier and assign log number. Confirm receipt of NDP form by completing this section and faxing back to the plasma supplier:

Receipt Date: _____ Time: _____ Log # _____ Initials: _____
(Next line for Talecris to be filled in only after confirmation of successful fax transmittal)
Confirmation fax (within 1 working day):

Date: _____ Time: _____ Initials: _____

Entries 2 — 5 For Talecris Use Only

2. Lookback Coordinator:
Complete "Disposition Code" column for all units.

Date: _____ Time: _____ Initials (2) _____/_____

3. Disposition Codes
#1 Pooled prior to notification
#2 Unit received; to be destroyed
#3 Unit in transit/off-site storage; to be destroyed
#4 Unit shipped to contract fractionator
#6 Unit shipped back to plasma supplier
#7 Unit used for research purposes
#8 Unit removed for reason other than NDP

4. Contract Fractionation Section:
Contract fractionator notified by fax (Code #4): Date/Initials: _____
Fractionator's acknowledgement of fax received: Date/Initials: _____
Fractionator's disposition report received: Date/Initials: _____

5. Completion and Final Review of NDP:
Reference attached "Work Complete" print screen from the NDP Database for the following:
- Pool Number
- Unit Removed/Destruction Date

Lookback Coordinator: Attach a "Work Complete" Print Screen to this NDP form. Verify each unit is reconciled and matches disposition on Work Complete Printout.

Date: _____ Time: _____ Initials _____
Lookback Coordinator "Work Complete" approval: Date/Initials: _____
QO Plasma 'Close' review and approval: Date/Initials: _____

Example Of Notification For Destruction Of Plasma Form

NOTIFICATION FOR DESTRUCTION OF PLASMA

CS-000-BE-053, NDP Form; Revision 12, March 2006
(Supercedes CS-000-AR-107, NDP Form; Revision 00)
Page ___ of ___

This side to be completed by plasma supplier:

Plasma Supplier Reference # (optional):

Center Code: | NDDR #: | Donor #:

This side to be completed by Talecris Biotherapeutics, Clayton:

Log #: _____

Collection Date	Control Number	Plasma Item or Material Number	Ship Doc # or Vendor Batch #	Case Number	Disp. Code

Disposition Codes

#1 Pooled prior to notification
#2 Unit received; to be destroyed
#3 Unit in transit/off-site storage; to be destroyed
#4 Unit shipped to contract fractionator
#6 Unit shipped back to plasma supplier
7 Unit used for research purposes
#8 Unit removed for reason other than NDP

Example Of Packing List Summary Form

CS-000-BE-053, PLS Form: Revision 11, March, 2006
(Supercedes: CS-000-AR-107, PLS Form: Revision 00)

Packing List Summary — Page 1

Center Name & Address:

Center Code: _____

NDDR #: _____

Vendor Batch # _____

Talecris P.O. #: _____

Plasma Material Number	# of Units	# of Shippers	Case Numbers	Liters

This shipment: Earliest Bleed Date: _____

Latest Bleed Date: _____

This is to certify that:

- All plasma units in this shipment are negative/non-reactive for the following tests:

  HBsAg, Anti-HCV, Anti-HIV-1/2, HCV / HIV-1 / HBV by NAT, and ALT values less than or equal to 2X the upper limit of normal.
- Applicant Donor units in this shipment have been qualified by the receipt of acceptable test results obtained on a second unit within six months of the first unit.
- Applicant Donor units in this shipment, with the exception of Anti-D specialty plasma donors, are negative for Anti-D.
- Entire Anti-D shipment has an Anti-C titer of less than or equal to 1:8.
  - Donors participating in an Anti-D stimulation program have not contributed to this shipment unless it is an Anti-D plasma shipment.
- All donors have tested negative for syphilis as required by the Code of Federal Regulations.
- Hyperimmune Anti-D, Rabies, Tetanus, and Hepatitis plasma have been pre-qualified by the Raleigh Test Lab.
- All plasma units in this shipment have been collected and stored in compliance with all regulatory requirements and Talecris specifications.

Check one:

o The plasma in this shipment was stored at -20°C or colder, and is designated Source Plasma.

o The plasma in this shipment was stored at -20°C or colder, with an allowable temperature excursion (See PLS page 2 attached along with required temperature records), and is designated Source Plasma.

o The plasma in this shipment is designated Source Plasma, Salvaged (temperature records required).

Total number of storage temperature excursions warmer than -20ºC from earliest bleed date to shipping date:

_____

(if answer is other than zero complete PLS page 2 and attached to this form.)

PLASMA APPROVED FOR RELEASE:

_____ / _____ _____ / _____

Quality Date Management Date

Example Of Packing List Summary Form

CS-000-BE-053, PLS Form: Page 2 Revision 11, March, 2005

Packing List Summary — Page 2

Center Code: _____

NDDR #: _____

Vendor Batch #: _____

Material Number: _____

Attach copies of temperature records (freezer graph(s), freezer logs and any associated investigation and/or CAPA documents) related to the excursion(s) described below:

Date of Excursion(s)	Maximum Temperature Reached	Duration of Temperature Excursion(s)	Reason for Excursion(s)

Note: If temperature excursions warrant plasma to be classified as “salvaged”, reference Talecris Plasma Supplier Supplemental Directions 7.8, requiring pre-approval from Talecris before shipment.

Signatures and Date

_____ / _____ _____ / _____

Management Date Quality Date

Example Of Bill Of Lading

UNIFORM BILL OF LADING

CARRIER NAME _____

TO: TALECRIS
c/o Nordic Warehouse
2400 Hodges Chapel Road
Benson, NC 27504

FROM: Plasma Center
1234 Main Street
Any Where, USA 11111

Vendor Batch #	# Of Cases	Plasma Type (NX, TX, CX, etc)	SAP Material #

_____ Total Cases Shipped

MAINTAIN -20ºC OR COLDER IN TRANSIT

LOAD AT -25ºC OR COLDER

SHIPPER SECTION:

Truck Temperature	Shipper's Signature	Date	Time (military) E C M P (Circle Time Zone)

TRUCK DRIVER SECTION:

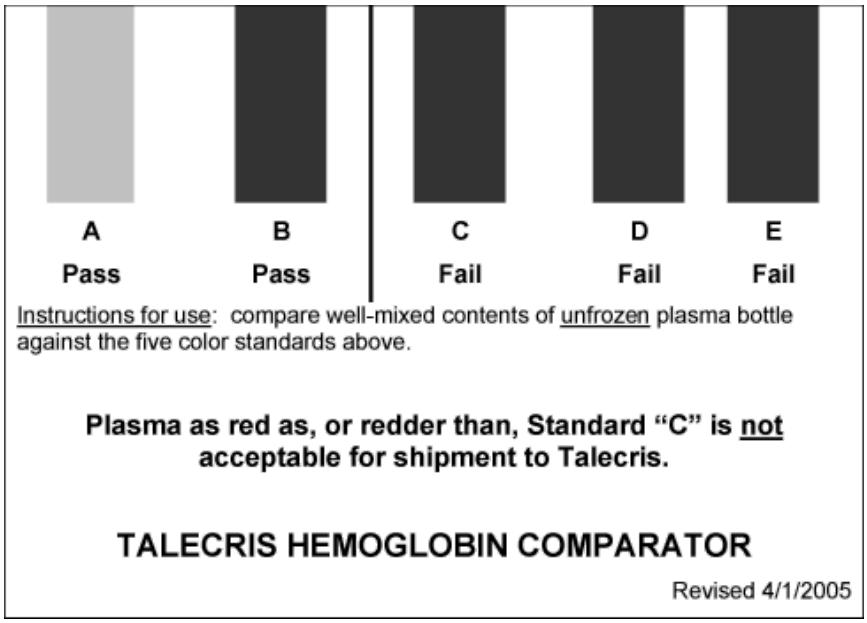
Driver's Signature	Date

Trailer #

Example Of Daily Startup Scanner/Printer Test Record

Date	Printed Labels Same As Sample? Yes No	COMMENTS (Explain any NO responses and corrective action taken)	Initials

Example Of Talecris Hemoglobin Comparator



NOTE: Example shown in black and white, color version distributed to plasma suppliers.

Example Of Talecris Shipment Request/Approval Form For Source Plasma, Salvaged

Revision 11

Talecris Shipment Request/Approval Form For Source Plasma, *Salvaged*

Center Management must complete this form and submit to Talecris Account Manager minimally one week prior to the proposed shipping date with applicable documentation for salvaged plasma intended for approval and subsequent shipment to Talecris

Plasma Center Name _____ **Talecris Center Code** _____

Plasma Material Number _____
Bill of Lading Number(s) _____
Vendor Batch Number(s) _____

Section 1 — To be completed and submitted for approval to Talecris Account Manager

Plasma Center Information/Action	**Info/Action**	**Initials/Date**
Number of units of Source Plasma, Salvaged		
Number of cases of Source Plasma, Salvaged		
Earliest collection date of Source Plasma, Salvaged		
Latest collection date of Source Plasma, Salvaged		
Total time which the temperature was warmer than -20°C (recorded in hours)		
Warmest temperature reached by freezer		
Number of times plasma was exposed to temperatures warmer than -20°C during the entire freezing and storage period of the product.		
Incident Report detailing the cause of the incident and CAPA taken (circle yes or no)	**Y / N**	
All cases marked — “Source Plasma — Salvaged” (circle yes or no)	**Y / N**	
BOL marked — “Source Plasma — Salvaged” (circle yes or no)	**Y / N**	
Packing List Summary marked — “Source Plasma — Salvaged” (circle yes or no)	**Y / N**	
Plasma re-classified/relabeled as Normal plasma if originally hyperimmune plasma (Anti-D plasma cannot be relabeled as Normal plasma nor shipped as salvaged plasma) (circle yes, no or N/A)	**Y / N / N/A**	
Freezer temperature charts included with submission of Talecris Shipment Request/Approval Form of Source Plasma, Salvaged accounting for the **date plasma was placed in freezer until date of this request (include period temperature of freezer was warmer than -20°C)** (circle yes or no)	**Y / N**	

Example Of Talecris Shipment Request/Approval Form For Source Plasma, Salvaged

Section 2 — To be completed by Talecris Account Manager:

Talecris Account Manager reviewed supplier's Incident Report and found complete and acceptable **Y / N**

Section 3 — To be completed at time of shipment: [ ] N/A if Section 2 is answered "NO".

Number of times plasma was exposed to temperature warmer than - -20°C during the **entire freezing and storage period**

Freezer temperature charts included in shipping document packet accounting for the **entire storage period** (circle yes or no) **Y / N**

Plasma Center Manager _____ **Signature/Date**

Disposition of Request: (Circle One)

_____ / _____ Approve Reject
Talecris Account Manager / Date

_____ / _____ Approve Reject
Talecris Clayton Quality Operations Manager / Date

Example Of Talecris Shipper Label

SHIP — TO:
TALECRIS BIOTHERAPEUTICS
C/O NORDIC WAREHOUSE 2400 HODGES CHAPEL RD
BENSON, NC 27504

RETURN — TO:
OHIO BLOOD PLASMA, INC.
1116 MAIN STREET
CINCINNATI, OH 45202
U.S. LICENSE NO. 484

MATERIAL #: [BARCODE]
08634958

NORMAL, EU APPROVED (BOTTLES)

VENDOR BATCH

[BARCODE]
069424006003

CASE #: [BARCODE]
240054198

o NEW ☑ REVISED o TEMPORARY o ALL LOTS o LOT SPECIFIC o AS REQUESTED

Document Type: ☑ SOP o BPR o Other (Specify)

Document # CS-000-BE-053 Rev # 12 Prev. Doc. # N/A

Document Title: Plasma Supplier Supplemental Directions

Authored By: Amy Durham o Author Check/Sign/Date for Training Credit

Owner's Dept. Name: QO Plasma / Zone 1 Date Requested: 02/20/2006

Document Owner: Amy Durham

EFFECTIVE DATE MAR 31 2006 FINAL DATE USED

Type of Change: o D o C o B ☑ A Change Control #: 2006052 o N/A

Document processed by:

Signature: /s/ Christy Pychinka Print Name: Christy Pychinka Date: 2/21/06

Document reviewed in accordance with current requirements: o Check for Training Credit

Signature: /s/ Susan Dixon Print Name: Susan Dixon Date: 2/21/06

WRITE A PARAGRAPH IN THE SPACE BELOW, SUMMARIZING THE PRIMARY REASON(S) FOR THIS REVISION

CCR 2006052

1. Sections 3.4. and 7.6.1.c. — Indicate that the functions usually performed by the Talecris Plasma Operations Technical Services Manager may be performed by the Talecris Plasma Operations Account Mangers in the absence of the Technical Services Manager. Clarification by Plasma Operations of technical services functions performed in the absence of this position.
2. Add new Section 7.5.2. and re-number remaining sections — Add section defining lookback and post donation information (PDI) notification requirements for listed plasma bleeds collected under prior NDDR and center code references. Clarify what NDDR and center code is required on the notification form for bleeds collected under prior ownership or previous NDDR number.
3. Add new Section 7.6.1.d. and re-number remaining sections — Added for clarity of shipper information.
4. Section 7.7.2.b. and Appendix B — List specific documentation that is required for review if there is more than 1 temperature excursion. Clarification and consistency of needed documentation to review in cases of more than one storage temperature excursion (>20C).
5. Section 7.9.5.C. and Appendix C — Correct Benson address. It should be 2400 Hodges Chapel Road.
6. Section 7.9.5.1. Add or *AM/PM* designation for clarification.
7. New Section 7.9.7. — List minimum information that is required on the plasma shipper label. Added for clarification and consistency for shipper label information.
8. Appendix A — Change Bayer reference to Talecris and update revision number.
9. New Appendix G — Example of shipper label. As with NDP and the packing list summary form, include an example template for suppliers to reference for consistency.

As Document Owner, I state that the proposed changes and the entire document are consistent with all systems, documents, and current requirements. ☑ Check for Training Credit

Signature: /s/ Amy W. Durham Print Name: Amy W. Durham Date: 2/28/06

As Quality Approver, I have found the proposed changes and the entire document to be compliant with cGMPs and appropriate for the intended purpose of producing safe, pure and effective products. o Check for Training Credit

Signature: /s/ John W. Parrish Print Name: John W. Parrish Date: 2/28/2006

NOTIFICATION FOR DESTRUCTION OF PLASMA

This side to be completed by plasma supplier:

1. Plasma Supplier
Reference # (optional):

2. Center Code: | NDDR #: | Donor #

3. Center name and address:

(Circle as appropriate)
4. Lookback for: HBsAg anti-HCV anti-HIV1/2 HIV-1Ag HCV by NAT HIV-1 by NAT HBV by NAT
"Other" (explain below)

Date test result or other information received: _____

Collection Date	Control Number	Plasma Item or Material Number	Ship Doc # or Vendor Batch #	Case Number
		Reactive Unit for Viral or by NAT	N/A	N/A

Explanation for "Other": Collection date of last negative Unit:

5. Information verified:

Date: _____ Initials (2) _____ / _____
Phone Clayton of intent to fax (919) 359-4444 Initials:_____

6. Plasma Supplier fax:

7. Fax this form to Clayton: (919) 359-4428

Date faxed: _____ Initials: _____

This side to be completed by Talecris Biotherapeutics, Clayton:

1. Record receipt of fax from plasma supplier and assign log number. Confirm receipt of NDP form by completing this section and faxing back to the plasma supplier:

Receipt Date: _____ Time: _____ Log # _____ Initials: ____

(Next line for Talecris to be filled in only after confirmation of successful fax transmittal)

Confirmation fax (within 1 working day):

Date: _____ Time: _____ Initials: _____

Entries 2 — 5 For Talecris Use Only

2. Lookback Coordinator:
Complete "Disposition Code" column for all units.

Date: _____ Time: _____ Initials (2) _____/_____

Disp. Code
N/A

3. Disposition Codes
#1 Pooled prior to notification
#2 Unit received; to be destroyed
#3 Unit in transit/off-site storage; to be destroyed
#4 Unit shipped to contract fractionator
#6 Unit shipped back to plasma supplier
#7 Unit used for research purposes
#8 Unit removed for reason other than NDP

4. Contract Fractionation Section:
Contract fractionator notified by fax (Code #4): Date/Initials: _____
Fractionator's acknowledgement of fax received: Date/Initials: _____
Fractionator's disposition report received: Date/Initials: _____

5. Completion and Final Review of NDP:
Reference attached 'Work Complete' print screen from the NDP Database for the following:
- Pool Number
- Unit Removed/Destruction Date
Lookback Coordinator: Attach a 'Work Complete' Print Screen to this NDP form. Verify each unit is reconciled and matches disposition on Work Complete Printout.
Date: _____ Time: _____ Initials _____
Lookback Coordinator 'Work Complete' approval: Date/Initials: _____
QO Plasma 'Close' review and approval: Date/Initials: _____

NOTIFICATION FOR DESTRUCTION OF PLASMA

CS-000-BE-053, NDP Form: Revision 12, March 2006
(Supercedes CS-000-AR-107, NDP Form: Revision 00)
Page ___ of ___

This side to be completed by plasma supplier

Plasma Supplier Reference # (optional):

Center Code: | NDDR #: | Donor #:

This side to be completed by Talecris Biotherapeutics, Clayton:

Log #: _____

Collection Date	Control Number	Plasma Item or Material Number	Ship Doc # or Vendor Batch #	Case Number	Disp. Code

Disposition Codes

#1 Pooled prior to notification
#2 Unit received; to be destroyed
#3 Unit in transit/off-site storage; to be destroyed
#4 Unit shipped to contract fractionator
#6 Unit shipped back to plasma supplier
7 Unit used for research purposes
#8 Unit removed for reason other than NDP

Packing List Summary — Page 1

Center Name & Address:	Center Code: _____ NDDR #: _____ Vendor Batch: _____ Talecris P.O. #: _____

Plasma Material Number	# of Units	# of Shippers	Case Numbers	Liters

This Shipment: Earliest Bleed Date: _____
Latest Bleed Date: _____

This is to certify that:

- All plasma units in this shipment are negative/non-reactive for the following tests: HBsAg, Anti-HCV, Anti-HIV-1/2, HCV / HIV-1 / HBV by NAT, and ALT values less than or equal to 2X the upper limit of normal.
- Applicant Donor units in this shipment have been qualified by the receipt of acceptable test results obtained on a second unit within six months of the first unit.
- Applicant Donor units in this shipment, with the exception of Anti-D specialty plasma donors, are negative for Anti-D.
- Entire Anti-D shipment has an Anti-C titer of less than or equal to 1:8.
  - Donors participating in an Anti-D stimulation program have not contributed to this shipment unless it is an Anti-D plasma shipment.
- All donors have tested negative for syphilis as required by the Code of Federal Regulations.
- Hyperimmune Anti-D, Rabies, Tetanus, and Hepatitis plasma have been pre-qualified by the Raleigh Test Lab.
- All plasma units in this shipment have been collected and stored in compliance with all regulatory requirements and Talecris specifications.

Check one:

o The plasma in this shipment was stored at -20°C or colder, and is designated Source Plasma.

o The plasma in this shipment was stored at -20°C or colder, with an allowable temperature excursion (See PLS page 2 attached along with required temperature records), and is designated Source Plasma.

o The plasma in this shipment is designated Source Plasma, Salvaged (temperature records required).

Total number of storage temperature excursions warmer than -20ºC from earliest bleed date to shipping date:

_____

(If answer is other than zero complete PLS page 2 and attached to this form.)

PLASMA APPROVED FOR RELEASE:

_____ / _____ _____ / _____
Quality Date Management Date

Packing List Summary — Page 2

Center Code: _____

NDDR#: _____

Vendor Batch #: _____

Material Number: _____

Attach copies of temperature records (freezer graph(s), freezer logs and any associated investigation and/or CAPA documents) related to the excursion(s) described below:

Date of Excursion(s)	Maximum Temperature Reached	Duration of Temperature Excursion(s)	Reason for Excursion(s)

Note: If temperature excursions warrant plasma to be classified as “salvaged”, reference Talecris Plasma Supplier Supplemental Directions 7.8, requiring pre-approval from Talecris before shipment.

Signatures and Date

_____ / _____ _____ / _____

Management Date Quality Date

Revision 11

Talecris Shipment Request/Approval Form For Source Plasma, Salvaged

Center Management must complete this form and submit to Talecris Account Manager minimally one week prior to the proposed shipping date with applicable documentation for salvaged plasma intended for approval and subsequent shipment to Talecris

Plasma Center Name _____ **Talecris Center Code** _____
Plasma Material Number _____
Bill of Lading Number(s) _____
Vendor Batch Number(s) _____
_____

Section 1 — To be completed and submitted for approval to Talecris Account Manager

Plasma Center Information/Action	**Info/Action**	**Initials/Date**
Number of units of Source Plasma, Salvaged		
Number of cases of Source Plasma, Salvaged		
Earliest collection date of Source Plasma, Salvaged		
Latest collection date of Source Plasma, Salvaged		
Total time which the temperature was warmer than -20°C (recorded in hours)		
Warmest temperature reached by freezer		
Number of times plasma was exposed to temperatures warmer than -20°C during the entire freezing and storage period of the product.		
Incident Report detailing the cause of the incident and CAPA taken (circle yes or no)	**Y / N**	
All cases marked — “Source Plasma — Salvaged” (circle yes or no)	**Y / N**	
BOL marked — “Source Plasma — Salvaged” (circle yes or no)	**Y / N**	
Packing List Summary marked – “Source Plasma – Salvaged” (circle yes or no)	**Y / N**	
Plasma re-classified/relabeled as Normal plasma if originally hyperimmune plasma (Anti-D plasma cannot be relabeled as Normal plasma nor shipped as salvaged plasma) (circle yes, no or N/A)	**Y / N / N/A**	
Freezer temperature charts included with submission of Talecris Shipment Request/Approval Form of Source Plasma, Salvaged accounting for the **date plasma was placed in freezer until date of this request (include period temperature of freezer was warmer than –20°C)** (circle yes or no)	**Y / N**	

Section 2 - To be completed by Talecris Account Manager:

Talecris Account Manager reviewed supplier’s Incident Report and found complete and acceptable	**Y / N**

Section 3 - To be completed at time of shipment: [ ] N/A if Section 2 is answered “NO”.

