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## **FORM 10-K**

**Emergent BioSolutions Inc. - EBS**

**Filed: March 05, 2010 (period: December 31, 2009)**

Annual report which provides a comprehensive overview of the company for the past year

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549  
FORM 10-K  
(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2009

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-33137

**EMERGENT BIOSOLUTIONS INC.**  
(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

14-1902018

(IRS Employer Identification No.)

2273 Research Boulevard, Suite 400, Rockville, Maryland

(Address of Principal Executive Offices)

20850

(Zip Code)

Registrant's Telephone Number, Including Area Code: (301) 795 - 1800  
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class  
**Common stock, \$0.001 par value per share**  
**Series A junior participating preferred stock purchase rights**

Name of Each Exchange on Which Registered  
**New York Stock Exchange**  
**New York Stock Exchange**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.  
See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer  
 Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2009 was approximately \$212,378,000 based on the price at which the registrant's common stock was last sold on that date as reported on the New York Stock Exchange.

As of February 26, 2010, the registrant had 30,859,259 shares of common stock outstanding.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2010 annual meeting of stockholders scheduled to be held on May 20, 2010, which is expected to be filed with the Securities and Exchange Commission not later than 120 days after the end of the registrant's fiscal year ended December 31, 2009, are incorporated by reference into Part III of this annual report on Form 10-K. With the exception of the portions of the registrant's definitive proxy statement for its 2010 annual meeting of stockholders that are expressly incorporated by reference into this annual report on Form 10-K, such proxy statement shall not be deemed filed as part of this annual report on Form 10-K. BioThrax®, *spi-VEC*<sup>™</sup>, MVAator<sup>™</sup> and Typhella<sup>™</sup> are the registrant's trademarks. Each of the other trademarks, trade names or service marks appearing in this annual report on Form 10-K are the property of their respective owners.

**EMERGENT BIOSOLUTIONS INC.**  
**ANNUAL REPORT ON FORM 10-K**  
**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2009**  
**INDEX**

**PART I**

- Item 1. [Business](#)
- Item 1A. [Risk Factors](#)
- Item 1B. [Unresolved Staff Comments](#)
- Item 2. [Properties](#)
- Item 3. [Legal Proceedings](#)
- Item 4. [Removed and Reserved](#)

**PART II**

- Item 5. [Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities](#)
- Item 6. [Selected Financial Data](#)
- Item 7. [Management's Discussion and Analysis of Financial Condition and Results of Operations](#)
- Item 7A. [Quantitative and Qualitative Disclosures About Market Risk](#)
- Item 8. [Financial Statements and Supplementary Data](#)
- Item 9. [Changes in and Disagreements with Accountants on Accounting and Financial Disclosure](#)
- Item 9A. [Controls and Procedures](#)
- Item 9B. [Other Information](#)

**PART III**

- Item 10. [Directors, Executive Officers and Corporate Governance](#)
- Item 11. [Executive Compensation](#)
- Item 12. [Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters](#)
- Item 13. [Certain Relationships and Related Transactions, and Director Independence](#)
- Item 14. [Principal Accountant Fees and Services](#)

**PART IV**

- Item 15. [Exhibits and Financial Statement Schedules](#)  
[Signatures](#)  
[Exhibit Index](#)

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K and the documents incorporated by reference herein contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. All statements, other than statements of historical fact, including statements 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 ability to perform under our contracts with the U.S. government for sales of BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, including the timing of deliveries;
- our plans for future sales of BioThrax, including our ability to obtain new contracts with the U.S. government;
- our plans to pursue label expansions and improvements for BioThrax;
- our ability to win a development award with the U.S. government for our recombinant protective antigen anthrax vaccine product candidate;
- our ability to win an award with the U.S. government for the scale-up, qualification and validation of our new manufacturing facility in Lansing, Michigan for the manufacture of 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 collaborations and our ability to selectively enter into additional collaborative 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 annual report, 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 annual report, including the documents that we have incorporated by reference herein or filed as exhibits hereto, completely and with the understanding that our actual future results may be materially different from what we expect. We disclaim any obligation to update any forward-looking statements.

## PART I

### ITEM 1. BUSINESS

#### Overview

We are a biopharmaceutical company focused on the development, manufacture and commercialization of vaccines and antibody therapies that assist the body's immune system to prevent or treat disease. For financial reporting purposes, we operate in two principal business segments: biodefense and commercial. Our biodefense segment focuses on vaccines and antibody therapies for use against biological agents that are potential weapons of bioterrorism and biowarfare, while our commercial segment focuses on vaccines and antibody therapies targeting infectious diseases that represent significant unmet or underserved public health needs.

We are currently focused on vaccines and antibody therapies targeting the following disease areas: anthrax, tuberculosis, typhoid, influenza and chlamydia. Set forth below is a list of each of our products or product candidates that are designed to address these disease areas.

#### *Anthrax*

*BioThrax* — also referred to as Anthrax Vaccine Adsorbed, is the only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax disease. BioThrax is approved for pre-exposure prevention of anthrax disease by all routes of exposure, including inhalation.

*BioThrax related programs* — initiatives designed to further improve BioThrax as a medical countermeasure, and include seeking approval for use as a post-exposure prophylaxis against anthrax disease in combination with antibiotic treatment, extending expiry dating from four years to five years and reducing the number of required doses from five to three. We are also developing a BioThrax dual adjuvant vaccine product candidate designed to provide rapid immunity, in part with funding from the National Institute of Allergy and Infectious Diseases, or NIAID, and the Biomedical Advanced Research and Development Authority, or BARDA.

*rPA vaccine* — an anthrax vaccine product candidate that is composed of a purified recombinant protective antigen, or rPA, protein with an aluminum hydroxide adjuvant.

*Double-mutant rPA vaccine* — an anthrax vaccine product candidate based on a double-mutant form of rPA combined with adjuvant CpG 7909 and an aluminum hydroxide adjuvant, which we are developing in part with funding from NIAID and BARDA.

*Anthrax immune globulin therapeutic* — a therapeutic antibody product candidate for the treatment of symptomatic anthrax disease, which we are developing in part with funding from NIAID and for which we initiated a Phase I/II clinical trial and pilot animal studies in 2009.

*Anthrax monoclonal antibody therapeutic* — a human monoclonal antibody product candidate for treatment of patients who present symptoms of anthrax disease, which we are developing in part with funding from NIAID and BARDA.

### ***Tuberculosis***

*Tuberculosis vaccine* — a single-dose, injectable vaccine product candidate for use in persons who have been vaccinated with Bacille Calmette-Guerin, or BCG, the vaccine currently available against tuberculosis, for which we have commenced a Phase IIb clinical trial in South Africa that is expected to conclude in 2012, and which we are developing as part of our joint venture with the University of Oxford with funding and services from The Wellcome Trust and the Aeras Global Tuberculosis Vaccine Foundation.