Number of times plasma was exposed to temperature warmer than -20°C during the **entire freezing and storage period**	
Freezer temperature charts included in shipping document packet accounting for the **entire storage period** (circle yes or no)	**Y / N**

Plasma Center Manager _____ **Signature/Date**

Disposition of Request: (Circle One)

_____ / _____ Approve Reject
Talecris Account Manager / Date

_____ / _____ Approve Reject
Talecris Clayton Quality Operations Manager / Date

/s/ Amy W. Durham	2/28/06	/s/ John W. Parrish	2/28/2006
Document Owner	Date	Quality Approver	Date

Supercedes: 19-71XX-XXX

Date Effective: **MAR 31 2006**

1. PURPOSE

1.1. To provide and describe the requirements specified by Talecris Biotherapeutics for the procurement of Source Plasma intended for manufacture of therapeutic biological products, both domestic and foreign. This specification is intended to assure that incoming plasma meets all Talecris requirements, in addition to established domestic and international regulations and standards for Source Plasma.

2. SCOPE

2.1. These requirements are applicable to all Source Plasma purchased by Talecris.

3. REFERENCE(S)

3.1. 21 CFR 210 — Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General

3.2. 21 CFR 211 — Good Manufacturing Practice for Finished Pharmaceuticals

3.3. 21 CFR 606 — Current Good Manufacturing Practice for Blood and Blood Components

3.4. 21 CFR 610 — General Biological Products Standards

3.5. 21 CFR 640 — Additional Standards for Human Blood and Blood Products, Plasma and Source Plasma

3.6. 42 CFR 493 — CLIA regulations

3.7. FDA approved Standard Operating Procedures Manuals

3.8. EU Pharmacopoeia monograph for Human Plasma for Fractionation, Revision to Annex 14 to EU Guide to GMP: Manufacture of products derived from human blood or plasma.

3.9. All current FDA guidance documents relating to collecting, testing, processing, storing or transporting Source Plasma

3.10. RS-000-AA-011 Protocol for Submission of Plasma Samples to Talecris' RTL

3.11. PPTA Viral Marker Standard, Revised October 26, 2004 and PPTA Viral Marker Data Collection Form Instructions with attached samples

3.12. PPTA Qualified Donor Standard

3.13. PPTA NAT Testing Standard and NAT Technical Standard

3.14. CS-000-AR-027 Auditing of Plasma Suppliers and Associated Test Laboratories

3.15. CS-000-BE-053 Plasma Supplier Supplemental Directions

3.16. CS-000-BE-057 Method for Evaluating the Suitability of Source Plasma Collection Facilities and Test Laboratories

3.17. EMEA/CHMP/BWP/3794/03 Guideline on the Scientific Data Requirements for A Plasma Master File (PMF)

3.18. EMEA/CHMP/BWP/125/04 Guideline on Epidemiological Data on Blood Transmissible Infections

4. RESPONSIBILITIES

4.1. Plasma supplier

4.1.1. Assures that all conditions of this specification and supply contract are met.

4.2. Talecris Plasma Operations, Account Manager

4.2.1. Serves as point of contact for all communication with the Plasma Supplier and is responsible for disseminating information to and from the Plasma Supplier and appropriate departments within Talecris.

4.2.2. Assists Plasma Supplier in developing and implementing training programs relevant to new Talecris requirements.

4.2.3. Assists Plasma Supplier in developing and implementing corrective action plans in response to deficiencies identified in relation to Talecris specifications and regulatory agency requirements and recommendations.

4.2.4. Conducts periodic review of suppliers' contractual issues, delivery schedules and any proposed changes in center operations.

4.2.5. Coordinates the evaluation process for all proposed plasma suppliers, collection and/or testing facilities.

4.2.6. Communicates to the plasma supplier any quality issues (discrepancies) with product received.

4.2.7. Coordinates communications between supplier and Talecris concerning investigations, CAPA and final resolution of product quality issues.

4.3. Talecris Plasma Operations Technical Services Manager

4.3.1. Approves use of specific plasma collection materials and supplies, all packaging and shipping materials, sample tubes, labels and bar code systems used by plasma suppliers. These functions may be performed by the Talecris Plasma Operations Account Managers in the absence of the Technical Services Manager.

4.4. QO Compliance

4.4.1. Maintains Supplier Information Database.

4.4.2. Maintains current files for all plasma suppliers, collection and testing facilities, storage and transport facilities.

4.4.3. Determines, communicates and has final approval of all changes in plasma supplier status and plasma testing facilities.

4.4.4. Receives, evaluates and distributes viral marker data in accordance with current regulation requirements.

4.5. Talecris Regulatory Affairs

4.5.1. Maintains and updates Plasma Master File.

4.5.2. Coordinates implementation of any new regulatory requirements.

4.5.3. Files any necessary BPDRs.

4.6. Talecris Quality Operations — Plasma

4.6.1. Communicates to the plasma supplier and appropriate Talecris departments (e.g. Plasma Ops, QO Compliance) any quality issues (discrepancies) with product received.

4.6.2. Approves final assessment and disposition of quality issues (discrepancies) arising at collection facilities.

4.6.3. Reviews and dispositions all incoming plasma and modeled manufacturing pools.

4.7. Talecris Plasma Receiving

4.7.1. Receives all incoming plasma shipments.

4.7.2. Receives all plasma notifications regarding the status of units shipped.

4.7.3. Communicates to Talecris QO Plasma and Plasma Operations any discrepancies noted during plasma receipt.

5. GENERAL REQUIREMENTS

5.1. QO Compliance

5.1.1. Plasma Supplier Approval – All plasma intended for use by Talecris must be collected by approved suppliers and collection facilities, and tested by approved laboratories using approved test kits, and stored and transported using approved establishments.

5.1.2. Supplier Files – All supplier information is maintained by QO Compliance. Copies of the following documents must be current and updates provided by the supplier, when applicable:

a. FDA approved ELA, PLA or BLA

b. CLIA registration certificate for the facility

c. Individual state licenses, as required

d. iQPP certification for the collection facility

e. FDA approved SOP manual

f. Epidemiology Data– provided no less than quarterly (compiled monthly) using the Talecris form (Appendix C).

g. FDA written approval to collect hyperimmune plasma, if shipped to Talecris.

h. The supplier must notify the Talecris Plasma Operations Account Manager of any changes in the following, at the corporate level, or at an individual facility:

1). Facility address or location, phone and fax numbers.

2). Hours of operation.

3). Management or medical supervisory personnel:

Lab Director
Medical Director
Physician Substitute
Center Director, Manager or Assistant Manager
Quality Assurance Specialist
Regional Manager

i. The supplier must notify Talecris Plasma Operations Account Manager prior to any changes in the following:

1). Tests performed

2). Methods/reagents/equipment or procedures used

3). Plasma types collected

4). Facility address

5). Plasma collection materials

j. For all collection, testing, storage and transport establishments, the following documentation is required to be provided to Talecris as soon as it becomes available:

1). Copy of EU competent authority certificate, inspection observations and follow-up/corrective actions.

2). U.S. FDA Form 483, inspection observations and follow-up/corrective actions.

k. For all testing establishments, the following documentation is required to be provided to Talecris upon request:

1). Copies of viral marker tests and NAT validation reports/data.

2). Results of proficiency testing programs.

5.1.3. Compliance Audits — QO Compliance group will conduct audits of all facilities on a periodic basis, not less than once every 24 months.

5.1.4. Epidemiology Data – In accordance with current regulatory requirements and with some consideration given to the PPTA Viral Marker Standard, epidemiology data (viral marker serological and NAT), compiled monthly, must be provided for each facility collecting Source Plasma. The data is required to be reported to Talecris monthly for the entire year (Jan. 1 through Dec. 31) for each collection center supplying plasma to Talecris at any point in a given year regardless of duration of supply during the year. This is necessary to meet regulatory requirements for an epidemiological profile to be established and reported for each individual center supplying plasma to the manufacturing facility.

a. Failure on the part of any collection facility to meet PPTA (iQPP) Standards will result in the removal of the collection facility from the approved supplier list.

b. Data must be submitted using the attached form, Appendix C, by the end of the month following the close of each quarter (i.e.- Q1 due by 4/30, Q2 due by 7/31, Q3 due by 10/31 and Q4 due by 1/31). An alternate format may be used if requested in writing by the collection organization stating that the definitions as listed in Appendix C would be adhered to and the request is subsequently approved in writing by Plasma Operations, Quality Operations and Regulatory Affairs.

c. Complete the form for each month and follow the instructions as indicated on the form, Appendix C. Definitions are provided below:

1). “First time tested donor” – person whose blood/plasma is tested for the first time for viral markers without evidence of prior testing. The first time tested donor population represents a subset of applicant donors (“applicant donors” that are tested for the first time in the given system).

2). “Repeat tested donor” – person whose blood/plasma has been tested previously for viral markers in the given system. This includes “applicant donors” tested for the second time, “applicant donors” re-qualifying after 6 months or more, and “qualified donors”.

3). “Qualified donor” – an individual who has provided a plasma sample at a specified plasma center, at least twice in a six month period, and all screening requirements have been met for both a) questions and tests and for b) the donor and the plasma sample, according to the iQPP Qualified Donor Standard.

4). Total number “First time tested donors” the total number of unique/individual donors presenting at a center at any time during the entire reporting calendar year (January 1 to December 31) who are tested for the first time for viral markers without evidence of prior testing. Do not count the same donor as identified by the unique donor ID more than once in a given year. These data should be provided when the December epidemiology data are reported and is to be a

comprehensive annual count. When reporting Jan. through Nov. epidemiology data, simply N/A this box for each center.

5). Total number “Repeat tested donors” — the total number of unique/individual donors presenting at a center at any time during the entire reporting calendar year (January 1 to December 31) who have been tested previously for viral markers in the given system. Do not count the same donor as identified by the unique donor ID more than once in a given year. These data should be provided when the December epidemiology data are reported and is to be a comprehensive annual count. When reporting Jan. through Nov. epidemiology data, simply N/A this box for each center.

6). Total number donations from “Repeat tested Donors” — the total number of donations collected from Repeat tested Donors during the entire reporting calendar year (January 1 to December 31). These data should be provided when the December epidemiology data are reported and is to be a comprehensive annual count. When reporting Jan. through Nov. epidemiology data, simply N/A this box for each center.

7). Donation frequency — applies only to the “Repeat tested donors”. This should be calculated as the total number of donations from “Repeat tested donors” divided by the total number of “Repeat tested donors” for the entire reporting calendar year (January 1 through December 31) for each center. These data should be provided when the December epidemiology data are reported. When reporting January through November epidemiology data, simply N/A this box for each center.

8). Confirmed seropositive: donors testing repeat reactive with a serological screening test (HBsAg, anti-HIV-1/2, anti-HCV)and who are subsequently confirmed positive by a supplementary method (Western Blot, RIBA, etc.). Do not count the same donor more than once in a given year.

9). NAT only positive: confirmed positive in a NAT assay for a specific virus (HIV-1, HCV or HBV), and not found repeat reactive for that virus in serological screening i.e., window period cases. NAT only positives may or may not be subsequently confirmed by serological testing. Do not count the same donor more than once in a given year.

5.1.5. All plasma suppliers must have a QA program in place, which is consistent with the current CBER document entitled “Guideline for Quality Assurance in Blood Establishments”.

5.1.6. Deviations from Talecris Specifications

a. Any proposed deviation to Talecris specification must be submitted in writing to the Talecris Plasma Operations Account Manager **prior** to implementation. Plasma Operations will initiate any required change control, on which QO disposition will

be documented.

5.2. Regulatory Affairs

5.2.1. The supplier must notify the Talecris Plasma Operations Account Manager, **no longer than 72 hours/3 working days from discovery**, in the event that any of the following occur, at the corporate level, or at an individual facility:

a. Any fatal donor reaction, as defined in 21 CFR 640.73.

b. Any FDA or other regulatory inspection results that may affect the approval status of any facility.

c. Any regulatory action (i.e., warning letter, injunction, suspension) that would adversely affect, or bring into question, the quality of product produced for Talecris.

5.2.2. The supplier must notify the Talecris Plasma Operations Account Manager and Clayton Plasma Receiving, and QO **within [**] of notification** for product seizure or recall.

5.2.3. The supplier must notify Talecris Plasma Receiving **within 72 hours/3 working days** of any lookback notification as detailed in the Table of Actions. Reference section 5.2.2 for product seizure or recall.

5.2.4. The supplier must notify Talecris Plasma Receiving in a timely manner (e.g. as soon as investigation and unit trace are completed) of any Post Donation Information notifications (examples, but not limited to, are tattoos, body piercings, high risk, etc.) as detailed in the Table of Actions. Reference section 5.2.2 for product seizure or recall.

5.2.5. Regulatory actions **may** result in the removal of a facility from Talecris' approved supplier list.

5.3. Plasma Operations

5.3.1. Supplier agreements – Each supplier group will sign a written statement agreeing to meet the Talecris specifications.

5.3.2. The Supplier will communicate directly all concerns, questions and changes to the Talecris Plasma Operations Account Manager assigned to the supplier group, and in turn, the Account Manager will disseminate, within Talecris, all communications to and from the Supplier.

5.4. Documents and Records, requirements as defined in 21 CFR 640.72, and in addition:

5.4.1. Copies of this specification are sent to Plasma Operations Account Managers with each revision. From the date the specification is approved, the effectivity date will be stamped one month in advance and sent to plasma suppliers to conduct training.

5.4.2. All facility documents and records pertaining to the collection, processing, QA/QC, storage, shipment and testing of plasma intended for manufacture by Talecris must be available for review for a minimum of **33 years**.

5.4.3. Each facility collecting or testing Source Plasma will be assigned a unique four-digit facility identification code. All documentation and records accompanying plasma units shipped to Talecris must be clearly identified with the facility identification code.

5.4.4. If original documents are required, but are unavailable, a copy may be substituted as long as it is stamped with the statement “This is a true and accurate copy of the original.” Verification must be provided to assure that all copies are accurate, legible and accounted for.

5.5. European Product

5.5.1. Product intended for shipment to Europe must be collected and tested by EU approved facilities.

5.5.2. EU Requirements are as follows:

a. Inspection and approval by a European Competent Authority.

b. Listed on the Talecris GMP certificate.

6. DONOR SUITABILITY

6.1. Requirements as defined in 21 CFR 640.61, 640.62, 640.63, 640.65(b), and 640.71 must be met, and in addition:

6.1.1. Applicant donor procedures and policies must be in effect in accordance with the iQPP Qualified Donor Standard.

6.1.2. Donors must be at least 18 years old. Donors older than 65 may donate if an acceptable physical examination and medical history is acquired annually.

6.1.3. Normal Source Plasma, collected from donors who have been re-entered through FDA approved re-entry programs, is not acceptable for delivery to or use by Talecris (except Anti-D plasma, refer to Talecris Anti-D plasma specification for requirements. No other plasma type, including NX, may be shipped to Talecris from re-entered donors).

6.1.4. Donors participating in an Anti-D stimulation program are not allowed to contribute to any other plasma type (NX, TX, HX, CX, RX) shipped to Talecris. Only Anti-D plasma may be shipped from donors participating in an Anti-D stimulation program.

7. PLASMA COLLECTION

7.1. Requirements defined in 21 CFR 640.62, 640.64, 640.65, 640.66, and 640.71 must be met, and in addition:

7.1.1. Plasma identification systems and labels, plasma collection containers, anticoagulant, supplies and equipment, sample tubes, and all packaging and shipping materials used must be approved in writing, prior to use, by Talecris Plasma Operations, Technical Services (Appendix D).

7.1.2. Only plasma collected in approved bottles using approved anticoagulant solutions (ref. Appendix D) are allowed to ship to Talecris.

7.1.3. Each collection facility must adhere to PPTA (iQPP) and PPTA voluntary standards.

7.1.4. A FDA approved nomogram must be used.

7.1.5. Plasma Identification:

a. A unique Control Number/Bleed Number must be assigned to one specific unit of plasma and all associated samples, which must be traceable to an individual donor and donation.

b. The Source Plasma Label applied to the unit of plasma must also contain the facility identification code, name, address and US license number of the collection facility, or minimally, the address of the plasma supplier corporate office.

c. Material Numbers:

1). Talecris will determine and provide the appropriate material number(s) for use by the collection facility.

2). In the event that it is ever necessary to change a material number on plasma already received or in transit to Talecris, the plasma supplier will communicate this change to the Talecris Plasma Operations Account Manager.

3). In the event that it is necessary to change a material number on plasma that is in storage at a supplier's facility, the supplier will be notified by the Talecris Plasma Operations Account Manager and requested to correct the shipping documents for the affected plasma, prior to shipment.

d. The case shipper label must minimally contain the "ship from" and "ship to" address, the complete vendor batch number, the case number, and the product description. Reference the example label in CS-000-BE-053, Plasma Supplier Supplemental Directions, for preferred format and other preferred label information.

8. PLASMA PROCESSING

8.1. Requirements defined in 21 CFR 640.68, 640.69(d), 640.70, 640.71 and 640.72 must be met, and in addition:

8.1.1. All plasma units must be placed in the freezer within one hour of collection and maintained at -20°C or colder.

8.1.2. All plasma units must be evaluated for unacceptably high hemoglobin concentration using the Talecris Hemoglobin Comparator (reference CS-000-BE-053), following the instructions for use printed on the card. Plasma units with unacceptably high hemoglobin concentrations must not be shipped to Talecris.

9. PLASMA PACKING

9.1. Plasma must remain frozen during packing procedures.

10. PLASMA STORAGE

10.1. Requirements defined in 21 CFR 640.71, 640.76 and the EP Monograph for Human Plasma for Fractionation must be met, and in addition:

10.1.1. Hyperimmune plasma, designated as Salvaged Plasma, must be relabeled as Normal X plasma. Talecris will **not** accept salvaged hyperimmune plasma.

Note: Anti-D plasma cannot be relabeled as Normal X plasma nor shipped as salvaged.

11. PLASMA SHIPPING

11.1. Requirements defined in 21 CFR 640.71 and 640.76, and in addition:

11.1.1. Maximum volume of normal plasma to be shipped in a vendor batch is 3700 liters.

11.1.2. Plasma Aging — Plasma must not be older than 24 months when shipped to Talecris.

11.1.3. Plasma that falls into one of the following categories is unacceptable for shipment to Talecris:

a. units with reactive or positive test results – refer to Appendix A-Table of Actions

b. prior and/or subsequent units from TMR or PMR donors – refer to Appendix A- Table of Actions

c. hemolyzed units, units with red spots in or on the plasma containers

d. lipemic units

e. units with frozen plasma on the outside of the container

f. broken, cracked or contaminated units

g. untested, or units with incomplete testing

h. orphan units

i. units collected from donors re-entered through a FDA approved donor re-entry program (except Anti-D plasma, refer to Talecris Anti-D plasma specification for requirements).

j. recovered plasma

k. unlabeled or mislabeled units, or units with torn or unreadable labels

l. units tested by a non-approved laboratory, or by non-approved test methods, reagents or equipment

m. units collected at non-approved facilities or by non approved owner groups

n. units having errors that breech traceability, such as units that cannot be traced back to an individual donor

o. parvo elevated units

p. units with ALT greater than 2 times the upper limit of normal

q. units with < 200 mL / bottle

r. plasma shipped to Talecris out of collection sequence

s. unit(s) with prior notification to supplier of unacceptable status by Talecris

11.1.4. Quarantine Plasma Shipments

a. Quarantined plasma shipments must be pre-approved by CBER.

b. Quarantined plasma shipments must be pre-approved by Talecris. Notification, in writing, including documentation of CBER approval, must be provided to the Talecris Plasma Operations Account Manager and written approval received from Talecris prior to shipment.

11.1.5. Source Plasma — Salvaged

a. Salvaged Plasma shipments must be pre-approved by Talecris. Notification, in writing, must be provided to the Talecris Plasma Operations Account Manager and written approval received from Talecris prior to shipment.

11.1.6. A documentation packet must accompany each shipment of plasma and must be QA approved.

11.1.7. Transport/Carriers and Off-Site Storage

a. All carriers used to transport Source Plasma and off-site storage facilities must be pre-approved by Talecris.

b. The temperature of the transport trailer must be -25°C or colder prior to loading the plasma shipment.

12. TESTING REQUIREMENTS

12.1. Testing requirements as described in 21 CFR 640.67 and 640.71 must be met, and in addition all plasma units intended for use by Talecris must meet the following criteria prior to shipment:

Test Type	Test Requirements
HBsAG[1, 4]	Non-reactive[3]
Anti-HIV-1/2[1, 4]	Non-reactive[3]
Anti-HCV[1, 4]	Non-reactive[3]
ALT[4]	Less than or equal to 2X the upper limit of normal
Syphilis[4, 7]	Negative or Non-reactive[3] for donor
Atypical Antibody[2,4,5,6]	Negative or Non-detectable (<1:1)
HCV NAT[1,4]	Negative[3]
HIV NAT[1,4]	Negative[3]
HBV NAT[1,4]	Negative[3]
Parvo, B-19 NAT[8]	Non-Elevated

Notes:

1. Most current version or generation available of a FDA approved test method must be used.
2. Test reagents for atypical antibody screening tests must include specific anti-D antibody. Detection of other atypical antibodies is not required, except anti-C for Rho-D plasma.
3. Some manufacturer’s package inserts use the terms “negative” and “non-reactive” interchangeably.

4. Prior to use, the test kit manufacturer, test kit methodology and testing facility must be approved by Talecris.
5. Test not performed on anti-D specialty plasma.
6. Test applicant or qualified donors. Testing must be performed and acceptable prior to sending units from donor.
7. Donor test performed every 4 months.
8. Parvo elevated units are unacceptable to ship to Talecris.

12.2. Testing must be performed by a testing facility that meets all regulatory and licensing requirements and has been pre-approved by Talecris . The Talecris Director of Plasma Operations will approve one of the Talecris eligible viral marker testing labs for each plasma supplier. The Talecris Director will also approve any switch of viral marker testing laboratories prior to change.

12.3. Notification for Destruction of Plasma

12.3.1. Notification to Talecris Plasma Receiving must be made

a. within three working days/72 hours upon receipt of a reactive or positive test result for a donor from whom prior or subsequent units have been shipped to Talecris (lookbacks).

b. within one working day/24 hours of notification of Post Donation Information resulting in product recalls or seizure concerning units shipped to Talecris.

c. within a timely manner for Post Donation Information not resulting in a seizure or recall (example: tattoo, body piercing, high risk).