### ***Typhoid***

*Typhella*<sup>™</sup> (*typhoid vaccine live oral ZH9*) — a single-dose, drinkable vaccine product candidate that we are developing with funding from the Wellcome Trust, for which we have completed Phase I clinical trials in the United States, the United Kingdom and Vietnam, and Phase II clinical trials in Vietnam and the United States.

### ***Influenza***

*Influenza vaccine* — a vaccine product candidate for prevention of influenza strains across multiple seasons.

### ***Chlamydia***

*Chlamydia vaccine* — a vaccine product candidate designed to prevent disease caused by clinically relevant strains of *Chlamydia trachomatis*.

We have derived substantially all of our product revenues from sales of BioThrax to the U.S. Department of Defense, or DoD, and the U.S. Department of Health and Human Services, or HHS, and expect for the foreseeable future to continue to derive substantially all of our product revenues from the sale of BioThrax to U.S. government customers. Product revenues were \$217.2 million in 2009, \$169.1 million in 2008 and \$169.8 million in 2007. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other international and domestic customers and pursuing label expansions and improvements for BioThrax.

We also seek to advance development of our product candidates through external funding arrangements. Revenues from contracts and grants were \$17.6 million in 2009, \$9.4 million in 2008 and \$13.1 million in 2007. We continue to actively pursue additional government-sponsored development contracts and grants and to encourage both governmental and non-governmental agencies and philanthropic organizations to provide development funding or to conduct clinical studies of our product candidates.

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 our wholly owned subsidiary. We subsequently renamed BioPort as Emergent BioDefense Operations Lansing Inc.

## Our Strategy

Our goal is to become a leading, fully integrated biopharmaceutical company focused on the manufacture, development and commercialization of vaccines and antibody therapies that assist the body's immune system to prevent or treat disease. We are focused on four key strategic priorities to achieve this goal and drive our long-term growth. These priorities are:

*Expand anthrax franchise.* We derive several benefits from our anthrax-related business that are typically not present in a non-governmentally funded setting. For example, many of our costs of development are reimbursed by the U.S. government, reducing our risk and in some cases also providing a profit margin for our development work. We believe that if the government supports the development of a biodefense product candidate, it will be more likely to procure that product. Furthermore, cash flows generated by BioThrax sales fund our development efforts, which we believe gives us an advantage over many of our competitors that rely primarily on non-governmental external sources of funds. We are focused on increasing sales of BioThrax to the U.S. government, creating new markets for BioThrax domestically and internationally and pursuing label expansions and improvements for BioThrax. Product candidates in our anthrax franchise, such as our anthrax immune globulin therapeutic, human monoclonal antibody therapeutic, and rPA vaccine, have the potential to generate product revenue in advance of marketing approval.

*Grow immune-related product pipeline using platform technologies.* Focusing on platform technologies can help optimize our research and development investment. Our live attenuated modified vaccinia Ankara virus, or MVA, platform technology can potentially be used as a viral vector for delivery of multiple vaccine antigens for different disease-causing organisms using recombinant technology. Development of multiple product candidates on a common platform enables us to build on common expertise in process development and manufacturing scale-up, leverage platform manufacturing facilities and, we believe, establish proprietary and competitive advantages. We anticipate conducting proof-of-concept studies in new product candidates using our proprietary MVA platform, and may consider opportunistic acquisitions of additional platform technologies.

*Expand core biologics manufacturing capabilities.* Since 1998, we have manufactured BioThrax at our vaccine manufacturing facility in Lansing, Michigan. To augment our existing manufacturing capabilities, we constructed a 50,000 square foot manufacturing facility on our Lansing campus. In October 2009, we submitted a proposal to BARDA for scaleup, qualification, validation and licensure of BioThrax in this facility. In late 2009, we purchased a 56,000 square foot manufacturing facility in Baltimore, Maryland. We expect to use this facility to support our future product development and manufacturing needs, and are currently renovating and improving this facility so that it will be capable of supporting development of our product candidates. We also anticipate using a commercial manufacturing partner for the manufacture of one or more of our commercial products, and may explore additional alternatives to support the manufacture of our platform products. Our employees possess manufacturing, quality and regulatory expertise that we believe provides advantages in bringing new products to market, and provides us with a competitive advantage.

*Complement organic growth with strategic acquisitions.* We seek to obtain product candidates through acquisitions and licensing arrangements with third parties, with a primary focus on late-stage development programs. This approach enables us to avoid the expense and time entailed in early-stage research activities and, we believe, to minimize product development and commercialization risks and may enable us to accelerate product development timelines. Specifically, we are primarily seeking to acquire one or more additional product candidates either in Phase III clinical trials or that are well positioned for entry into Phase III clinical trials in the near term. We are also seeking to in-license one or more novel antigens for development using our platform technology. Additionally, we may announce, from time to time, the acquisition or license of approved or early stage product candidates or the entry into collaborations to continue to grow our product portfolio.



## **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 effective public health management. According to a 2008 report issued by Kalorama Information, a market research organization, the world market for preventative vaccines in 2007 totaled \$16.3 billion, up from \$11.7 billion in 2006. The Kalorama report estimates that the world vaccines market will grow at a compound annual rate of 13.1% from 2008 to 2013, and exceed \$36 billion by 2013, as new product introductions continue and usage of current products expands further. New vaccine technologies, coupled with a greater understanding of how infectious microorganisms, 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 paid for either directly by patients or paid for or reimbursed by managed care organizations, other private health plans or public insurers. With respect to certain diseases affecting general public health, particularly in developing countries, public health authorities or non-governmental organizations may fund the cost of developing vaccines against these diseases. According to a 2006 report issued by Frost & Sullivan, a market research organization, public purchases of vaccines, including immunization programs and government stockpiles, account for approximately 90% of the total volume of worldwide vaccine sales. Although private market purchases of vaccines represent only 10% of total worldwide vaccine sales in terms of volume, they accounted for approximately 60% of total worldwide vaccine revenues in 2005.

The market for biodefense countermeasures, including vaccines and antibody therapies, 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. Most U.S. government spending on biodefense programs is in the form of development funding from NIAID, BARDA and the DoD (including the Defense Advanced Research Projects Agency, or DARPA), and procurement of countermeasures by BARDA, the Centers for Disease Control, or CDC, and the DoD. The U.S. government is now the largest source of development and procurement funding for academic institutions and biotechnology companies conducting biodefense research or developing vaccines and immunotherapies directed at potential agents of bioterror or biowarfare.

The Project BioShield Act, which became law in 2004, authorizes the procurement of countermeasures for chemical, biological, radiological and nuclear attacks for the Strategic National Stockpile, or SNS, which is a national repository of medical assets and countermeasures designed to provide federal, 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. Project BioShield provided appropriations of \$5.6 billion to be expended over ten years into a special reserve fund. The Pandemic and All-Hazards Preparedness Act, passed in 2006, established BARDA as the agency responsible for awarding procurement contracts for biomedical countermeasures and providing development funding for advanced research and development in the biodefense arena, supplements the funding available under Project BioShield for chemical, biological, radiological and nuclear countermeasures, and provides funding for infectious disease pandemics. Funding for BARDA is provided by annual appropriations by Congress. Congress also appropriates annual funding for the CDC for the procurement of medical assets and countermeasures for the SNS and for NIAID to conduct biodefense research. This appropriation funding supplements amounts available under Project BioShield.

The DoD, primarily through the Military Vaccine Agency, or 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 level of spending by the DoD for MilVax is a function of the size of the U.S. military and the DoD's protocols with respect to vaccine stockpile management and active immunization. The DoD provides development funding for biodefense vaccines through its Joint Vaccine Acquisition Program, or JVAP. The DoD procures doses of BioThrax from HHS, rather than from us directly, to satisfy ongoing requirements for its active immunization program in accordance with an October 2007 Presidential Directive that outlines the U.S. government's objective to enhance coordination and cooperation among federal agencies with respect to countermeasure procurement and stockpile management.

In addition to the U.S. government, we believe that other potential markets for the sale of biodefense countermeasures include:

- state and local governments, which we expect may be interested in these products to protect emergency responders, such as police, fire and emergency medical personnel;
- foreign governments, including both defense and public health agencies;
- non-governmental organizations and multinational companies, including the U.S. Postal Service and transportation and security companies; and
- health care providers, including hospitals and clinics.

Although we have had modest sales to these markets to date, we believe that they may comprise an important growth opportunity for the overall biodefense market in the future.

### **Scientific Background**

The human body's immune system provides protection against pathogens, such as bacteria and viruses, through immune responses that are generated by a type of white blood cell 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 to that antigen is recalled. Generally, there are two types of specific immune responses: humoral immune response and cell-mediated immune response. Humoral immunity is provided by proteins, known as antibodies or immunoglobulins, that are produced by specific 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 by interacting with other immune cells to initiate the production of antibodies or activating cells that kill and eliminate infected cells.

A vaccine is normally given to a healthy person as a prophylaxis in order to generate an immune response that will protect against future infection and/or disease caused by a specific pathogen. Following vaccination against a specific disease, the immune system's memory of antigens induced by the vaccine allows for a protective immune response to be generated against the pathogen when encountered in the future. The use of a vaccine to stimulate a person's immune system to generate a protective response is termed active immunization.

An immune globulin, also known as a polyclonal antibody, is a therapeutic that provides an immediate protective effect. Immune globulin is normally made by collecting plasma from individuals who have contracted a particular disease or who have been vaccinated against a particular disease and whose plasma contains a mixture of protective antibodies. This mixture can be composed of antibodies that recognize and bind to different pathogen antigens or antibodies that recognize and bind to different sites on a single antigen. These polyclonal antibodies are isolated by fractionation of the plasma, purified and then administered either intravenously or by intramuscular injection to patients.

A monoclonal antibody is also a therapeutic that provides an immediate protective effect. However, unlike immune globulins, which can recognize and bind to multiple antigens, monoclonal antibodies are specific to a single antigen and are generally produced in cell culture rather than collected from humans. Monoclonal antibodies are administered either intravenously or by intramuscular injection to patients.

Because it normally takes several weeks for the immune system to generate antibodies after vaccination, immune globulins and monoclonal antibodies are used in situations in which it is not possible to wait for active immunization to generate the protective immune response. This use of immune globulins and monoclonal antibodies is therefore termed passive immunization.

## **Products**

The following table summarizes key information about our marketed product, BioThrax, and our product candidates. We use multiple technologies to develop our product candidates, including bacterial fermentation, cell culture and recombinant DNA technologies. For each 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 commercial rights to BioThrax and the product candidates listed below.

<b>Disease</b>	<b>Product or Candidate</b>	<b>Description</b>	<b>Stage of Development</b>
Anthrax	BioThrax	The only FDA approved vaccine for pre-exposure prevention of anthrax disease	FDA approved
	rPA vaccine*	Pre/post-exposure prophylactic	Phase II
	Double-mutant rPA vaccine*	Pre/post-exposure prophylactic	Preclinical
	Immune globulin*	Therapeutic	Phase I/ II
	Monoclonal antibody*	Therapeutic	Preclinical
Tuberculosis	Tuberculosis vaccine	Prophylactic	Phase II
Typhoid	Typhella™ (typhoid vaccine live oral ZH9)	Prophylactic	Phase II
Influenza	Recombinant virally vectored influenza vaccine	Prophylactic	Preclinical
Chlamydia	Chlamydia vaccine	Prophylactic	Preclinical

*\* We currently intend to rely on the FDA animal rule in seeking marketing approval for indications or 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 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 product candidates can be considered definitive until all clinical trials needed to support a submission for marketing approval are completed and a license is granted by the FDA. The results of our completed preclinical tests and Phase I and Phase II clinical trials do not ensure that our ongoing and planned later stage clinical trials for our product candidates will be successful. A failure of one or more of our clinical trials can occur at any stage of testing.

The results of a clinical trial are statistically significant if they are unlikely to have occurred by chance. We have determined the statistical significance of clinical 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 potential efficacy and are neither required nor sufficient to enable a product candidate to proceed to Phase II or later stages of 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.

## **Anthrax**

*Disease 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. Anthrax infections occur if the spores enter the body through a cut, abrasion or open sore, or by ingestion or inhalation. Once inside the body, anthrax spores germinate into anthrax bacteria that then multiply. Anthrax bacteria secrete three proteins: protective antigen, lethal factor and edema factor. Each of these proteins individually are non-toxic, but if allowed to interact on the surface of human or animal cells, they can form the highly potent toxins known as lethal toxin (protective antigen and lethal factor) or edema toxin (protective antigen and edema factor).

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%.

Gastrointestinal anthrax is also a rare form of anthrax. Gastrointestinal anthrax is generally acquired through the consumption of meat and other food products contaminated with anthrax spores.

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, malaise, or weakness, lasting up to a few days. After a brief period of improvement, the release of anthrax toxins may cause an abrupt deterioration in the health of the infected person, with the sudden onset of symptoms, including fever, shock and respiratory failure as the lungs fill with fluids. 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.