12.3.2. Concerning instances of owner transfer of plasma centers, the NDDR and Talecris center code reported on the NDP sent to Talecris must reflect the NDDR / center code at the time of unit collection (not at time of reporting).

13. ATTACHMENTS

13.1. Appendix A –Table of Actions – Unacceptable Plasma and Donors

13.2. Appendix B – Glossary of Terms

13.3. Appendix C – Epidemiology Data Form

13.4. Appendix D – List of Approved Materials, Supplies and Vendors

APPENDIX A — TABLE OF ACTIONS — UNACCEPTABLE PLASMA AND DONORS

Test Results or Behavior or Circumstances	Action on This Donation	Action on Subsequent Donations	Action on Prior Donations	Action on Donor
ALT Elevated (greater than 2 x the upper limit of normal)	Destroy (1)	No Action	No Action	No Action
Sexual Partner	No Action	No Action	No Action	No Action
ATYA Positive (Atypical Antibody)	Destroy (1)	Destroy (1)	No Action, unless the positive unit was the second donation from an applicant donor. In this case, the first donation is also unacceptable for Talecris.	Not acceptable for Talecris
Sexual Partner	No Action	No Action	No Action	No Action
Parvo, B-19 by NAT Elevated	Destroy (1)	No Action	No Action	No Action

Footnotes: (1) — The option to divert plasma units from Talecris is allowed at those plasma centers that have approved SOPs to do so.

NOTE:

Exceptions to this Table of Actions are to be managed according to directions in section 5.1.6 in the General Specification — Source Plasma .

APPENDIX A — TABLE OF ACTIONS — UNACCEPTABLE PLASMA AND DONORS

Test Results or Behavior or circumstances	Action on This Donation	Action on Subsequent Donations	Action on Prior Donations	Action on Donor
vCJD: Information or Post Donation Information (PDI) from a donor who has been diagnosed with vCJD, suspected vCJD, or CJD diagnosis and Age < 55 years.	Destroy (1)	Destroy (1)	Destroy (1) LB to include all in-date Source Plasma units	PMR
Sexual Partner	No Action	No Action	No Action	No Action
CJD: Information or Post Donation Information (PDI) from a donor who has been diagnosed with CJD and Age ³ 55 years	Destroy (1)	Destroy (1)	Destroy (1) LB not to exceed 3 years from date of center notification	PMR
Sexual Partner	No Action	No Action	No Action	No Action
CJD/vCJD Increased Risk: Information or Post Donation Information (PDI) from a donor who has received a dura mater graft, or human pituitary growth hormone (HPGH).	Destroy (1)	Destroy (1)	Destroy (1) LB to date of event	PMR
Sexual Partner	No Action	No Action	No Action	No Action

Footnotes: (1) — The option to divert plasma units from Talecris is allowed at those plasma centers that have approved SOPs to do so.

(2) — UK Countries include: England, Scotland, Wales, Northern Ireland, Isle of Man, the Channel Islands, Gilbraltar or the Falkland Islands.

NOTE:

Exceptions to this Table of Actions are to be managed according to directions in section 5.1.6 in the General Specification — Source Plasma.

APPENDIX A — TABLE OF ACTIONS — UNACCEPTABLE PLASMA AND DONORS

Test Results or Behavior or Circumstances	Action on This Donation	Action on Subsequent Donations	Action on Prior Donations	Action on Donor
CJD/vCJD Potential Risk: Donor with a family history of one or more blood relatives diagnosed with CJD/vCJD, recipient of bovine-derived insulin since 1980, or who has accumulated travel or residence in the UK of 3 months or more between 1980 and 1996,* (2) This information may be received as PDI.	Destroy (1)	Destroy (1)	Destroy (1) LB not to exceed 3 years from date of center notification for familial risk	PMR for familial risk
			Destroy (1) LB not to exceed 3 years from date of center notification for travel risk and bovine insulin.	Indefinite deferral for travel risk and bovine insulin
Sexual Partner	No Action	No Action	No Action	No Action

Footnotes: (1) — The option to divert plasma units from Talecris is allowed at those plasma centers that have approved SOPs to do so.

(2) — UK Countries include: England, Scotland, Wales, Northern Ireland, Isle of Man, the Channel Islands, Gilbraltar or the Falkland Islands.

NOTE:

Exceptions to this Table of Actions are to be managed according to directions in section 5.1.6 in the General Specification — Source Plasma.

*Who has spent 5 years or more cumulatively in France from 1980 to the present or who has received a transfusion of blood or blood components in the U.K. between 1980 and the present. Additionally, donors who are former or current U.S. military personnel, civilian military personnel or their dependents who resided at U.S. military bases in Northern Europe (Germany, United Kingdom, Belgium and the Netherlands) for 6 months or more, from 1980 through 1990 or, who resided at U.S. military bases elsewhere in Europe (Greece, Turkey, Spain, Portugal and Italy) for 6 months or more, from 1980 through 1996.

APPENDIX A — TABLE OF ACTIONS — UNACCEPTABLE PLASMA AND DONORS

Test Results or Behavior or Circumstances	Action on This Donation	Action on Subsequent Donations	Action on Prior Donations	Action on Donor
Diagnosed Acute West Nile Virus Illness or Infection (3)	Destroy (1)	Destroy (1) Time period to cover 14 days prior to the onset of symptoms and 28 days subsequent to the onset of illness.	Destroy (1) Time period to cover 14 days prior to the onset of symptoms and 120 days subsequent to the onset of illness.	TMR 120 days following diagnosis or onset of illness, whichever is the later date
Sexual Partner	No Action	No Action	No Action	No Action
Suspected Acute West Nile Virus Illness or Infection (2)	Destroy (1) (if quarantine and retrieval is decided by the center Medical Director)	N/A	Destroy (1) (if quarantine and retrieval is decided by the center Medical Director) LB to 14 days prior to and 120 days subsequent to the onset of symptoms.	TMR 120 days following diagnosis or onset of illness, whichever is the later date
Sexual Partner	No Action	No Action	No Action	No Action

Footnotes:
(1) — The option to divert plasma units from Talecris is allowed at those plasma centers that have FDA approval to do so.
(2) — According to CBER guidance, the minimum time frame to ask questions regarding suspected acute WNV infection is from May 1st to November 30th each year. If the plasma center medical directors suspects a case of acute WNV infection, at any time of year, the plasma units and plasma donor should be managed as stated in the table of actions.
(3) — In the absence of current or recent symptoms, an IgM positive antibody test result alone should not be grounds for deferral.

NOTE:
Exceptions to this Table of Actions are to be managed according to directions in section 5.1.6 in the General Specification — Source Plasma.

APPENDIX A — TABLE OF ACTIONS — UNACCEPTABLE PLASMA AND DONORS

Test Results or Behavior or Circumstances	Action on This Donation	Action on Subsequent Donations	Action on Prior Donations	Action on Donor
HBsAg (EIA repeat reactive) or HBV by NAT	Destroy (1)	Destroy (1)	Destroy (1) LB units 12 months from last negative donation, not to exceed 3 years	PMR (NDDR)
Household Contact or Sexual Partner	Destroy (1)	Destroy (1)	Destroy (1) LB units 12 months from date of center notification	TMR 12 months from date of last household or sexual contact.
Anti-HCV (EIA repeat reactive) or HCV by NAT	Destroy (1)	Destroy (1)	Destroy (1) LB units 12 months from last negative donation, not to exceed 3 years	PMR (NDDR)
Household Contact or Sexual Partner	Destroy (1)	Destroy (1)	Destroy (1) LB units 12 months from date of center notification	TMR 12 months from date of last household or sexual contact.
Hepatitis Risk/Behavior: Pre-donation History, Clinical Signs or Symptoms	Destroy (1)	Destroy (1)	Destroy (1) LB units 12 months from date of center notification, not to exceed 3 years	PMR
Household Contact or Sexual Partner	No Action	No Action	No Action	No Action
IV Drug User: Past or present	Destroy (1)	Destroy (1)	Destroy (1) LB units 12 months from date of center notification	PMR
Sexual Partner	Destroy (1)	Destroy (1)	Destroy (1) LB units 12 months from date of center notification	TMR 12 months from date of last sexual contact

Footnotes: (1) — The option to divert plasma units from Talecris is allowed at those plasma centers that have FDA approval to do so.

NOTE:

Exceptions to this Table of Actions are to be managed according to directions in section 5.1.6 in the General Specification — Source Plasma.

APPENDIX A — TABLE OF ACTIONS — UNACCEPTABLE PLASMA AND DONORS

Test Results or Behavior or Circumstances	Action on This Donation	Action on Subsequent Donations	Action on Prior Donations	Action on Donor
PDI-Post Donation Information received describing possible exposure to Hepatitis or HIV	Destroy (1)	Destroy (1)	Destroy (1) LB units 12 months to date of exposure, not to exceed 12 months	TMR for 12 months from date of exposure
Household Contact (2) or Sexual Partner	No Action	No Action	No Action	No Action
Anti-HCV-1/2 (EIA repeat reactive), AIDS or HIV risk	Destroy (1)	Destroy (1)	Destroy (1) LB units 6 months from last negative donation, not to exceed 3 years	PMR (NDDR) (3)
Sexual Partner	Destroy (1)	Destroy (1)	Destroy (1) LB units 6 months from date of center notification	TMR 12 months from date of last sexual contact
HIV-1 NAT	Destroy (1)	Destroy (1)	Destroy (1) LB units 3 months from last negative donation, not to exceed 3 years	PMR (NDDR)
Sexual Partner	Destroy (1)	Destroy (1)	Destroy (1) LB units 3 months from date of center notification	TMR 12 months from date of last sexual contact

Footnotes: (1) — The option to divert plasma units from Talecris is allowed at those plasma centers that have FDA approval to do so.
(2) — Applies to exposure to Hepatitis only.
(3) — NDDR notification is for reactive results only; not for high risk.

NOTE:
Exceptions to this Table of Actions are to be managed according to directions in section 5.1.6 in the General Specification — Source Plasma.

APPENDIX A — TABLE OF ACTIONS — UNACCEPTABLE PLASMA AND DONORS

Test Results or Behavior or Circumstances	Action on This Donation	Action on Subsequent Donations	Action on Prior Donations	Action on Donor
Syphilis, confirmatory positive or confirmatory not performed	Destroy (1)	Destroy (1)	No Action	Not acceptable for Talecris
Sexual Partner	No Action	No Action	No Action	TMR 12 months from date of last sexual contact
Syphilis positive, confirmatory negative	No Action	No Action	No Action	No action if approved for further donations by the Medical Supervisor (2)
Sexual Partner	No Action	No Action	No Action	No Action

Footnotes: (1) — The option to divert plasma units from Talecris is allowed at those plasma centers that have FDA approval to do so.
(2) — FDA requires a licensed physician to approve donor for further donations.

NOTE:
Exceptions to this Table of Actions are to be managed according to directions in section 5.1.6 in the General Specification — Source Plasma.

APPENDIX A — TABLE OF ACTIONS – UNACCEPTABLE PLASMA AND DONORS

Test Results or Behavior or Circumstances	Action on this donation	Action on subsequent donations	Action on prior donations	Action on the Donor
Donors reporting a history of SARS or suspected SARS	Destroy (1)	Destroy (1) Time period to cover 28 days after complete symptom resolution AND the cessation of any treatment	Destroy (1) LB to date of exposure	TMR until 28 days after complete symptom resolution AND the cessation of any treatment
Close Contact (2) OR Travel / Residence Exposure	Destroy (1)(3)	Destroy (1)(3) Time period to cover NLT 14 days after last exposure OR 14 days after arrival in the US if travel/residence exposure	Destroy (1)(3) LB to date of exposure	TMR for NLT 14 days after last exposure OR for 14 days after arrival in the US if travel/residence exposure

Footnotes:
(1) – The option to divert plasma units from Talecris is allowed at those plasma centers that have FDA approval to do so.
(2) – Close contact is defined as having cared for, having lived with, or having had direct contact with respiratory secretions and/or body fluids of a patient known to be a suspect. SARS case.
(3) – If the donor is symptom-free more than 14 days post-exposure, product retrieval and quarantine are not necessary.

NOTE:

Exceptions to this Table of Actions are to be managed according to directions in section 5.1.6 in the General Specification – Source Plasma.

APPENDIX A — TABLE OF ACTIONS — UNACCEPTABLE PLASMA AND DONORS

Test Results or Behavior or Circumstances	Action on this donation	Action on subsequent donations	Action on prior donations	Action on the Donor
Recipient of Smallpox Vaccine – WITHOUT Vaccine Complications	Destroy (1)	A) Destroy — Time Period to Cover Date of Smallpox Vaccination and date the scab spontaneously separated or 21 days whichever is longer. B) Destroy — Time Period to Cover Date of Smallpox Vaccination and 2 months after Vaccination.	A) Destroy — Time Period to Cover Date of Smallpox Vaccination and date the scab spontaneously separated or 21 days whichever is longer. B) Destroy — Time Period to Cover Date of Smallpox Vaccination and 2 months after vaccination.	A) TMR until the vaccination scab has separated spontaneously, or for 21 days post-vaccination, whichever is the later date. B) If scab was removed prior to separating spontaneously, TMR for 2 months after vaccination.
Sexual Partner	No Action	No Action	No Action	No Action
Recipient of Smallpox Vaccine – With Vaccine Complications	Destroy (1)	Destroy — Time Period to Cover Date of Smallpox Vaccination and 14 days after all vaccine complications have completely resolved.	Destroy — Time Period to Cover Date of Smallpox Vaccination and 14 days after all vaccine complications have completely resolved.	TMR until 14 days after all vaccine complications have completely resolved.
Sexual Partner	No Action	No Action	No Action	No Action
Recipient of Antrax Vaccine	No Action	No Action	No Action	TMR 48 hours from time of vaccination.

Footnotes: (1) – The option to divert plasma units from Talecris is allowed at those plasma centers that have FDA approval to do so.

NOTE:

Exceptions to this Table of Actions are to be managed according to directions in section 5.1.6 in the General Specification — Source Plasma.

APPENDIX A — TABLE OF ACTIONS — UNACCEPTABLE PLASMA AND DONORS

Test Results or Behavior or Circumstances	Action on this donation	Action on subsequent donations	Action on prior donations	Action on the Donor
Symptomatic Contacts (of Smallpox Vaccinees) Exhibiting Localized Skin Lesions with No Other Complications	Destroy (1)	A) Destroy – Time Period to Cover Date of Contact with Smallpox Vaccinee (if known) and date the scab spontaneously separated. B) Destroy – Time Period to Cover Date of Contact with Smallpox Vaccinee (if known) and 3 months from the date of vaccination of the vaccine recipient with whom contact occurred or for 2 months from the present if the vaccination date is not known.	A) Destroy – Time Period to Cover Date of Contact with Smallpox Vaccinee (if known) and date the scab spontaneously separated. B) Destroy – Time Period to Cover Date of Contact with Smallpox Vaccinee (if known) and 3 months from the date of vaccination of the vaccine recipient with whom contact occurred or for 2 months from the present if the vaccination date is not known.	A) If the scab separated spontaneously, no action is taken. B) If the scab was removed prior to separating spontaneously, TMR for 3 months from the date or vaccination of the vaccine recipient with whom contact occurred or for 2 months from the present if the vaccination date is not known.
Sexual Partner	No Action	No Action	No Action	No Action
Symptomatic Contacts (of Smallpox Vaccinees) Exhibiting Vaccine Complications	Destroy (1)	Destroy – Time Period to Cover Date of Contact with Smallpox Vaccinee (if known) and 14 days after all vaccine complications have completely resolved.	Destroy – Time Period to Cover Date of Contact with Smallpox Vaccinee (if known) and 14 days after all vaccine complications have completely resolved.	TMR until 14 days after all vaccine complications have completely resolved.
Sexual Partner	No Action	No Action	No Action	No Action

Footnotes: (1) – The option to divert plasma units from Talecris is allowed at those plasma centers that have FDA approval to do so.

NOTE:

Exceptions to this Table of Actions are to be managed according to directions in section 5.1.6 in the General Specification – Source Plasma.

APPENDIX A — TABLE OF ACTIONS – UNACCEPTABLE PLASMA AND DONORS

Test Results or Behavior or Circumstances	Action on this donation	Action on subsequent donations	Action on prior donations	Action on the Donor
Vaccines with killed /inactivated viruses or bacteria recombinant, OR Toxoids	No Action	No Action	No Action	No Action if donor is acceptable according to the center medical director or supervisor.
Vaccines with attenuated bacteria or viruses	No Action	No Action	No Action	TMR for 4 weeks from vaccination date.
Other Vaccines: Rabies, tick-borne encephalitis	No Action	No Action	No Action	No Action if donor is acceptable according to the center medical director or supervisor. OR TMR for 1 year if vaccine was administered post-exposure. Deferral period is from last exposure to rabies.

NOTE:

Exceptions to this Table of Actions are to be managed according to directions in section 5.1.6 in the General Specification – Source Plasma.

APPENDIX A — TABLE OF ACTIONS – UNACCEPTABLE PLASMA AND DONORS

Test Results or Behavior or Circumstances	Action on this donation	Action on subsequent donations	Action on prior donations	Action on the Donor
Confirmed Medical Diagnosis of Anthrax of Any Form	Destroy (1)	Destroy (1) Time period to cover known date of exposure to Anthrax or 60 days prior to the onset of illness until the condition is considered resolved	Destroy (1) Time period to cover known date of exposure to Anthrax or 60 days prior to the onset of illness, whichever is the shorter period	TMR until donor completes a full course of appropriate treatment and condition is considered resolved.
Sexual Partner	No Action	No Action	No Action	No Action
Proven Anthrax Bacterial Colonization	No Action	No Action	No Action	TMR until donor completes a full course of prophylaxis with an appropriate antibiotic.
Sexual Partner	No Action	No Action	No Action	No Action
Undiagnosed Skin Lesions Expected to be Anthrax	No Action	No Action	No Action	TMR until either donor lesion is proven not to be Anthrax or donor completes full course of appropriate treatment and condition is considered resolved.
Sexual Partner	No Action	No Action	No Action	No Action
Undiagnosed Post-Donation Illness in Individuals Potentially Exposed to Anthrax	Destroy (1) (if quarantine and retrieval is decided by the center Medical Director)	N/A	Destroy (1) (if quarantine and retrieval is decided by the center Medical Director) Time period to cover known date of exposure to Anthrax or 60 days prior to the onset of illness, whichever is the shorter period	TMR until condition is considered resolved.
Sexual Partner	No Action	No Action	No Action	No Action

Footnotes: (1) – The option to divert plasma units from Talecris is allowed at those plasma centers that have FDA approval to do so.

NOTE:

Exceptions to this Table of Actions are to be managed according to directions in section 5.1.6 in the General Specification – Source Plasma.

APPENDIX B – GLOSSARY OF TERMS

Applicant Donor – A donor who has not acquired Qualified Donor Status or has had a lapse of six months or more between donations.

BPDR – Biological Product Deviation Report

SAP Case Number – Identifies the individual case of plasma within the vendor batch. The SAP case number cannot be duplicated within a given vendor batch.

CAPA – Corrective Action(s) and/or preventive action(s).

Catalog Number - see Plasma Material Numbers.

Control Number / Bleed Number - A unique plasma unit identification number.

CTR - Confidential Test Report – a form generated by RTL which serves as notification that a sample tested is reactive or positive for one of the required NAT tests.

Donor Number – A unique number assigned to each individual donor at the first donation, which is used to identify that individual donor throughout their donation history at a particular collection facility.

Facility Identification Code — A unique four character (usually alpha) code assigned by Talecris to identify plasma center and test facility locations.

Household Contact – Persons who have been in close contact with a case of hepatitis infection (acute or chronic).

ITS – Incident Tracking System captures the investigations and documents related to discrepant plasma reports that have been shipped and found at check-in by Talecris (RMR) or already processed by Talecris (ITS).

Last Negative Donation – For the purposes of evaluating lookback reporting timeframes, the last negative donation is applicable to both NAT and viral marker testing.

LB – Lookback. Plasma unit with acceptable viral marker testing associated with a donor who has either subsequently seroconverted, is initially reactive or is otherwise determined to be unacceptable.

NAT – Nucleic Acid Amplification Technology.

NDDR – National Donor Deferral Registry.

NDP – Notification for Destruction of Plasma form to be submitted to Talecris in the event plasma unit removal or disposition is required.

Orphan Unit - The first unit of plasma donated by an Applicant Donor, for which a second unit is not collected or successfully tested within six months of the first unit. An orphan unit is unacceptable for shipment to Talecris.

Plasma Material Numbers – Plasma types are assigned 8-digit Material Numbers that numerically code for the type antibody present in the plasma, as well as other important characteristics, such as EU product eligibility and level of NAT testing.

Note: Plasma material numbers were formerly referred to as plasma item numbers. The correspondence between the current material numbers and the legacy item numbers is detailed in the table below:

APPENDIX B

PLASMA DESCRIPTION	PLASMA MATERIAL #	LEGACY ITEM #
Normal, EU approved, bottles	08634958	19-7100-110
Normal, non-EU approved, bottles	08634966	19-7100-111
Normal, EU “Flash Frozen” approved, all products, bottles	08754430	N/A
Normal, EU approved from Configured Pools (ZLB)	08936601	N/A
CMV, EU approved, bottles	08635318	19-7122-110
CMV, non-EU approved, bottles	08635326	19-7122-111
Tetanus, non-EU approved, bottles	08635024	19-7103-111
Rabies, non-EU approved, bottles	08635083	19-7106-111
Anti-D, non-EU approved, bottles	08635156	19-7108-111
Hepatitis, non-EU approved, bottles	08635458	19-7145-111

PLS – Packing List Summary – the form to be completed for each individual Vendor Batch Number.

PMR - **Permanent Medical Reject** - The status of a donor who has been permanently deferred from donating Source Plasma due to an unacceptable medical condition, unacceptable test results or post donation information.

PPL – Plasma Packing List – The form used to document plasma units in individual cases and test results for each plasma unit (or certification of negative test results).

PPTR – Plasma Packing & Test Report – A form generated by Raleigh Test Lab (RTL), listing test results for samples tested by NAT.

Qualified Donor - An individual who has provided a plasma sample at a specified plasma center, at least twice in a six month period, and all screening requirements have been met for both a) questions and tests and for b) the donor and the plasma sample, according to the iQPP Qualified Donor Standard.