*Market opportunity and current treatments.* To date, the principal customer for anthrax medical countermeasures has been the U.S. government, specifically HHS and the DoD. We believe that federal, state and local governments and allied foreign governments are significant potential customers for anthrax medical countermeasures.

The only FDA-approved vaccine for pre-exposure prophylaxis against anthrax disease is BioThrax. The only FDA-approved products for post-exposure prophylaxis against anthrax disease are antibiotics, which are typically administered over a 60-day period. Antibiotics are effective against anthrax post-exposure by killing the anthrax bacteria before the bacteria can release anthrax toxins into the body. However, antibiotics are not effective against anthrax toxins once the toxins are present in the body. Antibiotics also are ineffective against anthrax spores that are in the body and that remain dormant following exposure. Anthrax spores may remain in the body, for extended periods, which can potentially germinate into anthrax bacteria after antibiotic treatment has ended and lead to infection and disease. Infection may also 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. In addition, antibiotics may not be effective against antibiotic resistant strains of anthrax. Because of these limitations, the CDC has recommended administering BioThrax in combination with antibiotics under an investigational new drug application, or IND, with informed consent of the patient as a post-exposure prophylaxis against anthrax disease as an emergency public health intervention. BioThrax may also be administered in a post-exposure setting without informed consent under an Emergency Use Authorization, or EUA, which can be issued in the event of a declared emergency by the commissioner of the FDA.

Although BioThrax is not currently approved by the FDA for post-exposure prophylaxis, we are pursuing a label expansion for this indication. We are also developing an anthrax immune globulin therapeutic product candidate and an anthrax monoclonal antibody therapeutic product candidate, both of which are designed for treatment of symptomatic patients. Several other companies also are developing post-exposure anthrax therapeutic products. We intend to progress the development of and pursue development and procurement contracts for both our anthrax immune globulin and monoclonal therapeutic product candidates. We believe that anthrax therapeutics would be eligible to be procured by HHS under Project BioShield for inclusion in the SNS prior to receiving marketing approval, provided that the specific product candidate is deemed to be licensable.

#### *BioThrax and BioThrax Related Programs*

*BioThrax.* BioThrax is the only FDA-approved vaccine for the prevention of anthrax disease. 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 sterile culture filtrate, made from a non-virulent strain of *Bacillus anthracis*. Based on its current product labeling, BioThrax is administered by intramuscular injection in five doses over an 18-month period, with an annual booster dose recommended thereafter. After the initial dose, four additional doses are given at one, six, 12 and 18 months. BioThrax includes aluminum hydroxide as an adjuvant. BioThrax is not currently approved as a post-exposure prophylaxis. Following the October 2001 anthrax letter attacks, however, the CDC provided BioThrax under an IND protocol for administration as a post-exposure prophylaxis on a voluntary basis to Capitol Hill employees and certain others who may have been exposed to anthrax.

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, or VAERS, database maintained by the CDC and the FDA with respect to BioThrax. The report of any such adverse event to the VAERS database is not proof that the vaccine caused such an event. These putative serious adverse events, including diabetes, heart attacks, autoimmune diseases, Guillain-Barre syndrome, lupus, multiple sclerosis, lymphoma and death, have not been causally linked to the administration of BioThrax. In June 2009, we received approval from the FDA of our supplemental biologics license application, or BLA, to extend the expiry dating of BioThrax from three years to four years, which will allow BioThrax to be stockpiled for a longer period of time.

- *Reduced dosing schedule.* The CDC completed a clinical trial in December 2009 to evaluate whether as few as three doses of BioThrax administered over six months, with booster doses up to three years apart, will confer an adequate immune response. The CDC trial assessed 1,563 healthy civilian men and women between the ages of 18 and 61, randomized to one of six groups: Group A (original vaccination schedule of 0, 2, 4 weeks, and 6, 12, 18 months with annual boosters out to 42 months), Group B (same schedule as Group A, but all vaccinations given by intramuscular route), Group C (same as Group B, but with 2-week dose dropped), Group D (same as Group B, but with 2-week, 12- and 30-month doses dropped), Group E (same as Group B, but with 2-week, 12-, 19-, and 30-month doses dropped), and the control group that received saline placebo. According to the statistical analysis plan of the trial, a switch in the dosing schedule would be justified by demonstrated non-inferiority of immune response of the test arm with a modified vaccination schedule (Group C, D, or E) to the original approved schedule (Group A). The primary endpoints for comparison to determine non-inferiority were (1) geometric mean antibody titer (GMT), (2) geometric mean antibody concentration (GMC), and (3) the proportion of subjects achieving 4-fold increase in antibody titer after vaccination. Noninferiority had to be demonstrated for all primary endpoints in order to support the use of specific regimens. In accordance with applicable regulatory guidance and the FDA's recommendations to the CDC on trial design, all non-inferiority tests were done at the 0.025 significance level to insure that results were not due to random variation. A conclusion of non-inferiority, to be accepted by the FDA, required that the upper limits of 95% confidence intervals be less than 1.5 for GMT and GMC ratios (i.e. Group A/Group C, D, or E) and less than 0.1 for differences in proportions of subjects achieving 4-fold increase in antibody titer (i.e. Group A – Group C, D, or E). In this trial, the immunogenicity for Group C, Group D, and Group E were all non-inferior to Group A for all primary endpoints. Based on these results, we expect to file a supplement to our BLA requesting a change in the label to vaccinate people using a 0, 1, 6 month schedule, with triennial boosters.

In this trial, the intramuscular route of administration resulted in significantly fewer adverse events when compared to the subcutaneous route for six of the eight solicited local (injection site) adverse events (warmth, tenderness, erythema, swelling, bruising and itching). Intramuscular administration resulted in a shorter duration of the adverse event than subcutaneous administration for the same six solicited adverse events. Few statistically significant differences were detected in the occurrence of systemic adverse events between the intramuscular treatment groups and the subcutaneous treatment group.

- *Expanded label indication to include post-exposure prophylaxis.* We plan to seek approval of BioThrax for post-exposure prophylaxis against anthrax disease, to be administered along with antibiotics. In October 2007, we completed a human clinical trial of BioThrax for post-exposure indication using the anticipated dosing schedule of three doses of BioThrax given two weeks apart to collect data that, in combination with data from our non-clinical studies, will be used to design our anticipated pivotal human clinical trial. Emergent is employing the FDA animal rule to attempt to demonstrate efficacy of BioThrax in an anthrax post-exposure setting. We have conducted non-clinical studies for a post-exposure indication to evaluate the effect of a humanized dose of BioThrax in combination with antibiotics compared to antibiotics alone in rabbits exposed by inhalation to anthrax spores.

In 2005, NIAID completed a proof-of-concept study 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 similar 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 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 the administration of BioThrax in combination with an antibiotic to non-human primates infected with anthrax. We have also completed pre-exposure active immunization studies in rabbits and non-human primates. We believe that the data from our planned non-clinical efficacy studies, together with the human immunogenicity data, if favorable, will be sufficient to support the filing with the FDA of a BLA supplement for marketing approval of BioThrax for the post-exposure indication. In February 2007, the FDA granted Fast Track designation for BioThrax as a post-exposure prophylaxis against anthrax disease. In September 2007, BARDA awarded us up to \$11.5 million in development funding for this indication, \$8.8 million of which was paid in the fourth quarter of 2007. We are currently engaged in discussions with the FDA regarding further steps to secure a post-exposure prophylaxis indication.

- *BioThrax dual adjuvant vaccine.* We are developing, in part with funding from NIAID and BARDA, a product candidate based on BioThrax combined with CpG 7909, an adjuvant that we licensed from Pfizer, Inc. We anticipate that this candidate will, among other things, have one or more of the following advanced characteristics: reduced number of doses required to produce a protective immune response, room temperature storage, enhanced immune response, longer expiry dating or a novel delivery method. We previously collaborated with Coley Pharmaceuticals, the owner of CpG 7909 before its sale to Pfizer, to conduct a double-blind Phase I clinical trial of BioThrax combined with CpG 7909 that was funded by DARPA. That trial, which was completed in 2005 and involved 69 healthy volunteers, was designed to evaluate the safety and immunogenicity of this product candidate compared to BioThrax alone and to CpG 7909 alone. In this Phase I trial, the product candidate was administered in three doses by intramuscular injection at two week intervals, and elicited an enhanced immune response. We have obtained additional U.S. government funding to supplement the further development of this vaccine product candidate.

The immunogenicity parameters for the Phase I clinical trial of BioThrax combined with CpG 7909 were the mean peak antibody concentration and the median time to achieve mean peak immune response in trial participants who received BioThrax combined with CpG 7909 as compared to trial participants who received BioThrax alone. 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 geometric anti-PA IgG concentration approximately 42.5 days after first injection. Participants who received BioThrax combined with CpG 7909 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 CpG 7909 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, to BioThrax or to CpG 7909.

### *Additional Anthrax Product Candidates*

- *rPA vaccine.* We are developing a recombinant form of the protective antigen protein as an anthrax vaccine. This vaccine contains purified rPA formulated with an aluminum hydroxide adjuvant and is designed to induce antibodies that neutralize anthrax toxins in a manner similar to BioThrax. The vaccine product candidate is based on development work at USAMRIID. Our rPA vaccine product candidate has been the subject of two research and development grants from NIAID totaling approximately \$100 million. It has also been evaluated in one Phase II clinical trial, but this trial did not achieve statistically significant results due to product stability issues. We believe these stability issues have since been resolved, and that future trials will not be adversely affected by stability concerns. In December 2009, BARDA cancelled a previously issued procurement request for proposal, or RFP, for an rPA vaccine for the SNS in favor of a Broad Agency Announcement, or BAA, for rPA vaccine development. We submitted a proposal responding to the BAA in January 2010 to develop our product candidate.
- *Double-mutant rPA vaccine.* We are developing an anthrax vaccine product candidate based on a double-mutant form of rPA, or dmPA, combined with CpG 7909 and Alhydrogel, an aluminum hydroxide adjuvant. In September 2009, we received an award from NIAID under the American Recovery and Reinvestment Act that included funding for development of a dry powder formulation and for the manufacture of bulk drug substance and final drug product in a current Good Manufacturing Practice, or cGMP, environment. We expect our development efforts for this product candidate to continue throughout 2010.
- *Immune globulin therapeutic.* We are developing a human anthrax immune globulin, or AIG, therapeutic product candidate, which is a polyclonal antibody therapeutic, as a treatment for patients who have been exposed to anthrax spores and who present with symptoms of anthrax disease. We expect that, if approved, this product candidate would be prescribed as an intravenous infusion either as a monotherapy or in conjunction with a regimen of antibiotics. We are developing our anthrax immune globulin therapeutic product candidate using plasma produced by healthy donors who have been immunized with BioThrax. We have engaged Talecris Biotherapeutics, Inc. to fractionate, purify and fill our AIG at its FDA-approved facilities, and have manufactured three full-scale lots under cGMP conditions using the validated and approved process at Talecris. We plan to rely on the FDA's animal rule to support approval of this product candidate.

In March 2009, we commenced a Phase I/II clinical trial to evaluate the safety and pharmacokinetics of our anthrax immune globulin therapeutic product candidate in healthy human volunteers. We expect to complete dosing in this trial in October 2010. In addition, we are continuing to conduct non-clinical efficacy studies. NIAID has provided us grant and contract funding for a combination of initiatives, including studies designed to assess the tolerability, pharmacokinetics and efficacy of this product candidate in non-clinical studies, the development and validation of product assays, and a human clinical trial to evaluate safety and pharmacokinetics. We are currently assessing applicable regulatory requirements in order to make a determination regarding further development of this product candidate.

- *Monoclonal antibody therapeutic.* We are developing a human monoclonal antibody therapeutic product candidate as an intravenous treatment for patients who present with symptoms of anthrax disease. The development of this product candidate is being funded in part by BARDA under our contract with NIAID to support efficacy testing in non-clinical studies and the establishment of a cGMP manufacturing process. We expect to file an Investigational New Drug Application, or IND, in 2010 for a Phase I clinical trial to evaluate the safety and pharmacokinetics this product candidate in healthy human volunteers.



## Tuberculosis

*Disease overview.* Tuberculosis, or TB, is an infection caused by *Mycobacterium tuberculosis*, which manifests primarily as an illness of the respiratory system and is spread by coughing, sneezing and associated respiratory actions. According to the World Health Organization, or WHO, TB is the world's second leading cause of death from infectious disease in adults, after HIV/AIDS.

*Prevalence, market opportunity and current treatment.* Approximately 2 billion people were infected with *Mycobacterium tuberculosis* worldwide in 2005, according to the Tuberculosis Vaccine Institute. One of ten people infected will develop the active form of the disease during their lifetime. A majority of TB cases occur in individuals between the ages of 25 to 54 years old. Between 1.6 and 2 million people die annually worldwide with more than 8 million new cases developing each year. The economic impact of TB in high-disease burden countries is significant. BCG, introduced in 1921, is currently the only available vaccine against tuberculosis.

BCG is administered to infants throughout the developing world and in certain countries in the developed world. However, BCG provides only variable protection against tuberculosis and is not sufficiently effective in adults.