QO – Talecris Quality Operations Department, comprising of both Quality Assurance and Quality Control functions.

RA – Regulatory Affairs

RMR – Raw Material Report. A report used to document discrepancies against plasma not yet processed (pooled).

APPENDIX B

Shipment –

a. **Single Shipment**: refers to a shipment from a single plasma center that meets all requirements stated in the general specification.

b. **Combined Shipment or "Master Ship Documents"**: expands the definition of shipment to include hyperimmune plasma shipped from multiple locations, all belonging to the same owner group. All centers are to be listed on Talecris' approved suppliers list. Combined shipments must not exceed 500 liters and must be pooled together.

Source Plasma - The fluid portion of human blood collected by plasmapheresis which meets the requirements of US CFR Title 21, Part 640, Subpart G – Source Plasma and is intended for further manufacture into therapeutic biological products.

Source Plasma, Salvaged – Source Plasma that is exposed to a temperature fluctuation that falls between -5°C, but colder than +10°C, or that is exposed to more than one temperature excursion warmer than -20°C during storage.

Supplier – A supplier of plasma units, or of testing services provided for samples from plasma units intended for shipment to and manufacture by Talecris.

TMR - **Temporary Medical Reject** - the status of a donor who has been temporarily deferred from donating Source Plasma due to a transient medical condition.

Vendor Batch Number – Identifies the shipment to Talecris. The vendor batch number is a unique identifier that is NEVER duplicated at the same center. Whenever a shipment comprises more than one plasma type, a unique vendor batch number must be assigned to each plasma type within the shipment. The first four (4) characters of the vendor Batch number must be the donor centers NDDR number.

Appendix C
Epidemiology Data[1]
Monthly Data Collection Form

To: QO Compliance/Audits & Systems – Epidemiology Data
Fax: (919) 359-7195

Month (1 only): _____
Owner Group: _____
Submitted By: _____ **Phone:** _____ **Date:** _____
Signature: _____

Center Code	NDDR #	Total # "First Time tested Donors"	Total # "Repeat tested Donors"	Total # Donations from "Repeat tested Donors"	Donation Frequency[4]	Anti-HIV-1/2			Anti-HCV			HBsAg			HIV-1 NAT			HCV NAT			HBV NAT		
						FTD[2]	RD[3]	QD[5]	FTD[2]	RD[3]	QD[5]	FTD[2]	RD[3]	QD[5]	FTD[2]	RD[3]	QD[5]	FTD[2]	RD[3]	QD[5]	FTD[2]	RD[3]	QD[5]

Note: Viral Marker and NAT results are confirmed positive.

1 Follow the definitions provided in section 5.1.4 of the General Specification – Source Plasma.

2 In all cases, FTD is to be representative of the number of confirmed positive "First time tested donors" (not donations).

3 In all cases, RD is to be representative of the number of confirmed positive "Repeat tested donors" (not donations).

4 In all cases, NAT refers to NAT only positives (donors testing NAT positive but not repeat reactive by EIA).

5 In all cases, QD is to be representative of the number of confirmed positive "Qualified donors" for the entire calendar year.

APPENDIX D – PLASMA COLLECTION EQUIPMENT AND SUPPLIES

Product	Part Number/Description	Purpose	Acceptable Materials
			Both Medisystems and JMS are included in the Talecris Plasma Master File
Apheresis Needle Set:			
15g	Medisystems/P9-9115MGLB (Medisystems code)		
16g	Medisystems/P9-9116MGLB (Medisystems code)/Baxter number 4R2440	Access donor's vein	
175	Medisystems/P9-9117MGLB (Medisystems code)/Baxter number 4R2441		
15g	JMS/820-1504		
16g	JMS/820-1609		
17g	JMS/820-1702		
			Two automated systems are licensed in the U.S. for collecting Source Plasma: Haemonetics PCS/PCS2 and Baxter Autopheresis-C (Plasmacell-C disposable)
Plasma Separation Device:		Separate plasma from whole blood	
Apheresis bowl	Haemonetics/L/N: 625B		
PCS2 harness	Haemonetics/L/N: 620		
or Plasmacell-C kit	Baxter/Fenwal/4R2256		
			Baxter and Haemonetics both make comparable FDA- licensed USP solutions, which are listed in the PMF.
Anticoagulant:			
		Prevent plasma from clotting	
4% Citrate, USP, 250 mL	Haemonetics/L/N: 420A (US)		
4% Citrate, USP, 250 mL	Baxter/Fenwal/4B7867Q		
4% Citrate, USP, 500 mL	Baxter/Fenwal/4B7889Q		
		Plasma Collection/Storage Container	- Baxter plasma bottles
Plasma Container:			- Haemonetics plasma bottles
Plasma Bottle (PlasmaLink)	Baxter/Fenwal/4R2067, 4R2068		
Plasma Bottle	Haemonetics 694, 694S, 694D		

APPENDIX D – PLASMA COLLECTION EQUIPMENT AND SUPPLIES

Product	Part Number/Description	Purpose	Acceptable Materials
NAT Sample tray:	All-Pak/HMS-Zero	NAT Sample Submission to RTL	MUST be manufacturer and P/N specified
NAT Sample Shipper:	All-Pak/HMS-69100	NAT Sample Submission to RTL	MUST be manufacturer and P/N specified
Gel Packs:	Tech Pak/ Frigid 15, All-Pak/SturdeeSeal	NAT Sample Submission to RTL	MUST be manufacturer and P/N specified
Sigma Printing System:	Allegro printer, BLS memory module, media kits	labeling documents for NAT samples and plasma cases	All centers NAT tested by Talecris RTL (Raleigh Test Lab) are furnished this equipment by Talecris
Plasma Shipper:	Corrugated plasma shipping carton	Plasma Shipments to Clayton	Prior approval by Manager of Technical Services of Plasma Operations.
Shipper Label:	various Talecris catalog #'s/(81-9999 series) Teslin material	Plasma Shipments to Clayton	Printed by Universal Graphics. Alternates acceptable if pre-approved by Manager of Technical Service, Plasma Operations.

Exhibit D

MONTH **Jun-2006**

Emergent — Anthrax Hyperimmune

Month	Date	Talecris Employee	Hours	Task/Subproject	Description	Dept
			0	**Total Hours**		
			$[**] per hour	**Rate**		
				Invoice		

Timesheets represent billable hours to Emergent and are required backup for invoicing. Externals are billed as passthru costs.

An average rate of $[**] per hour, plus any relevant travel expenses, for billing purposes regarding supplemental Talecris support regardless of functional area.

The detailed invoices will be submitted on a monthly basis using this form

Exhibit E

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	[**] Talecris	[**] Emergent	Talecris
GENERAL COMPLIANCE / REGULATORY	[**]	[**]	[**]	[**]
a. License holder with respect to Shared Manufacturing License process				
b. Compliance with US CFR / cGMP regulations during manufacture				
BATCH RECORDS	[**]	[**]	[**]	[**]
a. Write Master Production Records				
b. Review Master Production Records				
c. Approve Master Production Records				
d. Approval of changes to Master Batch Records that would have an effect on product				
e. Provide copies of approved Master Production Records and executed Production Batch Records				
f. Record Retention (original documents – Master Batch Records and executed Batch Records)				
MATERIAL CONTROLS	[**]	[**]	[**]	[**]
a. Responsibility to ensure source AIG plasma meets established plasma specification				
b. Responsibility to ensure all components and raw materials used in the manufacturing process meet pre-approved specifications				
SUBCONTRACTING	[**]	[**]	[**]	[**]
a. Notification of intent/need to subcontract				
b. Right to audit potential subcontractor accompanied by Talecris				
c. Prior approval to initiate subcontracting				
REPROCESSING / REWORK PER VALIDATED PROCEDURES AND LICENSE	[**]	[**]	[**]	[**]
a. Rework according to Talecris and Emergent approved license and validated procedures				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	[**] Talecris	[**] Emergent	Talecris
SPECIFICATIONS	[**]	[**]	[**]	[**]
a. Product Specifications, [**]				
b. Product Specification – [**]				
c. Labeling and packaging components				
d. Packaging inserts				
e. Compatibility with equipment				
STABILITY – Finished Product	[**]	[**]	[**]	[**]
a. Writing stability protocol				
b. Approving stability protocol				
c. Collection / storage of stability samples				
d. Testing – [**]				
e. Stability data interpretation – [**]				
f. Testing – [**]				
g. Writing stability report				
h. Approving stability report				
i. Establish expiration date/shelf life				
PRODUCT RETAINS	[**]	[**]	[**]	[**]
a. Identification of samples to be retained				
b. Approval of samples to be retained				
c. Retention / storage of samples at appropriate storage conditions				
d. Final disposition of retain samples				
PRODUCT RELEASE	[**]	[**]	[**]	[**]
a. Initial review of completed Batch Record				
b. Final review / approval of completed Batch Record				
c. Issuance/Approval of Certificate of Conformance				
d. Issuance/Approval of Certificate of Analysis [**]				
PRODUCT RELEASE continued				
e. Issuance of Certificate of Analysis [**]				
f. Lot Release				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	[**] Talecris	[**] Emergent	[**] Talecris
NON-CONFORMANCE EVENTS	[**]	[**]	[**]	[**]
Deviations				
a. Documentation of non-conformance event per established SOP's				
b. Notification to Emergent of non-conforming event [**]				
c. Investigation of non-conforming event and identifying appropriate CAPA's				
d. Approval of non-conforming event [**]				
OOS – Assays performed by Talecris [**]				
e. Documentation of OOS per established SOP's				
f. Notification to Emergent of confirmed OOS event with established root cause				
g. Review of confirmed OOS and retest plan with established root cause				
h. Investigation of OOS event and identification of appropriate CAPA's including proposed re-test plans				
i. Review of confirmed OOS event and re-test plan where **no** assignable root cause is established				
j. Approval of confirmed OOS event and re-test plan where **no** assignable root cause is established				
OOS – Assays performed by Emergent [**]				
k. Documentation of OOS per established SOP's				
l. Notification to Talecris of confirmed OOS event				
m. Investigation of OOS event and identification of appropriate CAPA's including proposed re-test plans				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	[**] Talecris	[**] Emergent	Talecris
n. Approval of OOS event and re-test plan				
AUDITING / MAN-IN-PLANT	[**]		[**]	[**]
a. Right to conduct scheduled routine audits of facility and quality systems not to exceed one (1) occurrence per year				
b. Right to conduct “for cause” audits of facility and quality systems as needed in response to specific noncompliance events [**]				
c. Right to maintain “man-in-plant” presence during process start up and execution of validation lots				
ADVERSE EVENTS / PRODUCT COMPLAINTS	[**]	[**]	[**]	[**]
a. Regulatory notification of AE’s Complaints as required by regulations				
b. Lead in AE / Complaint investigations				
c. Assistance in conducting AE / Complaint investigations, including manufacturing investigation				
d. Final written report for AE / Complaints				
e. Approval of report				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	 Talecris	 [**] Emergent	 Talecris
PRODUCT RECALL	[**]	[**]	[**]	[**]
a. Final Decision – [**]				
b. Notification of other Company regarding recall decision				
c. Notification of potential event that may initiate recall				
d. Impact of recall on Talecris filings				
e. Impact of recall on Emergent filings				
f. FDA notification of recall				
g. Management of recall event				
“LOOK BACK” PROCESS	[**]	[**]	[**]	[**]
a. Plasma collection center notification for look backs involving units at Talecris				
b. Tracing of plasma units effected by look back				
c. Destruction of plasma units not yet processed and documentation of destruction				
d. Supplying documentation of plasma unit destruction to Emergent				
e. Product impact assessment involving plasma units that have been processed				
f. Supply copies of documentation to include plasma pool date and product lot number(s) for processed/pooled plasma				
REGULATORY	[**]	[**]	[**]	[**]
a. Single IND Submission by Emergent for AIG Product				
b. BLA Submission				
c. Notification of any regulatory action which could affect finished product				
d. Providing regulatory advice as needed related to process related to Emergent filings				
e. Communications to Regulatory Authorities concerning Finished Product				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	 Talecris	 [**] Emergent	 Talecris
REGULATORY INSPECTIONS	[**]	[**]	[**]	[**]
a. Notification of regulatory inspection by FDA, EU Regulatory agency or other governmental agency in conjunction with the facilities, processes or quality systems used to manufacture or support Emergent finished product.				
b. Ability to maintain site presence during inspection [**]				
c. Approval of corrective actions associated with identified deficiencies or observations resulting from inspections [**]				
d. Review and approval of corrective actions associated with identified deficiencies or observations resulting from inspections [**]				
e. Submission of corrective actions to inspecting Authority				
BIOLOGICAL PRODUCT DEVIATIONS	[**]	[**]	[**]	[**]
a. Final Decision – submission of BPDR related to distributed product				
b. Submission of BPDR				
c. Lead – investigation for BPDR				
d. Assistance – investigation including manufacturing investigation				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	[**] Talecris	[**] Emergent	[**] Talecris
CHANGE MANAGEMENT	[**]	[**]	[**]	[**]
Talecris Initiated				
a. Approval of changes to facility or Gamunex process, including testing and specifications , that do not impact [**]				
b. Notification of non-routine changes to facility or Gamunex process, including testing and specifications, that have the potential to impact [**]				
c. Review and approval of non-routine changes to facility or Gamunex process, including testing and specifications, that have the potential to impact [**]				
d. Review of changes to facility or Gamunex process, including testing and specifications, required to maintain compliance to GMP during audit(s)				
e. Approval of changes to facility or Gamunex process, including testing and specifications, required to maintain GMP				
Emergent Initiated				
f. Approval of changes to process including specifications that do not impact facilities or Gamunex process				
g. Notification of changes to process including specifications that have the potential to impact facilities or Gamunex process				
h. Approval of changes to process including specifications that have the potential to impact facilities or Gamunex process				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	[**] Talecris	[**] Emergent	Talecris
VALIDATION	[**]	[**]	[**]	[**]
a. Maintaining validated state of facility and equipment used for Gamunex [**]				
b. Writing Process Validation Protocol				
c. Approval of Process Validation Protocol				
d. Writing Process Validation Report				
e. Approving Process Validation Report				
ANNUAL PRODUCT REVIEW / ANNUAL REPORT		[**]	[**]	[**]
a. Preparation of summary data for Emergent Annual Product Review Report				
b. Annual Product Review final report				
c. Submission of Annual Report to FDA				

EXHIBIT F

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QUALITY AGREEMENT

Emergent Product Development Gaithersburg Inc.
300 Professional Drive
Gaithersburg, MD 20879
(Hereafter called “Emergent”)

AND

Talecris Biotherapeutics, Inc.
4101 Research Commons/79 T.W. Alexander Drive
Research Triangle Park, NC 27709
(Hereafter called “Talecris”)

Approved by:	Date:
/s/ Edward Arcuri	7/31/06
Emergent BioSolutions Inc. Edward Arcuri Executive Vice President, Corporate Operations Chief Operating Officer	
/s/ Barbara Sneade	7/31/06
Talecris Biotherapeutics Inc. Barbara Sneade Senior Quality Manager, Quality Operations	

History of Revisions

Version	Date	Revised By	Description
01	July 27 2006	D. Bland	New

TABLE OF CONTENTS

1. DEFINITIONS

1.1 The definitions set forth in the Product Supply Agreement are applicable to this Quality Agreement.

2. SCOPE / GENERAL REGULATORY COMPLIANCE

2.1 This Quality Agreement is between Emergent and Talecris and applies to Finished Product manufactured with the intent to support Investigational New Drug (IND) applications, Biological License Applications (BLA) and Commercial Product as set forth in the Product Supply Agreement.

2.1.1. [**].

2.1.2. [**].

2.2 In the event of amendments or changes to the Product Supply Agreement, or at intervals not to exceed 1 (one) year, the Quality Agreement will be reviewed by Emergent and Talecris to ensure that the roles and responsibilities reflect current practice and can be modified as needed with the written approval of both parties.

2.3 For the avoidance of doubt the arrangements relating to the manufacture of Finished Product are governed by the Product Supply Agreement and subsequent amendments. In the event of any inconsistency between the terms and conditions of this Quality Agreement and the terms and conditions of the Product Supply Agreement and possible subsequent amendments between the parties, the terms and conditions of the Product Supply Agreement and the subsequent amendments shall prevail.

2.4 Emergent and Talecris shall conduct operations in compliance with cGMP as defined in applicable sections of 21 CFR (see definitions). Both parties agree to work together in good faith to resolve differences in interpretation of current issues of these regulations and guidelines.

2.5 Emergent and Talecris shall ensure that the receipt, manufacture, labeling, packaging, testing, release, storage and shipping of the Finished Product are in compliance with the above noted regulations and associated guidelines or equivalent standards.

3. PURPOSE

3.1 This Quality Agreement further defines the roles and responsibilities for the Emergent and Talecris Quality Departments for the services defined in the Product Supply Agreement. A summary of responsibilities is presented in Appendix II of this Quality Agreement.

3.2 This Quality Agreement also defines how Talecris Quality Departments and Emergent Quality Departments will interact during conduct of contracted services.

3.3 This Quality Agreement shall be considered an Exhibit to the Product Supply Agreement. Refer to Section 2.3 in the event of discrepancies between the Quality Agreement and Product Supply Agreement.

4. CONTACT INFORMATION

4.1 Emergent contact names: refer to Appendix I

4.2 Talecris contact names: refer to Appendix I

5. DURATION OF AGREEMENT

5.1 The Quality Agreement will be effective once representatives of Emergent and Talecris approve the document as designated by the signatures and date on the cover page of the Quality Agreement and will expire with termination or expiration of the Product Supply Agreement and any subsequent amendments except for provisions which, by their nature, are intended to survive.

6. MANUFACTURING cGMP COMPLIANCE

6.1 General

6.1.1. The manufacturing operations for the Finished Product to be performed by Talecris are defined in the Product Supply Agreement.

6.2 Premises

6.2.1. Talecris will manufacture the Finished Product at the Clayton facility. The floor plans of the manufacturing areas and corresponding room classifications will be made available by Talecris for review by Emergent during annual audits of the facility by Emergent.

6.2.2. The premises and equipment used to manufacture Finished Product will be maintained according to current regulatory requirements and in accordance with the approved procedures. The production of the Finished Product will be conducted in a suitably controlled environment and such facilities will be regularly monitored for parameters critical to the process to demonstrate compliance with appropriate cGMP and Regulatory Guidelines.

6.2.3. Talecris will maintain controlled access to the premises.

6.3 cGMP

6.3.1. The principles detailed in the referenced documents in Section 2 of this Quality Agreement will cover the standards of manufacture of the Finished Product. Applicable cGMP guidelines will cover the standards of quality assurance for the Finished Product.

6.4 Materials

6.4.1. For pooling of [**] plasma (source plasma), purification, and manufacture of the [**], Talecris will use only raw materials and components listed in the Bill of Materials or Master Production Records.

6.4.2. For manufacture of the [**] and Finished Product, packaging, and labeling activities, Talecris will use only packaging materials and labeling components listed in the Bill of Materials or Master Production Records, which have been reviewed and approved by Emergent.

6.4.3. Materials Procured by Talecris

6.4.3.1. Talecris is responsible for ensuring that all materials and components procured by Talecris for use in the manufacture of Finished Product are in full compliance with the approved specifications.

6.4.3.2. Talecris is responsible for ensuring that all materials are appropriately sampled, tested, and stored upon receipt, and that only released raw materials are used in the manufacture of Finished Product, as well as for holding the relevant Certificates of Analysis for the raw materials.

6.4.3.3. Talecris is responsible for ensuring all Finished Product related vendors and suppliers for materials procured by Talecris for the manufacture of Finished Product are approved for use by Talecris Quality.

6.4.4. Materials Provided by Emergent for Talecris – AIG Source Plasma

6.4.4.1. Emergent is responsible for ensuring that the AIG Source Plasma collected on behalf of Emergent and provided to Talecris by Emergent for use in the manufacture of Finished Product meets the requirements of the AIG Source Plasma Specifications, Talecris General Plasma Specification, and Plasma Supplier Supplemental Directions current revision.

6.4.4.2. Emergent Quality is responsible for ensuring all vendors and suppliers related to the supply of AIG Source Plasma are approved for use by Emergent Quality.

6.4.4.3. Talecris Quality is responsible for ensuring that all plasma centers supplying AIG Source Plasma are approved and are listed on the Talecris approved sources list.

6.5 Master Production Records

6.5.1. Talecris will create and maintain the manufacturing information in the form of a Master Production Record (MPR) in accordance with their established procedures and policies.

6.5.1.1. MPR's for the manufacture of the [**] will be reviewed by Emergent [**] prior to initiation of the first production campaign.

6.5.1.2. MPR's for manufacture of the [**] and Finished Product (filled, packaged, labeled) will be reviewed and approved by Emergent [**] prior to the first manufacture of the [**] and Finished Product.

6.5.2. Changes to approved MPR's will be documented and justified according to established [**] as outlined in the Change Management section of this Agreement (refer to Section 11).

6.6 Standard Operating Procedures

6.6.1. Talecris shall maintain the Standard Operating Procedures (SOP's) and/or Test Methods required to manufacture, test, and store the Finished Product [**] with the exception of the testing of the [**].

6.6.1.1. Emergent will review Standard Operating Procedures and/or Test Methods created exclusively for the manufacture of Finished Product.

6.6.2. Changes to approved SOP's and/or Test Methods will be documented and justified according to established [**] as outlined in the Change Management section of this Agreement (see Section 11).

6.7 Batch Numbers

6.7.1. Talecris will determine the manufacturing batch numbering system for raw materials and components used in the manufacture of Finished Product in accordance to their established procedures and policies. Each lot of Bulk Drug Substance and Final Drug Product will have unique identifiers assigned and recorded.

6.7.2. Talecris will be responsible for maintaining forward and backward lot traceability for all components and raw materials used in the manufacture of Finished Product.

6.8 Dates of Manufacture and Expiration

6.8.1. Date of Manufacture- Talecris will assign the Date of Manufacture in accordance to their established procedures and policies. Dates of Manufacture will be assigned to the Bulk Drug Substance and Final Drug Product. Date of Manufacture will not be assigned to in-process hold steps.

6.8.2. Expiration Date: Talecris will assign an Expiration Date for the Bulk Drug Substance in accordance with established procedures and policies.