Standard TB treatment involves a six to nine month treatment regimen with a combination of three or four antibiotic agents. These drugs are reasonably effective but poorly tolerated. Low patient compliance has contributed to the emergence of multi-drug resistant TB strains, or MDR-TB, and extensively-drug resistant strains, or XDR-TB. MDR-TB does not respond to the standard treatment using first line-drugs, such as isoniazid and rifampicin. Treatment of MDR-TB can last up to two years with drugs that produce more side effects and are more expensive. According to the WHO, each year an estimated 490,000 new MDR-TB cases occur, and more than 130,000 deaths are recorded worldwide as a result of MDR-TB infections. XDR-TB, is caused by bacteria resistant to all of the most effective drugs, including, for example, isoniazid, rifampicin, fluoroquinolone, and any of the second-line anti-TB injectable drugs, such as amikacin, kanamycin or capreomycin. As a result, XDR-TB is extremely difficult to treat. There are an estimated 40,000 new XDR-TB cases reported annually worldwide. By March 2008, XDR-TB cases had been confirmed in more than 45 countries and in all regions of the world. The emergence of MDR-TB and XDR-TB strains of *Mycobacterium tuberculosis* complicates treating the infection, indicating that a vaccine may be the most appropriate countermeasure for controlling TB.

*Tuberculosis vaccine.* Our tuberculosis vaccine product candidate uses the attenuated, or weakened, modified vaccinia Ankara virus, or MVA, as a vaccine platform to present antigen 85A to the immune system. Antigen 85A is a major antigen from *Mycobacterium tuberculosis*, which forms part of the antigen 85 complex. Antigen 85A is highly conserved among all mycobacterial species and is present in all strains of BCG, suggesting that antigen 85A should elicit a strong immune response in individuals vaccinated with BCG. The vector, or carrier, for our TB vaccine product candidate is MVA. MVA is an attenuated strain of Vaccinia virus, the small pox vaccine, which does not replicate in mammalian cells. Another strain of MVA has been administered to more than 120,000 individuals as part of the smallpox eradication program and was found to be safe and well tolerated, despite the deliberate vaccination of high risk groups. Our tuberculosis vaccine, a strain of MVA into which the Antigen 85A gene has been cloned - designated as MVA85A - has been designed to increase the immune response to Antigen 85A and thus increase vaccine protective efficacy in individuals previously vaccinated with BCG. The clinical development of MVA85A is aimed towards the production of an effective TB vaccine for infants, adolescents, and HIV-infected adults to augment the immunity induced by a previous BCG vaccination. We have licensed the commercial rights to our tuberculosis vaccine from the Oxford-Emergent Tuberculosis Consortium, or OETC.

To date, the MVA85A vaccine has been evaluated in seven Phase I clinical trials. These trials were conducted in an aggregate of 126 healthy adults (BCG-naive, BCG-vaccinated, or latently infected with TB) and 12 BCG vaccinated adolescents living in the UK, The Gambia or South Africa. All trials evaluated the safety and immunogenicity of various intradermal doses of MVA85A, first in healthy adults, both BCG-vaccinated and BCG-naive, and then also in special populations such as adolescents and TB/HIV-infected adults. The key findings from these clinical trials were that the MVA85A vaccine was well tolerated, with no significant safety concerns, and previous vaccination with BCG did not affect the safety profile. Additionally, MVA85A was effective at increasing cellular immune responses to antigen 85A in individuals previously vaccinated with BCG.

Ongoing Phase I trials are intended to investigate further the safety and immunogenicity of MVA85A in special populations such as adolescents and TB/HIV-infected individuals. There are 5 trials currently being conducted in adults. Additionally, three Phase II trials are also being carried out in infants and children in sub-Saharan Africa. In The Gambia, a Phase II open label, randomized dose escalation and non-interference trial intended to involve approximately 216 infants is being conducted. The purpose of this study is to evaluate the impact, if any, of MVA85A vaccination when given at two dose levels on the immunogenicity of Expanded Program on Immunization, or EPI, vaccines administered simultaneously to infants previously vaccinated with BCG. In South Africa, an open label, non-randomized placebo-controlled Phase II trial with approximately 168 subjects is being conducted to evaluate the safety and immunogenicity of MVA85A in healthy children and infants who received prior BCG vaccination.

A Phase IIb trial in infants commenced in South Africa in the first half of 2009. Designed as a double-blind, randomized placebo-controlled evaluation of MVA85A/AERAS-485 for safety, immunogenicity and prevention of TB in BCG-vaccinated, HIV-negative infants, this trial is expected to include 2,784 infants. The trial is being conducted at a single site in South Africa and infants will be followed both for the development of tuberculosis and for serious adverse events. We currently expect this trial to conclude in 2012.

## **Typhoid**

*Disease overview.* Typhoid, also known as typhoid fever, is caused by infection with the bacterium *Salmonella enterica* (type *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.

*Prevalence, market opportunity and current treatment.* Typhoid fever continues to be a public health problem in many developing countries with an estimated 22 million cases occurring per year worldwide, resulting in approximately 200,000 deaths annually. Increasing multi-drug resistance of the typhoid bacterium reduces effective treatment options, increases treatment costs and results in higher rates of serious complications and deaths. According to the CDC, approximately 400 cases of typhoid are reported annually in the United States, of which approximately 70% are contracted abroad. 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. According to the U.S. Office of Travel and Tourism, over 30 million people travel annually to typhoid endemic areas. This travelers market represents our primary target market. Potential additional markets include U.S. military personnel deployed in regions where typhoid is endemic, as well as children and adults living in these areas.

One oral typhoid vaccine and one injectable typhoid vaccine are currently approved for administration in both the United States and Europe and are primarily sold for use in the travelers market. The approved oral typhoid vaccine is available in liquid and capsule formulations. Both formulations require multiple 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 not effectively 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 for typhoid could be as high as 20%. Although vaccines are available, the WHO has stated that improved vaccines against typhoid fever are desirable, especially for children 2 years of age and older.

*Typhella*. We are developing Typhella, a live attenuated typhoid vaccine, which contains deletions in two genes of the *Salmonella typhi* bacterium designed to attenuate virulence and limit replication in the host. We have designed Typhella to be administered in a single drinkable dose prior to travel to countries where typhoid is endemic.

We have completed the following clinical trials of Typhella 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 product candidate. In this study, Typhella was immunogenic, eliciting both cell mediated and humoral immune responses, 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 product candidate. In this trial, Typhella was immunogenic and well tolerated at all dose levels.
- An open-label, non-placebo controlled, single dose Phase I clinical trial conducted in the United States in 32 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of two different presentations of Typhella, one using bottled water and another using tap water for reconstitution before administration. We vaccinated 16 subjects with each presentation. Because the two presentations were similarly immunogenic and both were well tolerated by trial participants, we selected the tap water presentation for further development based on its relative convenience.
- A single-blind, placebo controlled Phase I clinical trial of Typhella 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 Phase I trial in Vietnam. The purpose of the trial was to evaluate the safety and immunogenicity of Typhella when administered as a single oral dose in adults living in an endemic area. The primary immunogenicity endpoint for this trial was the proportion of trial participants with an immune response to *Salmonella typhi* following administration of a single oral dose of Typhella. Based on initial data from this trial, Typhella met the criterion for immunogenicity, with approximately 68% of subjects who received the vaccine product candidate mounting a humoral antibody response. Typhella was well tolerated by trial participants, with no serious adverse events reported.
- A single-blind randomized, placebo controlled, Phase II clinical trial of Typhella in Vietnam in 151 healthy children between the ages of 5 and 14 years. A total of 101 children received Typhella and 50 children received placebo. This was our first trial involving a pediatric population. We conducted this trial in collaboration with the Wellcome Trust, Oxford University and the Hospital for Tropical Diseases, Ho Chi Minh City, Vietnam. The Wellcome Trust provided funding for this trial. The purpose of this trial was to evaluate the safety and immunogenicity of Typhella in children in an endemic area. The immunogenicity parameter for this trial was the percentage of trial participants with an immune response to *Salmonella typhi* following administration of a single oral dose of Typhella. In this trial, 93% of the children receiving a vaccine dose developed an immune response as measured by increases in serum *Salmonella typhi* LPS-specific IgG antibody levels, 94% of the children receiving a vaccine dose developed an immune response as measured by increase in serum *Salmonella typhi* LPS-specific IgA antibody levels, and 97% of the children receiving a vaccine dose developed an immune response, which was statistically significantly greater than the percentage of children receiving placebo who developed an immune response. Typhella was well tolerated by trial participants, with no serious adverse events reported.
- A randomized, double blind, placebo controlled, single dose, dose escalating Phase II clinical trial conducted in the United States in 187 healthy adult volunteers. The purpose of this trial was to determine the immunogenicity, safety and tolerability of the vaccine product candidate manufactured at a new facility at dose levels across the range of the proposed manufacturing potency specification. The primary immunogenicity endpoint for this trial was the proportion of trial participants with an immune response to *Salmonella typhi* following administration of a single oral dose of Typhella. In this trial, the vaccine was immunogenic and well tolerated across the range of doses tested.

In these six clinical trials, Typhella 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 safety and immunogenicity of a single dose regimen at an appropriate dose level in populations in both endemic and non-endemic areas.

We are currently evaluating manufacturing alternatives in countries in which we believe manufacturing costs will be feasible because we do not currently have manufacturing resources, either internal or through a contract manufacturer, to produce Typhella at competitively viable costs. Once we have engaged a contract manufacturer, we expect that the remainder of our planned clinical development program for this vaccine product candidate will consist of the following:

- *Phase II clinical trial.* We plan to conduct a Phase II clinical trial in India in children under five years of age as a step towards conducting a Phase III clinical trial in an area where the incidence of disease is prevalent. The purpose of this Phase II trial is to evaluate the safety and immunogenicity of Typhella in this endemic population in preparation for our planned Phase III clinical trial.
- *Challenge study.* We plan to initiate a vaccine protection study using a human challenge model, pending the provision of funding by Oxford to establish that model.
- *Disease surveillance study.* We plan to conduct a disease surveillance study in India to confirm that a sufficient number of subjects will be included in our planned Phase III clinical trial. The Wellcome Trust has provided funding for a portion of this surveillance study.
- *Phase III clinical trial.* We plan to conduct a single-blind Phase III clinical trial in India, where typhoid is endemic. The purpose of this trial will be to evaluate the efficacy of Typhella in children who are likely to be exposed to the typhoid bacterium. We expect to undertake the primary analysis of the data from the trial after approximately one year, which, if the results are favorable, we plan to use the data to support the filing with the FDA of a BLA for marketing approval of Typhella. We plan to continue to monitor the incidence of typhoid in the trial participants for several years after vaccination. We are currently seeking external funding to support this trial.
- *Tolerability and immunogenicity study.* Concurrently with our planned Phase III clinical trial in India, 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 Typhella to support marketing approval in the United States and Europe. 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. We will seek to establish an immune correlate of protection in the Phase III efficacy trial to allow us to extrapolate efficacy to developed world populations. The currently approved typhoid vaccines relied on similar clinical trials for regulatory approval.

## **Influenza**

*Disease overview.* Influenza, or the flu, is a highly contagious respiratory illness caused by influenza viruses. While there are only two types of influenza viruses that cause significant illness in humans, types A and B, these flu viruses can easily mutate to give rise to new subtypes, such as H1N1, H3N2 or H5N1. These new subtypes are often sufficiently different from previous strains so that prior immunity from vaccination or natural illness provides little to no protection against infection. Once infected, illness can range from a mild, upper-respiratory infection to an acute, life-threatening illness. Influenza is often characterized by a sudden onset of high fever, cough (usually dry), headache, muscle and joint pain, severe malaise, sore throat and runny nose. Influenza viruses are transmitted from person to person primarily through contact with infected airborne droplets generated by coughing and sneezing. The time from infection to illness can be as short as two days. The infectious period for influenza is defined as one day before fever begins until 24 hours after the fever ends.

*Prevalence, market opportunity and current treatment.* Influenza tends to spread rapidly in seasonal epidemics that occur yearly during autumn and winter in temperate regions. Illness resulting in hospitalization or death occurs mainly among high-risk groups, including the very young, elderly or chronically ill. According to the WHO, these annual epidemics result in approximately three to five million cases of severe illness and 250,000 to 500,000 deaths worldwide. According to the CDC, in the United States on an annual basis, influenza affects on average 5% to 20% of the population, more than 200,000 people are hospitalized from flu-related complications, and approximately 30,000 to 35,000 people die from flu or flu-related causes.

The WHO recommends vaccination as the most effective way to prevent the disease or severe outcomes from the illness. Safe and effective vaccines have been available and used for more than 60 years. Among healthy adults, an influenza vaccine can prevent 70% to 90% of influenza-specific illness during seasons where there has been little change in the virus. Among the elderly, the vaccine reduces severe illnesses and complications by up to 60%, and deaths by up to 80%. Most healthy symptomatic people recover within a week without requiring medical attention. In some cases, an antiviral drug may be prescribed.