Expiration dates will be assigned to in-process hold steps per Talecris. Expiration dating and/or shelf-life period for Final Drug Product will be established by Emergent.

6.9 Manufacturing and Equipment Data

6.9.1. Talecris is responsible for keeping records of equipment usage, cleaning, and any maintenance and calibration performed according to cGMP requirements.

6.9.2. As applicable, Talecris is responsible for labeling all non-disposable Finished Product dedicated equipment and storing this equipment appropriately to prevent its use and or cross contamination with other products.

6.9.3. Talecris is responsible for having adequate cleaning validation for all non-disposable non-dedicated equipment used in the manufacture of Finished Product.

6.9.4. Talecris is responsible for having adequate room clearance procedures, including decontamination procedures appropriate for the degree of exposure of the Finished Product for all non-dedicated rooms in which the Finished Product is manufactured.

6.10 Reprocessing and Rework

6.10.1. Reprocessing and rework at any stage of the manufacture of Finished Product, including re-labeling, will be according to Talecris and Emergent license and process validation.

6.10.2. Documentation of re-labeling or re-inspection will be included in the production batch record documentation submitted to Emergent.

6.11 Storage and Shipment

6.11.1. Talecris will store Finished Product under conditions as specified in approved specifications and the Product Supply Agreement.

6.11.2. Talecris will ensure that during storage of the Finished Product at Talecris appropriate cGMP controls are in place to prevent interference, theft, product contamination, or admixture with any other materials.

6.12 Finished Product will be suitably packaged and labeled for transit. Emergent shall specify the design and content of the package insert and labels in accordance with Talecris' equipment limitations. At the request of Emergent, Talecris shall work with Emergent to specify the design of the labels and insert.

6.12.1. Emergent will authorize Talecris to ship Finished Product in writing. Samples associated with the manufacture of Finished Product required for testing or other purposes may be shipped prior to the Finished Product.

6.12.2. Talecris will prepare shipments of Finished Product as directed by Emergent using shipping containers, temperature controls and recorders as determined appropriate by Emergent.

7. QUALITY CONTROL

7.1 General

7.1.1. The testing activities for Finished Product that are to be performed by Talecris are to be performed in accordance with approved Test Methods and SOP's and according to established specifications.

7.1.2. Talecris will notify Emergent and obtain prior approval for the sub-contract of any analytical testing related to the manufacture of Finished Product.

7.2 Materials supplied by Talecris

7.2.1. Quality control of materials supplied by Talecris will be performed by Talecris.

7.2.2. Talecris will notify Emergent of any significant Quality Assurance non-conformance investigations related to the testing, storage and handling of any raw materials used to manufacture Finished Product as defined in Section 8.2.

7.3 In-Process and Final Drug Product Testing

7.3.1. Talecris will perform testing on in-process samples, [**] plasma, bulk drug substance and final drug product as agreed upon by Talecris and Emergent, using approved specifications, SOP's and/or Test methods.

7.3.2. Emergent will perform product-specific testing on in-process samples, [**] plasma, bulk drug substance and final drug product as agreed upon by Talecris and Emergent, using approved specifications, SOP's and/or Test methods.

7.3.3. In-Process and [**] plasma test results generated by Talecris and Emergent will be documented either in the executed MPR or separately on a document that will be included with the MPR.

7.3.4. For each lot of [**] manufactured for and Final Drug Product delivered to Emergent, Talecris will provide to Emergent a Certificate of Conformance (CofC) to confirm each lot has been manufactured per approved procedures and in conformance with appropriate cGMP requirements. At a minimum, the CofC will contain the following information:

- Ø Product/Lot description/name
- Ø Lot number
- Ø Date of Manufacture
- Ø Expiration Date
- Ø Quantity/Dose/Volume
- Ø Storage conditions
- Ø Declaration that the product was manufactured in compliance with GMP regulations
- Ø Signature/Date of a responsible Quality representative

7.3.5. For each lot of [**] and Final Drug Product delivered to Emergent, Talecris will provide a Certificate of Analysis (CofA) to confirm each lot has been

tested in accordance with and has met the approved Specifications. At a minimum, the CofA will contain the following information:

- Ø Product/Lot description/name
- Ø Lot number
- Ø Test method name
- Ø Corresponding test method procedure number
- Ø Test method acceptance criteria as applicable (e.g. specific value(s), range of values, or pass/fail)
- Ø Actual test result
- Ø An indication of whether the actual test result represents a “Pass” or “Fail” result when compared to the test method acceptance criteria.
- Ø Attestation of lot conformance to release specifications
- Ø Signature/Date of a responsible Quality representative

7.3.6. All In-Process and Release Testing results are to be reviewed and approved by the appropriate Talecris Quality Management.

7.4 Retain Samples

7.4.1. Talecris is responsible for storing retain samples of the Bulk Drug Substance and Final Drug Product per 21 CFR Part 211.170.

7.5 Stability Testing

7.5.1. Talecris is responsible for conducting stability studies on the Finished Product, and identifying the batch number and quantity of samples for the lots to be tested.

7.5.2. Stability protocols will be generated by Talecris and approved by Talecris and Emergent.

7.5.3. Stability reports will be generated by Talecris and approved by Talecris and Emergent. Emergent will be responsible for any required action as a result of the stability data.

7.6 Out-of-Specification (OOS) Investigations

7.6.1. Talecris is responsible for investigating any in-process or Finished Product testing performed by Talecris that fails to meet approved specifications. Talecris will notify a designated Emergent Quality representative per the requirements for notification of deviations as outlined in Section 8.1.

7.6.1.1. Each OOS investigation will be reviewed by Talecris designated Quality representative(s), and will follow the procedures defined in appropriate Talecris SOPs for OOS Investigations.

7.6.1.2. For each confirmed Finished Product OOS result in which the investigation has not determined a root cause, Emergent will be allowed to review the investigation and approve the proposed re-test plan prior to any re-testing being performed.

7.6.1.3. For each OOS result in which the investigation has determined a root cause, Emergent reserves the right to review the

investigation and will be notified by Talecris of the intent to re-test prior to any re-testing being performed.

7.6.2. Emergent is responsible for investigating any in-process or Finished Product testing performed by Emergent that fails to meet approved specifications. Emergent will notify a designated Talecris Quality representative per the requirements for notification of deviations as outlined in Section 8.1.

7.6.2.1. Each OOS investigation will be reviewed by Emergent designated Quality representative(s), and will follow the procedures defined in appropriate Emergent SOPs for OOS Investigations.

7.6.3. Talecris shall retain final authority for the content of investigation reports for testing performed by Talecris and directly related to the [**] manufacture.

7.6.4. Emergent shall retain final authority for the content of investigation reports for product-specific testing performed by Emergent for all stages of manufacture.

7.6.5. Copies of all completed investigation reports will be included in the released, executed production batch record documentation provided to Emergent.

8. QUALITY ASSURANCE

8.1 Deviations and Investigations

8.1.1. Deviation and Investigation Reports – Any deviation from the process during manufacture, including but not limited to, batch record execution, environmental monitoring excursions or aseptic processing procedures, must be documented and investigated per Talecris approved procedures for conducting non-conformance investigations.

8.1.1.1. All non-conformance investigations will include an explanation of the non-conformance event, root cause analysis, impact assessment and corrective/preventive actions.

8.1.1.2. All non-conformance investigations directly related to the manufacture of Finished Product must be approved by Talecris Quality and the affected area management, and be included in the released, executed production batch record.

8.1.1.3. Any non-conformance event which has the potential to impact the safety, identity, strength, purity, or quality of the Finished Product will be communicated to Emergent Quality not more than [**] working days after discovery.

8.1.1.4. Emergent Quality will have the right to participate in and approve any investigation associated with a non-conformance event which has the potential to impact the safety, identity, strength, purity, or quality of the Finished Product.

8.1.2. Talecris will provide notification to Emergent and investigate any adverse trends, including review of media fills and environmental monitoring data, which may directly impact Finished Product, either in process or that has previously shipped to Emergent, within [**] working days of initiation of the investigation.

8.2 Batch Disposition Documentation

8.2.1. Talecris is responsible for the review and final approval of the executed batch record(s) associated with [**].

8.2.2. For each lot of [**] manufactured by Talecris for Emergent, Talecris will provide Emergent with the following documentation:

- Ø Certificate of Conformance
- Ø Certificate of Analysis (excluding testing performed by Emergent)
- Ø A summary of non-conformances (i.e. deviation and/or OOS)
- Ø Copies of any non-conformances that have been determined to have potential impact on the safety, identity, strength, purity, or quality of the [**]
- Ø Lot Release Certificate signed by Talecris Quality

8.2.3. Prior to shipment, Talecris is responsible for the review and approval of the executed batch production record(s) associated with each lot of Finished Product manufactured for Emergent.

8.2.4. For each lot of Finished Product manufactured for Emergent, Talecris will provide Emergent with the following documentation:

- Ø A copy of the product-specific executed production batch record(s), from the [**] forward, reviewed and approved by Talecris Quality
- Ø Certificate of Conformance
- Ø Certificate of Analysis (excluding testing performed by [**])
- Ø A summary of non-conformances (i.e., deviation and/or OOS)
- Ø Copies of any non-conformances which have been determined to have potential impact on the safety, identity, strength, purity, or quality of the Finished Product

8.2.5. Emergent must authorize in writing [**] any lot of Finished Product [**] by Talecris prior to its disposition.

8.3 Product [**]

8.3.1. [**] is the sole responsibility of Talecris.

8.3.2. [**] is the sole responsibility of Emergent.

8.3.3. Any issue(s) discovered by Emergent associated with production batch record documentation, disposition documentation or samples provided to Emergent by Talecris that may impact or prevent the final release of the Finished Product, or that has the potential to cause the rejection of Finished Product by Emergent, will be communicated to Talecris by Emergent within [**] of discovery. Talecris is responsible for working with

Emergent in the conduct of any additional investigations that may be warranted to resolve the issue(s).

8.4 Records Retention

8.4.1. Talecris will retain production batch records for all stages of the manufacture of Finished Product for a minimum of at least one (1) year after the expiration date of corresponding lot of Finished Product or for such longer period as may be required by applicable law.

8.4.2. Talecris will not destroy any batch production records or associated documentation without obtaining written approval from Emergent prior to destruction.

8.5 Manufacturing and Quality Presence in the Manufacturing Facility

8.5.1. Talecris will maintain adequate, qualified Manufacturing and Quality personnel to ensure compliance with cGMP and the consistent manufacture of Finished Product.

8.5.2. Talecris will permit Emergent representatives to be present at the facility during the manufacture of Finished Product for observational purposes only. This presence will be limited to the manufacture of the initial Validation Lots. These visits will be pre-arranged by mutual consent.

8.6 Product Complaints

8.6.1. Emergent is responsible for receiving and [**].

8.6.2. Emergent will notify Talecris within [**] of discovery of any complaints potentially associated with [**]. This notification may include a request for Talecris to initiate [**].

8.6.3. In the event [**] becomes aware of a complaint [**], including [**] will notify [**] within [**] hours of becoming aware of the complaint.

8.6.4. Talecris will initiate an [**] within [**] of an Emergent request, for any complaint associated with [**] will be forwarded to Emergent Talecris within thirty (30) calendar days of [**]. Extensions for the completion of the [**] Talecris, along with justification for the extension and a proposed completion date, within the initial thirty (30) calendar day period.

8.7 Product Recalls

8.7.1. Emergent retains final decision making authority for product recalls associated with [**].

8.7.2. Each party will notify the other party within [**] of (a) receipt of notification, written or otherwise, if any lot of [**] is alleged or proven to be the subject of a recall, market withdrawal or correction or (b) either party's determination that a recall may be warranted.

8.7.3. Emergent is responsible for instituting a recall of [**]. Emergent will notify Talecris of any recall decision within [**] of initiation if the recall is associated with the manufacture of the [**].

8.7.4. [**] issued by Talecris associated with the [**] of the recall [**] will be forwarded to Emergent within [**] after receipt of request. Extensions may be requested by Talecris, with justification and a proposed completion date, within the initial [**] period.

8.8 Adverse Events

8.8.1. Emergent shall advise Talecris of any adverse medical event or adverse drug event within [**] of Emergent receipt of notice thereof if thought to be due to manufacture of Finished Product.

8.8.2. Talecris will initiate an internal investigation within [**] of an Emergent notification of any adverse medical event or adverse drug event potentially associated with the manufacture of the Finished Product.

8.8.3. Investigation reports will be forwarded to Emergent by Talecris within [**] of initiation of the Talecris investigation. Extensions for the completion of the investigation may be requested by Talecris, along with justification for the extension and a proposed completion date, within the initial [**] period.

8.9 Look-Back Process for AIG source plasma provided by Emergent to Talecris under contract.

8.9.1. Emergent will arrange for the Plasma Collection Centers to notify Talecris and Emergent directly in the event a look-back notification occurs.

8.9.2. Talecris will investigate and act upon look-back notifications per approved procedures and policies.

8.9.3. For look back events affecting non-pooled [**], Talecris will provide Emergent documentation of destruction of the units identified on the notification (unit number/volume, donor number, date of destruction).

8.9.4. For look back events affecting pooled/processed plasma, Talecris will provide documentation to include the plasma pool date, associated product lot number(s), and the corresponding product impact assessment.

9. REGULATORY COMPLIANCE

9.1 Regulatory Inspections

9.1.1. Talecris will permit access by the Regulatory Authorities, as defined in the Product Supply Agreement, to Talecris premises. Talecris will inform Emergent of any announced regulatory inspections that involve the Finished Product within [**], to permit Emergent to be present on site during the inspection.

9.1.2. Talecris will immediately inform Emergent of any unannounced regulatory inspections that involve the Finished Product. Talecris will permit an Emergent representative to be present on site during the inspection involving Finished Product.

9.1.3. Talecris will secure the agreement of Emergent prior to making any commitment to a Regulatory Authority specifically regarding Finished

Product. Emergent shall be provided with draft responses to regulatory observations that directly involve the Finished Product and may provide comments to the responses and corrective actions within [**]. Emergent shall retain the final authority and responsibility for the content of responses directly related to Finished Product.

9.1.4. Talecris will forward to Emergent any observations and associated responses from a routine regulatory inspection directly related to Finished Product. Talecris reserves the right to appropriately redact this documentation to preserve client confidential information.

9.1.5. Emergent will inform Talecris in writing of any regulatory issues that impact Talecris' ability to manufacture the Finished Product.

9.2 Regulatory Actions

9.2.1. Talecris will notify Emergent in writing of any regulatory actions received by Talecris related to the Finished Product or regulatory actions received by Talecris that impact Talecris ability to manufacture the Finished Product.

9.2.2. Emergent will notify Talecris in writing of any regulatory actions received by Emergent related to the Finished Product or regulatory actions received by Emergent that impact Talecris ability to manufacture the Finished Product.

9.2.3. Talecris is responsible for supporting all investigations associated with regulatory actions related to the manufacture of the Finished Product.

9.3 Right to Audit

9.3.1. Talecris will permit Emergent to perform one standard cGMP compliance audit per year.

9.3.1.1. Talecris will allow representatives from Emergent to have access to Talecris manufacturing, warehousing, laboratory premises, records, regulatory filings and communications (i.e., FDA Form 483) directly associated with the manufacture of Finished Product for audit purposes provided, however, that Talecris has the obligation to protect the confidential information of its clients.

9.3.2. Talecris will permit Emergent to conduct "for cause" audits to address significant Finished Product quality or safety issues as discovered through Finished Product failures or complaints and determined to be potentially related to the manufacture of the Finished Product.

9.4 Emergent may audit with the presence of Talecris any subcontractors that are utilized by Talecris in the manufacture of the Finished Product. Talecris will use reasonable efforts to cause such vendors, contractors or subcontractors to allow such audits.

9.5 Audit Closeout

9.5.1. For audits of Talecris conducted by Emergent, an exit meeting will be held with representatives from Talecris and Emergent to discuss audit observations.

9.5.2. Emergent will provide a written report of all observations within thirty (30) calendar days to Talecris. Within thirty (30) calendar days of the audit report receipt, Talecris will provide a written response to all findings that details corrective action to be implemented. Talecris will follow up to ensure that all corrective actions are implemented.

10. DISPUTE RESOLUTION

10.1 Non-Conformity of [**]

10.1.1. In the event that a dispute arises between Talecris and Emergent regarding the conformity of a lot of [**], the resolution will proceed as follows:

10.1.1.1. Direct communication between the Quality units from both parties will occur who will in good faith promptly attempt to reach an agreement.

10.1.1.2. If direct communication between the Quality units from both parties does not resolve the dispute and Talecris Quality Unit considers the disputed lot to be in conformance, Talecris Quality retains sole authority over final disposition of the [**] lot; however Emergent retains the right to reject the lot.

10.2 Test Result Conflict

10.2.1. In the event that a dispute arises between Talecris and Emergent regarding test results obtained during the manufacture and release of product lots, the resolution will proceed as follows:

10.2.1.1. Talecris and Emergent will determine that the methods of analysis are the same and are being executed in the same manner at both sites.

10.2.1.2. If the investigation dictates, carefully controlled and split samples shall be sent from one site to another in an attempt to reach agreement.

10.2.1.3. Analysts from both Talecris and Emergent shall be required to work side by side through the analysis of a mutually agreeable sample.

10.2.1.4. If resolution is not achieved after following the foregoing procedure, the samples shall be sent to an independent,

qualified testing laboratory agreed upon by both Talecris and Emergent. Talecris and Emergent shall agree to be bound by the results obtained by the independent laboratory.

11. CHANGE MANAGEMENT

11.1 Changes to the Process, Documents or Facility are to be processed using Talecris approved Change Control procedures.

11.1.1. All proposed changes must document, at a minimum, the proposed change, the reason/justification for the proposed change, the target date for implementation of the proposed change, an impact assessment, and documentation of pre- and post- validation or qualification requirements. The assessment of impact must include an impact of the proposed change on any regulatory filings and any required notification to regulatory authorities.

11.2 Talecris shall not make any change to the Process, Documents or any Facility (other than routine maintenance, reconditioning and/or replacement of the equipment) that would reasonably be expected to have a negative impact on [**] or Finished Product or require submissions to or approvals from any Regulatory Authority with respect to the source plasma or Finished Product, except by prior written approval of Emergent.

11.2.1. Emergent will assess proposed changes requiring Emergent signature within [**] and those changes marked urgent within [**].

11.2.2. Completed change control documentation requiring Emergent approval shall be included as part of the Production Batch Record documentation forwarded to Emergent.

11.2.3. Proposed changes initiated by Emergent must be approved by Talecris and Emergent.

12. PRODUCT AND PROCESS VALIDATION

12.1 Equipment and Process Validation– Talecris is responsible for ensuring that all necessary equipment and process validations are conducted as required by cGMP and other Regulatory Guidance Documents for the manufacture of Finished Product.

12.2 Cleaning Verification/Validation – Talecris is responsible for ensuring that adequate cleaning of product contact parts used in the manufacture of Finished Product is carried out between batches of different product to prevent cross contamination.

12.3 Sterilization and Depyrogenation Validation – Talecris is responsible for ensuring that sterilization processes are validated and that adequate sterilization and depyrogenation, as applicable, is carried out on the components and appropriate equipment prior to the manufacture of each batch of Finished Product.

12.4 Equipment, Computer, Facility, and Utilities Qualification – Talecris is responsible for ensuring that any equipment, computer, facility, utility and support system used for the manufacture of Finished Product are qualified according to applicable regulatory requirements.

12.5 Assay Validation – Talecris is responsible for ensuring that all testing performed by Talecris related to Finished Product is conducted using appropriately validated assays. Emergent is responsible for ensuring that all testing performed by Emergent related to Finished Product is conducted using appropriately validated assays.

12.6 For any test methods specifically for Finished Product conducted by a Third Party laboratory contracted by Talecris, and approved by Emergent, Talecris is responsible for ensuring the required validation work is performed.

12.7 For any test methods conducted by a Third Party laboratory contracted by Emergent, Emergent is responsible for ensuring the required validation work is performed. Talecris will have the right to audit such labs jointly with Emergent upon request.

12.8 Packaging/Labeling/Shipping Qualification – Emergent is responsible for the packaging configuration and shipping validation for Finished Product.

13. NOTIFICATION OF NEW PRODUCT CLASSIFICATION

13.1 Talecris will notify Emergent [**] prior to introduction of a new product classification into the production areas used for the manufacture of Finished Product.

14. ANNUAL PRODUCT REVIEW, ANNUAL REPORT AND DRUG LISTING

14.1 Talecris will be responsible for providing reports as requested by Regulatory Authorities under the “shared license agreement”.

14.1.1. Annual Product Review –On an annual calendar-year basis, Talecris will prepare summary data for Finished Product processed within the prior calendar year. Such data will be prepared and sent to Emergent within [**] (unless otherwise agreed by Talecris and Emergent) of the end of the applicable calendar year during which the Finished Product was Processed hereunder. This data will include [**].

14.1.2. Annual Report – Emergent is responsible for preparing any Annual Reports for Investigational New Drugs and Licensed Product as required by applicable regulations. At least [**] before the Annual Report due date, Emergent shall request in writing from Talecris any information required by the regulations that must be provided by Talecris, including but not limited to a summary of any significant manufacturing or microbiological changes made during the past reporting year. Talecris will provide the requested information to Emergent within [**].

APPENDIX I – List of Contacts *
(Name, Phone, Fax, E-mail)

AREA OF RESPONSIBILITY	Emergent BioSolutions Inc.	Talecris Biotherapeutics, Inc.
Product Development	James McIver Ph: (301) 944-0149 Fax: (301) 590-1251 McIverJ@ebsi.com	Deborah Barnette Ph: (919)359-4601 Fax: (919)359-4280 deborah.barnette@talecris.com
Manufacturing	James McIver Ph: (301) 944-0149 Fax: (301) 590-1251 MciverJ@ebsi.com	Jerry Sellers Ph: (919)359-4533 Fax: (919)359-5462 jerry.sellers@talecris.com
Quality Control	Edward Arcuri Ph: (301) 944-0109 Fax: (301) 944-0173 ArcuriE@ebsi.com	Wayne Zunic Ph: (919)359-4601 Fax: (919)359-4431 wayne.zunic@talecris.com
Audits	Joy Dumont Ph: (517) 327-1655 Fax: (517) 327-7207 DumontJ@ebsi.com	Barbara Sneade Ph: (919)359-4415 Fax: (919)359-4677 barbara.sneade@talecris.com
Validation	Edward Arcuri Ph: (301) 944-0109 Fax: (301) 944-0173 ArcuriE@ebsi.com	Frank Highsmith Ph: (919)359-7251 Fax: (919)359-4000 frank.highsmith@talecris.com
Regulatory	Virginia Johnson Ph: (301) 944-0139 Fax: (301) 590-1252 JohnsonV@ebsi.com	Joan Robertson Ph: (919)359-7128 Fax: (919)359-7154 joan.robertson@talecris.com
Product Complaints / Adverse Events	Robert Hopkins Ph: (301) 944-0136 Fax: (301) 944-1252 HopkinsR@ebsi.com	Mary Ann Lamb Ph: (919)359-7143 Fax: (919)359-7304 maryann.lamb@talecris.com
Quality Assurance	Edward Arcuri Ph: (301) 944-0109 Fax: (301) 944-0173 ArcuriE@ebsi.com	John Parrish Ph: (919)359-4592 Fax: (919)550-4886 john.parrish@talecris.com

* All correspondence should be directed to David Sorrell of Talecris and Nili Leffers of Emergent

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	 Talecris	 [**] Emergent	 Talecris
GENERAL COMPLIANCE / REGULATORY	[**]	[**]	[**]	[**]
a. License holder with respect to Shared Manufacturing License process b. Compliance with US CFR / cGMP regulations during manufacture				
BATCH RECORDS	[**]	[**]	[**]	[**]
a. Write Master Production Records b. Review Master Production Records c. Approve Master Production Records d. Approval of changes to Master Batch Records that would have an effect on product e. Provide copies of approved Master Production Records and executed Production Batch Records f. Record Retention (original documents – Master Batch Records and executed Batch Records)				
MATERIAL CONTROLS	[**]	[**]	[**]	[**]
a. Responsibility to ensure source AIG plasma meets established plasma specification b. Responsibility to ensure all components and raw materials used in the manufacturing process meet pre-approved specifications				
SUBCONTRACTING	[**]	[**]	[**]	[**]
a. Notification of intent/need to subcontract b. Right to audit potential subcontractor accompanied by Talecris c. Prior approval to initiate subcontracting				
REPROCESSING / REWORK PER VALIDATED PROCEDURES AND LICENSE	[**]	[**]	[**]	[**]
a. Rework according to Talecris and Emergent approved license and validated procedures				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	 Talecris	 [**] Emergent	 Talecris
SPECIFICATIONS	[**]	[**]	[**]	[**]
a. Product Specifications, [**]				
b. Product Specification – [**]				
c. Labeling and packaging components				
d. Packaging inserts				
e. Compatibility with equipment				
STABILITY – Finished Product	[**]	[**]	[**]	[**]
a. Writing stability protocol				
b. Approving stability protocol				
c. Collection / storage of stability samples				
d. Testing – [**]				
e. Stability data interpretation – [**]				
f. Testing – [**]				
g. Writing stability report				
h. Approving stability report				
i. Establish expiration date/shelf life				
PRODUCT RETAINS	[**]	[**]	[**]	[**]
a. Identification of samples to be retained				
b. Approval of samples to be retained				
c. Retention / storage of samples at appropriate storage conditions				
d. Final disposition of retain samples				
PRODUCT RELEASE	[**]	[**]	[**]	[**]
a. Initial review of completed Batch Record				
b. Final review / approval of completed Batch Record				
c. Issuance/Approval of Certificate of Conformance				
d. Issuance/Approval of Certificate of Analysis [**]				
PRODUCT RELEASE continued				
e. Issuance of Certificate of Analysis [**]				
f. Lot Release				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	[**] Talecris	[**] Emergent	[**] Talecris
NON-CONFORMANCE EVENTS	[**]	[**]	[**]	[**]
Deviations				
a. Documentation of non-conformance event per established SOP's				
b. Notification to Emergent of non-conforming event [**]				
c. Investigation of non-conforming event and identifying appropriate CAPA's				
d. Approval of non-conforming event [**]				
OOS – Assays performed by Talecris [**]				
e. Documentation of OOS per established SOP's				
f. Notification to Emergent of confirmed OOS event with established root cause				
g. Review of confirmed OOS and retest plan with established root cause				
h. Investigation of OOS event and identification of appropriate CAPA's including proposed re-test plans				
i. Review of confirmed OOS event and re-test plan where **no** assignable root cause is established				
j. Approval of confirmed OOS event and re-test plan where **no** assignable root cause is established				
OOS – Assays performed by Emergent [**]				
k. Documentation of OOS per established SOP's				
l. Notification to Talecris of confirmed OOS event				
m. Investigation of OOS event and identification of appropriate CAPA's including proposed re-				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	 Talecris	 [**] Emergent	 Talecris
test plans n. Approval of OOS event and re-test plan				
AUDITING / MAN-IN-PLANT	[**]		[**]	[**]
a. Right to conduct scheduled routine audits of facility and quality systems not to exceed one (1) occurrence per year b. Right to conduct “for cause” audits of facility and quality systems as needed in response to specific noncompliance events [**] c. Right to maintain “man-in-plant” presence during process start up and execution of validation lots				
ADVERSE EVENTS / PRODUCT COMPLAINTS	[**]	[**]	[**]	[**]
a. Regulatory notification of AE’s Complaints as required by regulations b. Lead in AE / Complaint investigations c. Assistance in conducting AE / Complaint investigations, including manufacturing investigation d. Final written report for AE / Complaints e. Approval of report				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	 [**] Talecris	 [**] Emergent	 [**] Talecris
PRODUCT RECALL	[**]	[**]	[**]	[**]
a. Final Decision – [**]				
b. Notification of other Company regarding recall decision				
c. Notification of potential event that may initiate recall				
d. Impact of recall on Talecris filings				
e. Impact of recall on Emergent filings				
f. FDA notification of recall				
g. Management of recall event				
“LOOK BACK” PROCESS	[**]	[**]	[**]	[**]
a. Plasma collection center notification for look backs involving units at Talecris				
b. Tracing of plasma units effected by look back				
c. Destruction of plasma units not yet processed and documentation of destruction				
d. Supplying documentation of plasma unit destruction to Emergent				
e. Product impact assessment involving plasma units that have been processed				
f. Supply copies of documentation to include plasma pool date and product lot number(s) for processed/pooled plasma				
REGULATORY	[**]	[**]	[**]	[**]
a. Single IND Submission by Emergent for AIG Product				
b. BLA Submission				
c. Notification of any regulatory action which could affect finished product				
d. Providing regulatory advice as needed related to process related to Emergent filings				
e. Communications to Regulatory Authorities concerning Finished Product				
REGULATORY INSPECTIONS	[**]	[**]	[**]	[**]
a. Notification of regulatory inspection by FDA, EU				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	[**] Talecris	[**] Emergent	[**] Talecris
Regulatory agency or other governmental agency in conjunction with the facilities, processes or quality systems used to manufacture or support Emergent finished product.				
b. Ability to maintain site presence during inspection [**]				
c. Approval of corrective actions associated with identified deficiencies or observations resulting from inspections [**]				
d. Review and approval of corrective actions associated with identified deficiencies or observations resulting from inspections [**]				
e. Submission of corrective actions to inspecting Authority				
BIOLOGICAL PRODUCT DEVIATIONS	[**]	[**]	[**]	[**]
a. Final Decision – submission of BPDR related to distributed product				
b. Submission of BPDR				
c. Lead – investigation for BPDR				
d. Assistance – investigation including manufacturing investigation				

APPENDIX II
Summary of Responsibilities

Topic	RESPONSIBILITY Stage(s) of Manufacturing [**] Emergent	[**] Talecris	[**] Emergent	[**] Talecris
CHANGE MANAGEMENT	[**]	[**]	[**]	[**]
Talecris Initiated				
a. Approval of changes to facility or Gamunex process, including testing and specifications , that do not impact [**]				
b. Notification of non-routine changes to facility or Gamunex process, including testing and specifications, that have the potential to impact [**]				
c. Review and approval of non-routine changes to facility or Gamunex process, including testing and specifications, that have the potential to impact [**]				
d. Review of changes to facility or Gamunex process, including testing and specifications, required to maintain compliance to GMP during audit(s)				
e. Approval of changes to facility or Gamunex process, including testing and specifications, required to maintain GMP				
Emergent Initiated				
f. Approval of changes to process including specifications that do not impact facilities or Gamunex process				
g. Notification of changes to process including specifications that have the potential to impact facilities or Gamunex process				
h. Approval of changes to process including specifications that have the potential to impact facilities or Gamunex process				

APPENDIX II
Summary of Responsibilities

	RESPONSIBILITY			
	Stage(s) of Manufacturing			
	[**]		[**]	
Topic	**Emergent**	**Talecris**	**Emergent**	**Talecris**
VALIDATION	[**]	[**]	[**]	[**]
a. Maintaining validated state of facility and equipment used for Gamunex [**]				
b. Writing Process Validation Protocol				
c. Approval of Process Validation Protocol				
d. Writing Process Validation Report				
e. Approving Process Validation Report				
ANNUAL PRODUCT REVIEW / ANNUAL REPORT		[**]	[**]	[**]
a. Preparation of summary data for Emergent Annual Product Review Report				
b. Annual Product Review final report				
c. Submission of Annual Report to FDA				

EXHIBIT G

June 12, 2006

Mr. James A. Moose
Sr. Vice President
Talecris Biotherapeutics, Inc.
P.O. Box 110526
4101 Research Commons
79 T.W. Alexander Drive
Research Triangle Park, NC 27709

Re: Exclusivity Agreement

Dear Jim,

Reference is hereby made to the Product Supply Agreement ("Supply Agreement"), dated as of June 12, 2006, by and between Emergent Product Development Gaithersburg Inc. ("Emergent") and Talecris Biotherapeutics, Inc. ("Talecris"). This letter ("Letter Agreement") sets forth the understanding between Emergent, including Emergent BioSolutions Inc., and any and all Affiliates, and Talecris and Precision Pharma Services, and any and all Affiliates regarding each Party's noncompete and/or exclusivity obligations in connection with the Supply Agreement. Capitalized terms used herein but not otherwise defined herein shall have the meanings given to them under the Supply Agreement.

1. Talecris Restrictions.

(a) During the Term of the Supply Agreement, Talecris shall have the right to research, develop and obtain regulatory approval for any pharmaceutical product that contains AIG as an active ingredient ("Competing Product"), other than the Finished Product (as defined in the Supply Agreement), either by itself or in collaboration with or on behalf of a Third Party. Notwithstanding the foregoing, at all times during the Term of the Supply Agreement, Talecris shall not, and shall cause its Affiliates not to do either of the following
(except pursuant to the Supply Agreement):

(i) detail, promote, market, offer to sell, sell or otherwise dispose of any Competing Product in the Territory, either by itself or in collaboration with or on behalf of a Third Party; or,

(ii) acquire directly or indirectly any rights or interest in or to any Competing Product which is detailed, promoted, marketed, offered for sale, sold or otherwise disposed of in the Territory.

(b) In the event that Talecris elects to terminate the Supply Agreement pursuant to Section 10.02(b) thereof (Elective Termination by Talecris):

(i) the restrictions set forth in paragraph 1(a) above shall terminate upon the second (2nd) anniversary of the Talecris Elective Termination Notice; and

(ii) the restrictions set forth in paragraphs 2(a) and 2(b) below shall terminate on the date of delivery to Emergent of the Talecris Elective Termination Notice.

2. Emergent Restrictions.

(a) Pursuant to Section 4.01(c) (Pre-Commercial Target Yield) of the Supply Agreement, should the Parties mutually determine that the Target Yields have been met, or if the Parties mutually determine that the IgG Yields have failed to meet the Target Yields but Emergent's designated Third Party fails to achieve an AIG specific IgG Yield of at least [**] percent ([**]%) greater than Talecris' AIG specific IgG Yield, Emergent shall not purchase commercial supplies of Competing Product or Finished Product from a Third Party other than Talecris, from the Effective Date until the later of the end of (i) the Term of the Supply Agreement, or (ii) the Exclusivity Extension Period (as defined in paragraph 3 below). For the avoidance of doubt, Emergent may research, develop and obtain regulatory approval for any pharmaceutical product that contains AIG as an active ingredient, either by itself or in collaboration with or on behalf of a Third Party.

(b) Subject to Section 4.04 (Alternative Supplier) of the Supply Agreement, Emergent shall not purchase commercial supplies of Competing Product or Finished Product, from a Third Party other than Talecris, from the Effective Date until the later of the end of (i) the Term of the Supply Agreement, or (ii) the Exclusivity Extension Period. For the avoidance of doubt, Emergent may research, develop and obtain regulatory approval for any pharmaceutical product that contains AIG as an active ingredient, either by itself or in collaboration with or on behalf of a Third Party.

(c) In the event that Emergent elects to terminate the Supply Agreement pursuant to Section 10.02(a) thereof (Elective Termination by Emergent), the restrictions set forth in paragraph 1(a) above shall terminate on the date of delivery to Talecris of the Emergent Elective Termination Notice and the restrictions set forth in paragraphs 2(a) and 2(b) above shall terminate upon the second (2nd) anniversary of the Emergent Elective Termination Notice.

(d) In the event that Emergent terminates the Supply Agreement pursuant to Section 10.02(e) (Supply Failure), Section 10.02(g) (Material Breach by Talecris), Section 10.02(i) (Pre-Commercial Failure) or Section 10.02(k) thereof (Safety Concerns), the restrictions set forth in paragraphs 2(a) and 2(b) above shall terminate upon the effective date of termination of the Supply Agreement as set forth therein.

(e) In the event that Emergent terminates the Supply Agreement pursuant to Section 10.02(j) thereof (Termination of AIG Program), the restrictions set forth in paragraphs 2(a) and 2(b) above shall terminate upon the later of (i) the end of the Term of the Supply Agreement, (ii) the fifth (5th) anniversary of the Effective Date of the Supply Agreement, or (iii) the end of any Exclusivity Extension Period. If, following termination of the Supply Agreement pursuant to Section 10.02(j) thereof but prior to the end of the period set forth in the immediately preceding sentence, Emergent proposes to purchase commercial supplies of Finished Product from Talecris, Emergent shall Notify Talecris of such proposal and Talecris shall have thirty (30) days from the date of such Notice to reinstate the Supply Agreement.

3. Extension. No later than [**] months prior to the end of the Initial Term, Emergent may Notify Talecris that Emergent accepts extension of the exclusivity period, in which case the Exclusivity Extension Period shall be deemed to be in effect. If no such Notice is given, the restrictions set forth in paragraph 1(a) shall terminate upon the conclusion of the Initial Term. The "Exclusivity Extension Period" shall mean the period commencing upon the conclusion of the Initial Term and ending on the fifth (5th) anniversary thereof.

4. No Amendment. Other than as expressly set forth in this Letter Agreement, this Letter Agreement shall in no way limit or modify either of the Parties' obligations under the Supply Agreement, or any other agreement between the Parties.

5. Governing Law. This Letter Agreement shall be governed by and construed and enforced in accordance with the laws of the United States and the internal laws of the State of New York, without regard to conflicts of laws principles.

If Talecris is in agreement with the foregoing provisions, please acknowledge its agreement on the enclosed copy of this letter and return the signed copy to us.

EMERGENT PRODUCT DEVELOPMENT
GAITHERSBURG INC.

By /s/ R. Don Elsey
Name: R. Don Elsey
Title: Treasurer

Agreed and acknowledged:

TALECRIS BIOTHERAPEUTICS, INC.

By /s/ [Illegible]
Name:
Title: Pres-CEO
Date: 06/16/06

Agreed and accepted by:

EMERGENT BIOSOLUTIONS INC.

By: /s/ Daniel J. Abdun-Nabi
Name: Daniel J. Abdun-Nabi
Title: SVP, Corporate Affairs, General Counsel
Date: June 20, 2006

EXHIBIT H

Summary of Stability Testing

Samples will be stored at [**] through [**] from date of manufacture (Table 1) and for accelerated stability tests, samples will be stored at [**] for [**] (Table 2).

Table 1 Stability testing to support storage at [**]°C

	Test Interval [**]								
Test	**Initial**	**[**]**	**[**]**	**[**]**	**[**]**	**[**]**	**[**]**	**[**]**	**[**]**
Appearance: color, clarity	X	X	X	X	X	X	X	X	X
pH (diluted)	X	X	X	X	X	X	X	X	X
Molecular Weight Distribution	X	X	X	X	X	X	X	X	X
Anticomplement Activity	X	X	X	X	X	X	X	X	X
Prekallikrein Activator (PKA)	X	X	X	X	X	X	X	X	X
[**]	X	X	X	X	X	X	X	X	X
[**]	X	X	X	X	X	X	X	X	X
[**]	X								X

Table 2 Accelerated stability testing ([**]°C)

	Test Interval, [**]				
Test	**Initial**	**[**]**	**[**]**	**[**]**	**[**]**
Appearance: color, clarity	X	X	X	X	X
pH (diluted)	X	X	X	X	X
Molecular Weight Distribution	X	X	X	X	X
Anticomplement Activity	X	X	X	X	X
Prekallikrein Activator (PKA)	X	X	X	X	X
[**]	X	X	X	X	X
[**]	X	X	X	X	X

Note: Protocols, procedures, timing and other terms to be further defined and agreed upon by the parties in advance of implementation.

EXHIBIT I

Talecris Gamunex Activities

[**]

EXHIBIT J

Category A, B and C Bioterrorism Agents

Category A (definition below)

- Anthrax (*Bacillus anthracis*)
- Botulism (*Clostridium botulinum* toxin)
- Plague (*Yersinia pestis*)
- Smallpox (variola major)
- Tularemia (*Francisella tularensis*)
- Viral hemorrhagic fevers (filoviruses [e.g., Ebola, Marburg] and arenaviruses [e.g., Lassa, Machupo])

Category B (definition below)

- Brucellosis (*Brucella* species)
- Epsilon toxin of *Clostridium perfringens*
- Food safety threats (e.g., *Salmonella* species, *Escherichia coli* O157:H7, *Shigella*)
- Glanders (*Burkholderia mallei*)
- Melioidosis (*Burkholderia pseudomallei*)
- Psittacosis (*Chlamydia psittaci*)
- Q fever (*Coxiella burnetii*)
- Ricin toxin from *Ricinus communis* (castor beans)
- Staphylococcal enterotoxin B
- Typhus fever (*Rickettsia prowazekii*)
- Viral encephalitis (alphaviruses [e.g., Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis])
- Water safety threats (e.g., *Vibrio cholerae*, *Cryptosporidium parvum*)

Category C (definition below)

- Emerging infectious diseases such as Nipah virus and hantavirus

Category Definitions

Category A Diseases/Agents

The U.S. public health system and primary healthcare providers must be prepared to address various biological agents, including pathogens that are rarely seen in the United States. High-priority agents include organisms that pose a risk to national security because they

- can be easily disseminated or transmitted from person to person;
- result in high mortality rates and have the potential for major public health impact;

- might cause public panic and social disruption; and
- require special action for public health preparedness.

Category B Diseases/Agents

Second highest priority agents include those that

- are moderately easy to disseminate;
- result in moderate morbidity rates and low mortality rates; and
- require specific enhancements of CDC's diagnostic capacity and enhanced disease surveillance.

Category C Diseases/Agents

Third highest priority agents include emerging pathogens that could be engineered for mass dissemination in the future because of

- availability;
- ease of production and dissemination; and
- potential for high morbidity and mortality rates and major health impact.

Source: Center for Disease Control and Prevention (CDC)

EXHIBIT K

Studies to be Conducted for Emergent

1. The Container Closure Study is no longer applicable.
2. Details of the Process Validation Study is attached.

Talecris BIOTHERAPEUTICS

CLAYTON, NC

PROCESS VERIFICATION
OF
ANTHRAX IMMUNE GLOBULIN INTRAVENOUS (AIGIV)
FOR EMERGENT PRODUCT DEVELOPMENT GAITHERSBURG INC

Buildings [**]

PROTOCOL
[**]
7/21/2006
[**]

Document Attributes:
Building [**], Anthrax IGIV, CCF#2006395

PROTOCOL APPROVAL SIGNATURES

Signatures below indicate that contents related to the individual areas of responsibility have been reviewed and found to be acceptable. Emergent approvals are included on page 3.

Author — Date
/s/ Erin Sorrell — 7-21-06
Print Name and Title: Erin Sorrell, Validation Specialist

Reviewer:

Regulatory Affairs — Date
/s/ Joan Robertson — 7/21/06
Print Name and Title: Joan Robertson, Deputy Director, Regulatory Affairs

Talecris Approvers:

Qualification and Validation Engineering — Date
/s/ Jeff Crane — 7/21/06
Print Name and Title: Jeff Crane, Validation Manager

Technical Operations - Fractionation — Date
/s/ Joe Barbour — 07/24/06
Print Name and Title: Joe Barbour, Manager Production II

Technical Operations - Gamunex — Date
/s/ Jonathan Kent — 07/24/06
Print Name and Title: Jonathan Kent, Technical Support Manager

Technology — Date
/s/ Douglas B. Burns — 7/24/06
Print Name and Title: Doug Burns, Sr. Process Development Engineer II

Quality Operations - Fractionation — Date
/s/ Amy W. Durham — 7-24-06
Print Name and Title: Amy Durham, Manager Quality

Quality Operations - Gamunex — Date
/s/ Cherilyn Metzler for Clara Schreiner — 7-24-06
Print Name and Title: Clara Schreiner, Manager Quality

PROTOCOL APPROVAL SIGNATURES (Continued)

Signatures below indicate that contents related to the individual areas of responsibility have been reviewed and found to be acceptable.

Emergent Product Development Gaithersburg Inc Approvers:

Representative	Date
/s/ Jim Molver	24 July 2006
Print Name and Title: Jim Molver, Project Leader	

Representative	Date
/s/ [illegible]	24 July 2006
Print Name and Title: Mike Cowan, VP of Quality	

TABLE OF CONTENTS

1. PURPOSE

1.1. The purpose of this Process Verification (PV) protocol is to document the ability to manufacture Anthrax Immune Globulin (AIG) for Emergent Product Development Gaithersburg Inc (hereafter referred to as Emergent) from Source Plasma obtained from immunized donors in the Fractionation Facility, Building [**] and the IGIV Chromatography Facility, Building [**], at the Talecris Biotherapeutics Division in Clayton, NC.

2. SCOPE AND RATIONALE

2.1. The scope of this study is to verify that the [**] are capable of [**]. Emergent will [**] and will provide the plasma to Talecris. The source plasma must meet all FDA and Talecris requirements. The protocol requires samples at various points throughout the production process from plasma pool to final container. Additionally, all Batch Production Record (BPR) requirements must be met. The rationale for this approach is based on the following documents used to validate the existing fractionation and purification processes:

2.1.1 [**].

2.1.2 [**].

2.2. Study Design

2.2.1. [**].

2.2.2. [**].

2.2.3. [**].

2.2.4. [**].

3. REFERENCES

3.1. Validation Procedures and Documents

[**] [**]

[**] [**]

[**] [**]

[**] [**]

[**] [**]

[**] [**]

3.2. Standard Operating Procedures

[**] [**]

[**] [**]

[**] [**]

[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

3.3. Manufacturing Procedures - Batch Production Records

[**]	[**]
[**]	[**]
[**]	[**]

[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

4. ACRONYMS AND DEFINITIONS

Acronym	Definition
AIG	Anthrax Immune Globulin
AIGIV	Anthrax Immune Globuiin Intravenous
BPR	Batch Production Record
C	Celsius
CV	Column Volumes
CWFI	Cold Water For Injection
CZE	Capillary Zone Electrophoresis
EIA	Enzyme Immunoassay
HPLC	High Performance Liquid Chromatography
IGIV-C	Immunoglobulin Intravenous Chromatography
[**]	[**]
ITS	Incident Tracking System
kg	Kilograms
NLT	Not Less Than
NMT	Not More Than

OOS	Out Of Specification
PKA	Prekallikrein Activator
PV	Process Verification
QOPQM	Quality Operations — Product Quality Management
QOSCL	Quality Operations — Supply Chain Laboratory
QVE	Qualification and Validation Engineering
[**]	[**]
[**]	[**]
SOP	Standard Operating Procedure
[**]	[**]
[**]	[**]

5. RESPONSIBILITIES

5.1. Qualification and Validation Engineering.

5.1.1. Prepares protocol, final report and final report packet.

5.1.2. Coordinates the execution of the protocol including non-routine sampling with all involved groups.

5.1.3. Reviews all data collected during the execution for completeness and compliance with acceptance criteria.

5.1.4. Verifies that any incidents encountered during execution are documented and resolved in accordance with [**].

5.1.5. Reviews and approves the verification protocol, interim reports, and final report for quality, accuracy, and completeness. 5.2. Regulatory Affairs

5.2.1. Reviews the process verification protocol, interim reports, and final report for quality, accuracy, and completeness.

5.3. Technical Operations

5.3.1. Reviews and approves the process verification protocol, interim reports, and final report for quality, accuracy, and completeness.

5.3.2. Assists QVE in the execution of the protocol, including scheduling the lots and collecting samples,

5.4. Supply Chain / Materials Management

5.4.1. Schedules PV runs.

5.5. Engineering

5.5.1. Maintains all associated instruments in a calibrated state during the execution of this protocol.

5.5.2. Assists QVE in obtaining documentation required for the completion of the protocol execution.

5.6. Quality Operations — Product Quality Management

5.6.1. Approves the process verification protocol, any incidents, interim reports, and the final report.

5.7. Quality Operations — Supply Chain Laboratory / Bioanalytics

5.7.1. Completes all laboratory testing requirements stated in the protocol.

5.7.2. Provides a detailed report of the laboratory test results to be included in the final process verification report packet.

5.8. Emergent Representatives

5.8.1. Approves the process verification protocol, interim reports, and final report.

5.9. Technology

5.9.1. Approves the process verification protocol and final report.

6. EQUIPMENT/PROCESS FUNCTIONAL REQUIREMENTS

6.1. Plasma will be pooled in volumes of approximately [**] liters and fractionated by the Cohn- Oncley method of cold ethanol fractionation to [**] according to approved BPRs and SOPs at Talecris Biotherapeutics in Clayton, NC. Fractions will be held in cGMP condition at [**]°C or below until a combined paste equivalent to approximately [**] liters of plasma is collected. At that time, purification, formulation, fill and finish of the final AIG product will be completed by the licensed process used by Talecris to manufacture Gamunex®.

7. EQUIPMENT SYSTEM DESCRIPTION

7.1. The same equipment licensed for use in the fractionation ([**]), purification ([**]), filling ([**]) and packaging ([**]) of Gamunex® will be used for AIG manufacture.

8. REQUIRED DOCUMENTATION

8.1. All production data will be documented in approved BPRs at the time of execution. Talecris Quality Operations will review the BPRs to verify that all license parameters are met.

8.2. The original data in support of the verification lots will be maintained by the respective departments where testing is conducted. Copies of the original data will be included in the final report package. QOSCL data will be maintained in Quality Operations Release in lot packets.

8.3. Incidents will be documented on an Incident Tracking System Notification Form and recorded on the Incident Log sheet. Incident Reports will be included in the final report package.

9. TEST PROCEDURE

9.1. Processing will occur according to approved BPRs, Sample Tables and Standard Operating Procedures (SOPs).

9.2. All operators involved in this PV must be trained on the approved documentation prior to the execution of this protocol.

9.3. Execution

9.3.1. Routine samples will be collected concurrent with production according to the processing BPRs and approved sampling tables.

9.3.2. Non-routine samples will be collected as described in this protocol.

9.3.3. All routine samples will be submitted to Quality Operations — Supply Chain Laboratory or Bioanalytics for testing following sample collection. Non-routine samples to be tested by Emergent will be collected and stored as specified in this protocol prior to shipment.

9.3.4. The Run Number recorded on Test Function data sheets may be recorded as number and alphabet (1a and 1b) for pooled lots that will be combined.

9.3.5. Any results obtained outside of the specified test conditions or acceptance criteria will be documented on an Incident Tracking System Notification Form and recorded on the Incident Log sheet.

10. SAMPLING PLAN

10.1. The following table outlines samples for this process verification. Samples for "In-Process Testing Routinely Performed by Talecris" column will be pulled by the Sample Tables specified in each test function. (Qualification samples referred to in the Sample Tables are not required for this verification protocol.) Samples for "In-Process Testing Routinely Performed by Emergent" will be considered non-routine samples in this protocol. Non-routine samples will be collected according to the test functions in this protocol.

Sampling Point / Sample Description	Assays	In-Process Testing Routinely Performed by Talecris	In-Process Testing Routinely Performed by Emergent	Sampling for Reference Standard Preparation by Emergent
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]		[**]

Sampling Point / Sample Description	Assays	In-Process Testing Routinely Performed by Talecris	In-Process Testing Routinely Performed by Emergent	Sampling for Reference Standard Preparation by Emergent
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]		[**]
[**]	[**]	[**]		[**]

Run Number _____ Final Container Lot Number _____

11. TEST FUNCTION 1 — PLASMA TESTING

11.1. Purpose

11.1.1. To provide test Instructions to verify that the plasma used for the AIG meets predetermined acceptance criteria.

11.2. Rationale

11.2.1. The plasma must be acceptable to be used in this process verification.

11.3. Procedure

11.3.1.1. [**].

11.3.1.2. [**].

11.3.1.3. [**].

11.3.1.4. [**].

11.3.4.1 [**].

11.3.4.2 [**].

11.3.4.3 [**].

Sample progress	Verified by and Date
Samples collected	
Samples stored at [**]C	
Samples sent to Emergent	

Comments: _____

Reviewed By: _____ Date: _____

Run Number _____ Final Container Lot Number _____

TEST FUNCTION 1 (CONT'D) - PLASMA TESTING

11.4. Acceptance Criteria

11.4.1. [**].

11.4.2. [**].

Critical Parameters	Acceptance Criteria	Acceptance Criteria Source	Actual Result	Verified By/Date
[**]	[**]			
[**]	[**]			
[**]	[**]			
[**]	[**]	[**]		
[**]	[**]			
[**]	[**]			
[**]	[**]			
[**]	[**]	[**]		
[**]	[**]	[**]		

Comments: _____

Reviewed By: _____ Date: _____

Run Number _____ Final Container Lot Number _____

12. TEST FUNCTION 2 - PLASMA POOL TO [**]

12.1. Purpose

12.1.1. To provide test instructions to verify non-clarified pools can be successfully processed to [**].

12.2. Rationale

12.2.1. The [**] must meet specifications and quality attributes in accordance with Talecris' requirements to be used in this process verification.

12.3. Procedure

12.3.1. [**].

12.4. Acceptance Criteria

12.4.1 [**].

13. TEST FUNCTION 3 - [**] TO [**]

13.1. Purpose

13.1.1. To provide test instructions to verify [**] can be successfully processed to [**].

13.2. Rationale

13.2.1. [**] must meet specifications and quality attributes to be used in this process verification.

13.3. Procedure

13.3.1 [**].

13.4. Acceptance Criteria

13.4.1 [**].

Comments: _____

_____

Reviewed By: _____ Date: _____

Run Number _____ Final Container Lot Number _____

14. TEST FUNCTION 4 - PASTE SUSPENSION AND [**]

14.1. Purpose

14.1.1. To provide test instructions to verify [**] can be successfully processed to [**].

14.2. Rationale

14.2.1. [**] suspension and [**] must meet specifications and quality attributes to be used in this process verification.

14.3. Procedure

14.3.1 [**].

14.4. Acceptance Criteria

14.4.1 [**].

Comments: _____

_____

Reviewed By: _____ Date: _____

Run Number _____ Final Container Lot Number _____

15. TEST FUNCTION 5 - SODIUM CAPRYLATE TREATMENT AND [**]

15.1. Purpose

15.1.1. To provide test instructions to verify [**] can be successfully processed to [**].

15.2. Rationale

15.2.1. Caprylate treatment and [**] must meet specifications and quality attributes to be used in this process verification.

15.3. Procedure

15.3.1 [**].

15.4. Acceptance Criterion

15.4.1. [**].

15.4.2. [**].

Critical Parameters	Acceptance Criterion	Acceptance Criterion Source	Actual Result	Verified By/Date
Caprylate Treatment 2				
Caprylate	[**]	[**]		

Comments: _____

Reviewed By: _____ Date: _____

Run Number _____ Final Container Lot Number _____

16. TEST FUNCTION 6 - CHROMATOGRAPHY PROCESSING OF AIGIV

16.1. Purpose

16.1.1. To provide test instructions to verify [**] can be successfully processed through the Chromatography Columns.

16.2. Rationale

16.2.1. Chromatography flow-through must meet specifications and quality attributes to be used in this process verification.

16.3. Procedure

16.3.1. [**].

16.4. Acceptance Criteria

16.4.1 [**].

17. TEST FUNCTION 7 - [**]

17.1. Purpose

17.1.1. To provide test instructions to verify column flowthrough material can be successfully processed by [**].

17.2. Rationale

17.2.1. The [**] and formulation process must meet specifications and quality attributes to be used in this process verification.

17.3. Procedure

17.3.1 [**].

17.4. Acceptance Criteria

17.4.1 [**].

Comments: _____

_____

Reviewed By: _____ Date: _____

Run Number _____ Final Container Lot Number _____

18. TEST FUNCTION 8 - [**]

18.1. Purpose

18.1.1. To provide test instructions to verify that the formulated bulk can be successfully prepared and processed to [**].

18.2. Rationale

18.2.1. The [**] must meet specifications and quality attributes to be used in this process verification.

18.3. Procedure

18.3.1. [**].

18.3.2. Collect non-routine TNA concentration [**]sample for Emergent.

18.3.2.1. [**].

18.3.2.2. [**].

18.3.2.3. [**].

Sample progress	Verified by and Date
Samples collected	
Samples stored at [**]°C	
Samples sent to Emergent	

Comments: _____

Reviewed By: _____ Date: _____

Run Number _____ Final Container Lot Number _____

TEST FUNCTION 8 (CONT'D) - [**]

18.4. Acceptance Criteria

18.4.1. [**].

18.4.2. [**].

Critical Parameters	Acceptance Criteria	Acceptance Criteria Source	Actual Result	Verified By/Date
[**]				
Total Protein	[**]	[**]		
pH, diluted	[**]	[**]		
Glycine	[**]			
IgA	[**]	[**]		
IgM	[**]			
Anti-PA IgG ELISA	[**]	[**]		
TNA Assay (Potency)	[**]	[**]		
[**]				
Sterility	[**]	[**]		

Comments: _____

Reviewed By: _____ Date: _____

Run Number _____ Final Container Lot Number _____

19. TEST FUNCTION 9 - FINAL CONTAINER

19.1. Purpose

19.1.1. To provide test instructions to verify the [**] can be successfully processed to final container.

19.2. Rationale

19.2.1. Final containers must meet specifications and quality attributes to be used in this process verification.

19.3. Procedure

19.3.1 Fill the [**].

19.3.2 [**].

19.3.3 [**].

19.3.3.1 [**].

19.3.3.2 [**].

19.3.3.3 [**].

Sample progress	Verified by and Date
Samples collected	
Samples stored at [**]°C to [**]°C	
Samples sent to Emergent	

Comments: _____

Reviewed By: _____ Date: _____

Run Number _____ Final Container Lot Number _____

TEST FUNCTION 9 (CONT'D) - FINAL CONTAINER

19.4. Acceptance Criteria

19.4.1. [**].

19.4.2. [**].

Critical Parameters	Acceptance Criteria	Acceptance Criteria Source	Actual Result	Verified By/Date
Final Container				
Appearance	[**]	[**]		
Volumetric fill check	[**]	[**]		
Protein concentration	[**]	[**]		
Protein composition	[**]	[**]		
Glycine	[**]			
Sodium Caprylate	[**]			
Prekallikrein Activator	[**]			
Anticomplement Assay	[**]	[**]		
IgA	[**]	[**]		

Comments: _____

Reviewed By: _____ Date: _____

Run Number _____ Final Container Lot Number _____

TEST FUNCTION 9 (CONT'D) - FINAL CONTAINER

Critical Parameters		Acceptance Criteria	Acceptance Criteria Source	Actual Result	Verified By/Date
IgM		[**]		[**]	
Sterility, USP		[**]		[**]	
Pyrogen, USP		[**]		[**]	
Safety		[**]		[**]	
Isoagglutinin Titer		[**]		[**]	
Molecular	[**]		[**]		
Weight	[**]		[**]		
	[**]		[**]	[**]	
pH of 1% protein solution		[**]			
Turbidity		[**]		[**]	
Anti-D		[**]		[**]	

Comments: _____

Reviewed By: _____ Date: _____

Run Number _____ Final Container Lot Number _____

TEST FUNCTION 9 (CONT'D) - FINAL CONTAINER

Critical Parameters	Acceptance Criteria	Acceptance Criteria Source	Actual Result	Verified By/Date
Osmolatity	[**]	[**]		
Identity: [**]	[**]	[**]		
[**] (Potency)	[**]	[**]		
Anti-PA IgG ELISA	[**]	[**]		

Comments: _____

Reviewed By: _____ Date: _____

20. INCIDENT LOG

20.1. An Incident Tracking System Notification Form shall be completed for any incident encountered during the execution of the protocol as according to [**]. The table below will document the Incident number and the protocol section to which it applies as well as ensure that each Incident's Batch Disposition record has been satisfactorily resolved before final approval.

Incident Tracking System Log

Incident Number	Protocol Reference Section	ITS or Batch Disposition Approval Date	Verified By/Date

Comments: _____

Reviewed By: _____ Date: _____

Run Number _____ Final Container Lot Number _____

21. POST EXECUTION APPROVAL SIGNATURES

The signatures below indicate that all items in this executed protocol have been reviewed and found acceptable and that all incidents have been satisfactorily resolved.

Qualification and Validation Engineering Date

Print Name and Title:

Qualification Operations — Product Quality Management — Fractionation Date

Print Name and Title:

Qualification Operations — Product Quality Management — Gamunex Date

Print Name and Title:

Comments: _____

_____

Reviewed By: _____ Date: _____

Exhibit 10.43

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

[ENGLISH TRANSLATION]

AGREEMENT

between

The Free State of Bavaria, represented by the ministry of environment, health and consumer protection (*StMUGV*), Rosenkavalierplatz 2, 81925 Munich

(hereinafter referred to as "StMUGV")

and

VIVACS GmbH, Am Klopferspitz 19, 82152 Martinsried, Germany, represented by its managing director, Mr. Karl Heller

(hereinafter referred to as "VIVACS")

Preamble

1.a) The StMUGV intends and is obliged to strengthen Bavaria as development and research location. Thus the StMUGV is particularly interested in encouraging and supporting young innovative enterprises in the region.

b) The Free State of Bavaria owns a pre-vaccine for small pox that was approved between 1977 and 1987. The pre-vaccine contains the *Modified Vacciniavirus Ankara* (MVA) as active live vaccine. The Bavarian institute for vaccination had developed this vaccine and had documented its preparation.

2.a) VIVACS is a biotech company, located in the *Gründerzentrum IZB* (Founders' Center) in Munich that specializes in the development and production of viral vectors and recombinant viral vectors that may be used as vaccines against infectious diseases or cancer.

b) VIVACS works primarily with MVA as vector system. The employees of VIVACS are all experienced with the treatment, the breeding, the reproduction and the preparation of recombinants from MVA and from other *orto pox* viruses.

c) It is VIVACS' declared goal to harmonize the standards in the field of Vaccinavirus technology and to make the promising MVA technology available to a broad scientific and industrial community.

d) Based on this goal VIVACS considers itself a service provider that not only develops recombinant virus vectors by order of third parties but wishes to produce and offer standardized reference material, for example control vectors.

e) In order to reach the goals described under d) VIVACS prefers to work with standardized and well-documented starting materials (*Ausgangsmaterialien*) and executes all works according to a standard similar to GLP. Within medium term VIVACS aims for a GLP certification.

f) VIVACS is interested in using and marketing the pre-vaccine owned by StMUGV as starting material (*Ausgangsmaterial*) for the production of standardized control vectors, reference materials and for the production of recombinant virus vectors.

3. In order to realize their respective goals and in accordance with the following definitions the parties agree as follows:

1. Definitions

“Documentation” means the documentation of the Material’s development and all available documents regarding the clinical application that contain details on the term of application, the number of patients, the form of application, the compatibility etc. of the Material.

“Development Product” (*Entwicklungsprodukt*) means an MVA-Starting Material (*MVA-Ausgangsmaterial*) that has been genetically modified according to the requirements of a customer and that is only released for scientific purposes. Development Products are, for example, recombinant MVA-virus vectors that express a reference gene under a regulatory control region.

“Material” means small pox pre-vaccine, MVA strain according to schedule 1.

“MVA Starting Material” (*MVA-Ausgangsmaterial*) means a characteristic Isolate that was “plaque-isolated” from the Material. This isolate is then depurated, reproduced and tested as Master Seed Virus under GMP conditions. It constitutes the starting material (*Ausgangsmaterial*) for any of VIVACS’ further activities.

“License Fee” means the income generated by sales and license agreements regarding the application and use of the Products.

“Net revenue” means the amount invoiced for the Products without legal taxes and freight or packaging surcharges.

“Reference Material” means a suspension with a precisely defined concentration of MVA Starting Material or Development Product that helps customers to define the virus concentration in a test dilution and that is exclusively released for scientific purposes.

“Products” are viruses or viral products that are won by using the handed over Material (*überlassenes Material*) including but not limited to Development Products, Reference Materials and Reproduction Products or new developments from the handed over Material.

“Property Right” means all documented suggestions for improvements and applications for inventions and patents, utility models and know-how.

“Reproduction Product” means the MVA-Starting Material that is reproduced under standardized conditions.

2. Rights and Duties of StMUGV

1. StMUGV makes available to VIVACS Material according to Schedule 1 to be used as Starting Material for the production of recombinant virus vectors for research purposes and for the development of vaccines. In addition StMUGV hands over to VIVACS a copy of the relevant documentation and all existing information on clinical vaccination trials that were conducted with the small pox pre-vaccine.

2. StMUGV permits VIVACS to win an isolate from the provided Materials that may be then used and marketed as MVA Starting Material for further Products.

3. StMUGV undertakes to inform VIVACS in case MVA Starting Material is made available to a third party under generally similar but better conditions than the conditions agreed on under Section 3.6.1 of this agreement in connection with schedule 2 and agrees to amend Section 3.6.1 of this agreement in connection with schedule 2 based on such better conditions.

3. Rights and Duties of VIVACS

1. VIVACS does use the provided Materials and the Documentation exclusively for the development of standardized Reference Materials, control vectors and for the production of recombinant virus vectors in Bavaria.

2. VIVACS undertakes not to give the provided Materials in their starting form (*überlassene Materialien in ihrer Ausgangsform*) to third parties and to secure them against being taken away by third parties.

3. Any remaining Materials in their starting form must be returned to StMUGV in case VIVACS is liquidated and in case of termination of this agreement.

4. VIVACS is the sole producer of the Products.

5. VIVACS is the owner of the Products and is entitled to market or license them worldwide.

6.1 VIVACS undertakes to allow StMUGV a share in the marketing of the Products according to the breakdown in Schedule 2. Such share is to be paid in Euro.

6.2 VIVACS undertakes to transfer the due payments once a year and with effect of September 1 of each year respectively to the account of the “Staatsoberkasse Bayern, Buchungsstelle München”, account no. 24592 at the Bayer.Landesbank München, bank identification code 700 500 00.

6.3 VIVACS undertakes to forward StMUGV a report on its marketing activities, the marketing success that have been achieved according to Schedule 2 and the payments due to StMUGV by August 31, of each year respectively.

7.1 VIVACS undertakes to keep the most precise account on the development, the production and the marketing of Products that are based on the provided Materials. Such books must be retained for at least 10 years.

7.2 VIVACS undertakes to allow inspection of the books named in Section 7.1 during normal business hours and in VIVACS’ premises upon request of StMUGV or an independent auditor or other expert named by StMUGV. StMUGV shall bear the costs of such audit.

7.3 In case the audit reveals that the paid sum deviates from the sum payable to StMUGV by more than EUR 1,000, VIVACS shall bear the costs of the audit.

8. VIVACS may use the Material’s history for own marketing purposes.

4. Further/New Developments, Trademark Rights

1. To the extent that new inventions are made in the course of VIVACS' development and production of Products, VIVACS is solely entitled to apply for patents and to effect Trademark Rights.
2. VIVACS shall bear all costs for the application and enforcement of Property Rights.

5. Exclusion of Warranty and Liability

1. StMUGV does not warrant and is not liable for the quality and the security profile for the handed over Materials.
2. StMUGV does not warrant and is not liable for the applicability of the handed over Materials for the contractual purposes, in particular that the handed over Materials are viable and augmentable.
3. StMUGV does not warrant and is not liable for the completeness and correctness of the handed over documentation.
4. StMUGV is furthermore not liable for any damages whatsoever that may arise from the handed over Materials, particularly from the contact and the use of the handed over Materials.
5. VIVACS undertakes to indemnify StMUGV or its employees from all claims for damages of third parties that may arise from the use or marketing of Products from the originally handed over Materials.
6. VIVACS further undertakes to effect relevant liability insurances and to exclude any claims for damages of third parties in all marketing or licensing agreements with third parties.

6. Other

1. VIVACS may assign this agreement and possible Property Rights including all rights and obligations to a legal successor/assignee or contribute it to a trading company or other legal entity only upon StMUGV's consent.

2.1 VIVACS undertakes to pay a contractual penalty of up to EUR 50,000 in case it breaches the obligations provided for in Sections:

- 3.2
- 3.3
- 3.6.1
- 3.7.1
- 3.7.2

2.2 StMUGV is entitled to define the actual amount of the contractual penalty within the given frame of EUR 50,000 in each case.

2.3 In case VIVACS does not fulfill a contractual obligation at all or not in a proper manner, the contractual penalty becomes due if VIVACS is in breach according to the provisions of the German Civil Code (*BGB*). In case of a default the penalty becomes due with the default.

2.4 StMUGV reserves the right to claim further damages. In case StMUGV claims damages in addition to the contractual penalty, the forfeited contractual penalty shall be credited against the claim for damage.

7. Termination

1. Any party is entitled to terminate the agreement for cause without a notice period. Cause for termination is given if the other party has willfully breached one of its contractual obligations and such breach is not cured within a reasonable time limit, set by the other party.
2. Cause for a termination by StMUGV is given, in case of VIVACS' repeated default of payment or if VIVACS becomes insolvent or is liquidated.
3. Any rights and obligations related to marketing agreements that have at the time of the termination already been entered into by VIVACS shall not be affected by the termination. New marketing agreements may not be entered into.

8. Miscellaneous

1. This agreement is subject to German law.
2. The relevant court of Jurisdiction for any possible disputes shall be the Munich County Court I (*Landgericht München I*).
3. There are no side agreements. Any amendments to this agreement shall only be valid if they are made in written form and executed by the parties.
4. In case any of the provisions of this agreement is or becomes void or in case the agreement is unintentionally silent, the other provisions shall not be affected. Instead of the void provision a valid provision that comes closest to the parties intention shall be deemed agreed on. The same applies in case the agreement is unintentionally silent.

Signatures/June 16, 2005

Schedule 1

Specifications of the “Material”

The Material was produced in accordance with

- Guideline on general requirements for the production and trial of sera, vaccines and test – antigens (German Federal Gazette vol. 27, No. 206 dated November 5, 1975)
- Guideline on special requirements for the production and trial of Vaccinia virus vaccines for the pre-vaccination at the small pox first vaccination (German Federal Gazette vol. 29, No. 138 dated July 28, 1977)

MVA pre-vaccine:	approval	January 31, 1977
	approval expired	December 31, 1987

Handed over to VIVACS: Charge MVA 470 MG

(Including the copies of the production documentation of MVA 470 MG and the seed virus MVA 460 MG)

Release of Charge:	December 12, 1977
Amount:	5 containers of 0.5 ml each
	(before Lyophilisation)

The Material is not intended for consumers. The Material, which was developed by the Bavarian institute for vaccination and is currently stored for research purposes by the State Office for Health and security of food may exclusively be used for research purposes.

Schedule 2

In accordance with the agreement under Section 3.6, VIVACS undertakes to allow StMUGV shares in the profits pursuant to the following itemization:

1. From the marketing of Products that are given away for research purposes, the StMUGV receives:
   - - [**] % of the net revenue during the first year
   - - [**] % of the net revenue during the second year
   - - [**] % of the net revenue during the third, fourth and fifth year
   - - [**] % of the net revenue during any further year
2. From the marketing of Products that are given away or licensed for other purposes, particularly for medical and diagnostic use, the StMUGV receives:
   - - [**] % of the net revenue or the License Fees
3. From the marketing of Products that are licensed as Starting Material for the production of a small pox vaccine, the StMUGV receives:
   - - [**] % of the License Fees

Schedule 3

Declaration on ownership

The Free State of Bavaria owns a pre-vaccine against small pox that was admitted between 1977 and 1987.

This vaccine contains the Modified Vacciniavirus Ankara (MVA) as active live vaccine. This vaccine had been produced and its production documented by the Bavarian institute for vaccination.

Vivacs GmbH received according to the agreement dated June 16, 2005 5 containers containing 0.5 ml of this vaccine (Charge MVA 470 MG)

Signature/June 14, 2005

Exhibit 21.1

List of Subsidiaries

Name of Subsidiary	Jurisdiction of Incorporation or Organization
Emergent BioSolutions Inc.	Delaware
*Emergent BioDefense Operations Lansing Inc.	Michigan
Emergent Product Development Gaithersburg Inc.	Delaware
Emergent Commercial Operations Frederick Inc.	Maryland
Emergent Frederick LLC	Maryland
Emergent Sales and Marketing US LLC	Delaware
Emergent International Inc.	Delaware
Emergent Europe Inc.	Delaware
Emergent Product Development UK Limited	England and Wales
Emergent Sales and Marketing Germany GmbH	Germany
Emergent Product Development Germany GmbH	Germany
Emergent BioSolutions Malaysia SDN BHD	Malaysia
Emergent Sales and Marketing Singapore Pte. Ltd.	Singapore

*Emergent BioDefense Operations Lansing Inc. has registered to do business as Emergent BioDefense.

Exhibit 23.1

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 (Amendment No. 3 to Form S-1 No. 333-136622) 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
October 19, 2006

October 20, 2006

VIA EDGAR SUBMISSION

Brian A. Johnson

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+1 212 230 8888 (f)
brian.johnson@wilmerhale.com

Securities and Exchange Commission
Division of Corporation Finance
100 F Street, NE
Washington, DC 20549

Attention: Song P. Brandon, Esq.

Re: Emergent BioSolutions Inc.
Registration Statement on Form S-1
File Number 333-136622

Ladies and Gentlemen:

On behalf of Emergent BioSolutions Inc. (the "Company"), submitted herewith for filing is Amendment No. 3 ("Amendment No. 3") to the Registration Statement referenced above (the "Registration Statement").

Amendment No. 3 is being filed in response to comments contained in the letter dated October 11, 2006 from Jeffrey Riedler of the Staff (the "Staff") of the Securities and Exchange Commission (the "Commission") to Fuad El-Hibri, the Company's Chief Executive Officer. The responses set forth below are based upon information provided to Wilmer Cutler Pickering Hale and Dorr LLP ("WilmerHale") by the Company. The responses are keyed to the numbering of the comments and the headings used in the Staff's letter. Where appropriate, the Company has responded to the Staff's comments by making changes to the disclosure in the Registration Statement as set forth in Amendment No. 3.

On behalf of the Company, we advise you as follows:

Form S-1/#1

Our Business, page 1

1. *We note your response to comment 10. Please tell us if the IND filed by Microscience and that which is currently held by Emergent Product Development UK is for an IND filed with the FDA in the United States or with a similar agency in a foreign country.*

Response: The Company advises the Staff that the investigational new drug application ("IND") for the Company's typhoid vaccine candidate was filed by Microscience Limited ("Microscience") with the U.S. Food and Drug Administration ("FDA"). The IND number is BB-IND 10176.

Our Strategy, page 3

2. *We note your response to comment 12 and reissue the comment. The discussion of the risks and obstacles you will face in implementing your strategy should be as prominent as the discussion of your strategy. Please revise the discussion of the risks you face to include a similar level of detail for each of the risks you identify.*

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 3 and 4 of Amendment No. 3 such that the discussion regarding the risks facing the Company is consistent in both format and level of detail to the discussion regarding the Company's strategy.

"We will not be able to commercialize our product candidates if our preclinical development efforts are not successful, ...," page 20

3. *We note your statement in your response to comment 27 that you have had discussions with the FDA relating to the design of your Phase I clinical trial. Did the FDA indicate that it would not require a Phase II clinical trial?*

Response: In response to the Staff's comment, the Company has revised the disclosure on page 21 of Amendment No. 3 to clarify that the FDA has not approved the Company's plan to proceed directly to a donor stimulation program without conducting a Phase II clinical trial.

Use of Proceeds, page 45

4. *We note your response to comment 50 and your revised disclosure. However, our comment sought for you to provide disclosure on how much you anticipate spending for each product candidate and where in the development process you expect to be after the expenditure of these proceeds. Therefore, our comment is reissued in part. Please revise this section accordingly. Please also provide the approximate timing of these expenditures.*

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 46 and 47 of Amendment No. 3.

License Agreements, page 111

5. *We note your response to comment 63. We note your revised disclosure that you have paid $1.0 million minimum contractual commitments for each of the two developmental agreements you entered with HPA. Please disclose any amounts you have paid HPA to date with respect to the license agreements you have with them. You also indicate that with respect to the license agreement with HPA that if you fail to file an IND within a certain time period under either of your license agreement with HPA that you are*

obligated to pay HPA an annual fee until an IND has been filed. Please disclose the annual fee amount, if such amount is material.

Response: The Company advises the Staff that it has not paid the U.K. Health Protection Agency ("HPA") any amounts to date under the license agreements referenced in the Registration Statement. The Company further advises the Staff that the amount of the annual fee that the Company is required to pay HPA if the Company fails to file an IND within the specified time period is not material to the Company's business. The Company has requested confidential treatment of the amount of the annual fee. The Company directs the Staff to Section 2.6 of the unredacted copy of each license agreement, which the Company has previously provided to the Staff, for the amount of the annual fee. As disclosed in the Registration Statement, under the license agreements, the Company also is required to pay HPA royalties on future sales.

Typhoid Vaccine, page 96
Hepatitis B therapeutic vaccine, page 98
Group B streptococcus, page 100
Chlamydia vaccine, page 102
Meningitis B vaccine, page 94

6. *We note your response to comment 69. To the extent that the data from your clinical trials was analyzed for immunogenicity, the results of these analyses should be disclosed with the related p values and statements that they are merely indications of efficacy and not sufficient to enable a product to proceed to Phase II clinical development.*

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 92, 93, 99, 101, 102 and 104 of Amendment No. 3.

Management's discussion and analysis of financial condition
Critical accounting policies and estimates
Revenue recognition, page 56

7. *We have reviewed your response to comment number 54. Please disclose within your document similar information regarding the FDA review process as you have presented within your response. In addition, please disclose the number of instances, if any, that the FDA has denied sale of BioThrax and the effect on the financial statements of such denial. Lastly, please describe to us, and disclose, the point at which you capitalize cost as inventory. Given that you are unable to sell BioThrax until you have received FDA approval, please tell us how these costs meet the definition of an asset as described in paragraph 26 of CON 6. Specifically, address your ability to estimate the likelihood of obtaining FDA approval in determining whether there is a future economic benefit.*

Response: In response to the Staff's comment, the Company has revised the disclosure on page 57 of Amendment No. 3 to include additional information regarding the FDA review process. In addition, the Company advises the Staff that, as disclosed on page 58 of Amendment No. 3, it capitalizes the costs associated with the manufacture of BioThrax as inventory from the initiation of the manufacturing process through the completion of manufacturing, labeling and packaging. Manufacturing costs capitalized as inventory consist primarily of material, labor and manufacturing overhead expenses and include the services and products of third party suppliers within the period of production.

In determining if the costs incurred to manufacture BioThrax should be capitalized as an asset, the Company considered the guidance detailed in paragraph 26 of Statement of Financial Accounting Concepts No. 6, *Elements of Financial Statements* ("CON 6"). This guidance provides for three essential elements that must be present in order for an item to qualify as an asset. The Company's analysis of each element is as follows:

- The first element is that an asset "embodies a probable future benefit that involves a capacity, singly or in combination with other assets, to contribute directly or indirectly to future net cash inflows." The Company has a history of successfully manufacturing and selling BioThrax to several customers. Cash from BioThrax product sales supports the Company's operational, developmental and administrative activities.
- The second element is that "[a] particular entity can obtain the benefit and control others' access to it." The Company is the sole holder of an FDA license to manufacture BioThrax. Consequently, the Company can control access to the product through production decisions and market supply.
- The third element is that "[t]he transaction or other event giving rise to the entity's right to or control of the benefit has already occurred." The Company has maintained its FDA license and patents to prevent access to the availability of BioThrax. The Company acquired rights to BioThrax and related vaccine manufacturing facilities in Lansing, Michigan in 1998 from the Michigan Biologics Product Institute. The FDA approved a supplement to the Company's manufacturing facility license in December 2001.

The Company believes that all three elements established in paragraph 26 of CON 6 are met. Furthermore, the Company has a strong historical FDA product approval rate. During the period covered by the financial

statements included in the Registration Statement, the FDA has not denied the sale of any BioThrax lots that the Company has submitted for approval. As a result, the Company does not inadvertently capitalize unrealizable costs as inventory. Accordingly, the Company submits that it appropriately capitalizes costs related to the production of BioThrax.

Stock-based compensation, page 58

8. *Refer to your response to previous comment 54. We continue to believe that you have used an "independent valuation specialist" as an expert to help determine the fair value of your equity securities. Please name the independent valuation specialists and provide written consents, as appropriate, or provide to us a more robust and detailed analysis of Rule 436, including consideration of footnote 60 of the AICPA Practice Aid, which supports management's current determination that the independent valuation specialist is not an expert.*

Response: Based on a discussion with the Staff, the Company has removed all references in the Registration Statement to the independent valuation specialists to further clarify that the Company's board of directors was solely responsible for the determination of the fair value of the common stock for accounting purposes. Accordingly, the Company is not required to obtain the consent of any independent valuation specialist to be named as an expert.

Financial operations overview
Revenues, page 60

9. *We note your added disclosures regarding your expectation of successful delivery of the required 1 million doses of BioThrax to the DoD during the three month period ended September 30, 2006. Please update your disclosures to indicate whether you were successful in delivering these doses. If you were unable to deliver the doses as required, please disclose the implications of non-performance, including any effect on the financial statements that will be reflected in the September 30, 2006 financial statements.*

Response: The Company advises the Staff that it has revised the disclosure in Amendment No. 3 to provide information regarding the number of doses delivered to the U.S. Department of Defense ("DoD") through September 30, 2006 and to describe the amended terms of the Company's current contract with the DoD.

10. *Given the wide disparity in the price per dose charge under the HHS and DoD contracts, please revise your disclosure to discuss significant changes in price separate from your current discussion of volume.*

Response: The Company advises the Staff that there is not a meaningful difference in price per dose under the Company's contracts with the U.S. Department of Health and Human Services ("HHS") and the DoD, as the price per dose varies less than $1 per dose, or less than 3%, under these contracts. The Company also has revised the disclosure on page 62 of Amendment No. 3 to state the total minimum doses required to be delivered under the DoD contract.

Contractual Obligations, page 73

11. *We have reviewed your response to comment number 58. Please disclose within the footnote to the table, the material royalties and milestones related to current development programs that the Company estimated are not probable to occur and the basis for management's decision.*

Response: In response to the Staff's comment, the Company has revised the disclosure on page 74 of Amendment No. 3 to clarify that the contractual obligations table does not include contingent contractual milestone payments. The Company advises the Staff that it is not able to reliably estimate the amount of contingent milestone payments that are likely to become payable only upon the achievement of specified research, development and commercialization milestones. In addition, as disclosed, there are no contractually obligated minimum royalties payable.

Selling Shareholders, page 157

12. *We note your response to comment 74 and your response that Microscience Investment "may" be an affiliate of a broker-dealer. Please determine if Microscience Investment is an affiliate of a broker-dealer and if they are considered an affiliate of a broker-dealer, please revise your disclosure to include the following representations:*

- *The selling security holder purchased in the ordinary course of business; and*
- *At the time of the purchase, the selling security holder had no agreements or understanding to distribute the securities.*

If you are unable to make these statements in the prospectus, please revise the prospectus to state the seller shareholder is an underwriter.

Response: The Company advises the Staff that at such time as the Company files a subsequent amendment to the Registration Statement naming the selling stockholders, including, if applicable, Microscience Investments Limited, the Company will include disclosure to the effect that: "We issued these shares to Microscience Investments as consideration for our acquisition

from Microscience Investments of all the outstanding shares of capital stock of Microscience Limited in June 2005. Microscience Investments represented to us in connection with the issuance of these shares that it was acquiring the shares for its own account, for investment purposes and not with a view to the sale or distribution of the shares."

Nature of the business and organization, page F-7

13. *We have reviewed your response to comment number 78. Please note that Article 11- 01 (d) of Regulation S-X states that a "presumption exists that a separate entity, a subsidiary, or a division is a business." Additionally, in appears based upon your response that Microscience possessed physical facilities, employee base, operating rights, and production techniques. Accordingly, please provide additional information as to why financial statements for Microscience have not been provided in accordance with Rule 3- 05 of Regulation S-X. Please note that the determination of a business under EITF 98-3 and SFAS 141 is irrelevant to this analysis.*

Response: In determining if separate stand-alone financial statements for Microscience should be presented in the Registration Statement, the Company evaluated the guidance in Rule 11-01(d) of Regulation S-X. Rule 11-01(d) of Regulation S-X states that "the term 'business' should be evaluated in light of the facts and circumstances involved and whether there is sufficient continuity of the acquired entity's operations prior to and after the transactions so that disclosure of prior financial information is material to an understanding of future operations."

The facts and circumstances at the time of the acquisition were as follows:

- Microscience had very limited cash on hand to fund its operations and had failed in all efforts to raise additional capital, including a failed attempt at an initial public offering.
- The executive management team had experienced significant attrition, and key positions such as the Chief Scientific Officer and Chief Financial Officer were vacant.
- Microscience was not generating any revenues, and the Microscience business plan did not show any significant revenue generating capability for the foreseeable future.
- Microscience's product candidates were either in preclinical or Phase I clinical development. Product candidates at these stages of development require significant additional investment of time and effort prior to submission to a regulatory authority for the

evaluation of potential marketing approval. The Microscience development plan did not show marketability of any product candidates for the foreseeable future. Some of these product candidate programs were slowed down or placed on hold due to the inability of the entity to finance continuing work.

Subsequent to the acquisition, the Company installed a new management team and performed extensive evaluations of existing Microscience programs, resulting in the reallocation of resources among these programs. Some programs that had been dormant or slowed down were restarted and accelerated. As an example, after the acquisition, the Company quickly advanced the meningitis B program and entered into a contract with Sanofi Pasteur providing for an upfront license fee and the opportunity for significant future revenue. The Microscience transaction was primarily an acquisition of technology and development programs, as evidenced by the accounting for the transaction, in which 94% of the total consideration paid was taken as a purchased in-process research and development charge in accordance with FASB No. 2.

Section (1) of Rule 11-01(d) requires the evaluation of whether the nature of the revenue-producing activity will remain generally the same as before the transaction. The Company has concluded that, as described in the preceding paragraph, because Microscience did not have any revenue-producing activity at or prior to the time of acquisition, the nature of the revenue-producing activity at Microscience changed significantly after the acquisition.

The Company also evaluated the attributes in Section (2) of Rule 11-01(d) as follows:

(i) Physical facilities — Microscience had no clinical or production facilities. The entity had a small leased physical facility of approximately 16,000 square feet that was comprised of standard, uncustomized office and laboratory space. The Company maintained the facility after the acquisition.

(ii) Employee base — Microscience had an at will work force of approximately 50 employees with skill sets similar to most development stage companies and readily available in the market place.

(iii) Market distribution system — Microscience had no market distribution system.

(iv) Sales force — Microscience had no sales force.

(v) Customer base — Microscience had no customer base.

(vi) Operating rights — Microscience had certain intellectual property rights relating to its product candidates under development.

(vii) Production techniques — Microscience had no production techniques, as none of its product candidates had progressed beyond Phase I clinical development.

(viii) Trade Names — Although Microscience possessed trade names, their utility was extremely limited because Microscience did not have the business capability to develop product candidates beyond Phase I clinical development.

In summary, there was limited continuity of operations subsequent to the acquisition and there was no revenue producing activity prior to the acquisition. The attributes listed in Rule 11-01(d)(2) are either not applicable or are of such an immaterial nature as to render them inapplicable. The Company believes that disclosure of prior financial information for Microscience is not meaningful to an investor's understanding of future operations, due to the significant operational changes implemented subsequent to the acquisition. Accordingly, in reliance on Rule 11-01(d) of Regulation S-X, the Company concluded that Microscience did not meet the definition of a business based on the facts and circumstances that existed at the time of the acquisition, and therefore determined that stand-alone financial statements for Microscience are not required to be presented in the Registration Statement under Rule 3-05 of Regulation S-X.

Exhibits

14. *We note that a number of your agreements will be filed by amendment, including the form of underwriting agreement. Please file as promptly as possible all exhibits as we will need to review them prior to granting effectiveness of the registration statement. In that regard, to the extent you are able to provide us with a supplemental copy of the underwriting agreement, this may expedite our review of your filing.*

Response: The Company acknowledges the Staff's comment, has filed additional exhibits with Amendment No. 3 and, prior to requesting effectiveness of the Registration Statement, will file all remaining exhibits as soon as final forms of the exhibits are available.

* * * *

If you have any further questions or comments, or if you require any additional information, please contact the undersigned by telephone at (212) 937-7206 or facsimile at (212) 230-8888 or David E. Redlick of WilmerHale by telephone at (617) 526-6434 or facsimile at (617) 526-5000. Thank you for your assistance.

Very truly yours,

/s/ Brian A. Johnson

Brian A. Johnson

cc: Fuad El-Hibri
Daniel J. Abdun-Nabi, Esq.
David E. Redlick, Esq.
James A. Lebovitz, Esq.
Brian D. Short, Esq.