The current value of the seasonal flu market, based on the 2008-2009 flu season, is estimated to be approximately \$2.8 billion across the seven major markets, with growth of 12.6% since 2005-2006. This is the result of expanded recommendations in the United States regarding vaccination of infants and an increasing disease awareness resulting from recent pandemic flu threats. Improved vaccines for the elderly, and faster and more flexible manufacturing technologies are key unmet needs.

*Manufacturing overview.* Current flu vaccine manufacturing typically requires growing the influenza virus in fertilized chicken eggs. This can be a lengthy and time-consuming process and depends on the availability of a suitable supply of eggs. Most flu vaccines, both seasonal and pandemic, are currently produced using egg-based manufacturing processes. Influenza viruses can also be grown using more modern cell culture technologies, in which the influenza virus is allowed to infect and grow in mammalian cells that were propagated to high levels using bioreactors and sterile media. This manufacturing method is a simpler and more predictable process than traditional egg-based manufacturing processes, but has not yet been implemented domestically on a commercial scale.

*Influenza Vaccine.* We are developing a recombinant viral vaccine product candidate that, if successful, would provide protection against multiple influenza strains. We expect to design this product candidate to overcome the limitation of current seasonal influenza vaccines, which are highly strain specific and need to be manufactured every year to match the current circulating strains. Our approach relies on using our live, attenuated MVA vector as a vaccine delivery system. We believe that presentation of influenza antigens using this delivery vector could induce broad immune responses sufficient to provide protection against multiple influenza viruses and over multiple seasons. Unlike traditional influenza vaccines that predominately target the variable hemagglutinin, or HA, and neuraminidase, or NA, antigens present on the surface of the virus, we are evaluating both the HA antigen as well as internal, conserved antigens that do not change from year to year. In addition, MVA has the potential for cell-based, rather than egg-based manufacture, and we are developing this capability as part of this program. To date, we have generated initially promising preclinical data with these antigens and are in the process of conducting additional preclinical studies to optimize our MVA-based product candidates for potential future clinical development.

## **Chlamydia**

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

*Prevalence, market opportunity and current treatment.* The WHO estimates that approximately 92 million new cases of *Chlamydia trachomatis* infection occur annually worldwide, of which approximately four million 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. There is no vaccine currently on the market for *Chlamydia trachomatis*. However, screening tests and 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.

*Chlamydia vaccine.* We are evaluating a recombinant protein subunit Chlamydia vaccine for clinically relevant strains of *Chlamydia trachomatis*. We are designing our vaccine product candidate to be administered by intramuscular injection. We have cloned our recombinant vaccine product candidate and produced it in *E. coli*. In preclinical studies, our recombinant vaccine product candidate, when co-administered with an adjuvant, protected animals against both upper reproductive tract disease and lower reproductive tract infection induced by *Chlamydia trachomatis*. We are also developing an MVA-based chlamydia vaccine product candidate and expect to conduct preclinical immunogenicity and efficacy studies during 2010.

## **Manufacturing**

We manufacture BioThrax at our facilities in Lansing, Michigan using well-established vaccine manufacturing procedures. In 2009, we completed construction of a new 50,000 square foot manufacturing facility at the Lansing campus, and we submitted a proposal to BARDA in October 2009 for scale-up, qualification, validation and licensure for the manufacture of BioThrax in this facility.

In November 2009, we paid approximately \$8.2 million to purchase a 56,000 square foot manufacturing facility in Baltimore, Maryland. We expect to use this facility to support our future product development and manufacturing needs, and we are currently renovating and improving this facility so that it will be capable of supporting development of our pipeline product candidates. Our specific plans for this facility will be contingent on the progress of our existing development programs and the outcome of our efforts to acquire new product candidates.

We currently rely on contract manufacturers and other third parties to manufacture the supplies we require for preclinical studies and clinical trials and for supplies and raw materials used for the production of BioThrax and our product candidates. We typically acquire these supplies and raw materials on a purchase order basis in quantities adequate to meet our needs. We believe that there are adequate alternative sources of supply available for most of our raw materials if any of our current suppliers were unable to meet our needs. We anticipate that we may use our existing plant facilities in Michigan 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 to support some of our product candidates.

Hollister-Stier Laboratories LLC performs contract filling for BioThrax 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, 2010. We have also entered into an agreement for contract filling operations with JHP Pharmaceuticals, LLC, which must now be qualified and licensed by the FDA to fill BioThrax at its facilities.

Talecris Biotherapeutics, Inc. has agreed to perform plasma fractionation and purification and contract filling of our anthrax immune globulin therapeutic 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 manufacturing requirements for our anthrax immune globulin therapeutic product candidate 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. We have agreed to pay Talecris mid-single digit royalties on net sales on a country-by-country basis for commercial product manufactured by Talecris. Our contract with Talecris expires December 31, 2014, and 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. Our contract also provided for the commencement of commercial manufacturing activities as of January 1, 2010, which would have triggered an obligation on our part to purchase a significant amount of source plasma per year for a five-year term. Because our anthrax immune globulin therapeutic product candidate is not currently ready for commercial-scale manufacturing, we recently agreed to extend commencement of the commercial term to April 1, 2010, and are in negotiations with Talecris for a longer-term resolution regarding commercial production. In the event that we are not able to negotiate a satisfactory resolution, we may be required to explore other options for our anthrax immune globulin program. Under the existing agreement, after three years following initiation of commercial manufacturing, either party may terminate the contract upon two years' advance notice. We have the right to terminate the contract, under specified circumstances, including if we discontinue our production of anthrax immune globulin source plasma or the development of our anthrax immune globulin therapeutic product candidate.

We used a contract manufacturer for the supply of Typhella for the Phase I and Phase II trials in Vietnam, the United Kingdom and the U.S. We may use a different contract manufacturer for the supply of this vaccine product candidate for future trials. We have also entered into an agreement with a new contract manufacturer for our monoclonal anthrax antibody therapeutic product candidate.

We also expect that we will rely on third parties for a portion of the manufacturing process for commercial supplies of other product candidates that we successfully develop, including fermentation for some of our vaccine product candidates and contract fill and finish operations. The manufacture of biologic products and the scale-up process necessary to manufacture quantities of product sufficient for commercial launch are complex. If we are unable to secure relationships with third party contract manufacturers that can provide sufficient supplies for the commercial launch of our product candidates on commercially attractive terms, our ability to capture market share may be adversely affected.

## **Marketing and Sales**

We currently market and sell BioThrax directly to the U.S. government 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 for other biodefense product candidates that we successfully develop. We may expand our sales and marketing organization as we broaden our sales activities of biodefense products at the state and local level, where we expect there will be interest in these products to protect emergency responders such as police, fire and emergency medical personnel, and other personnel whose occupation may cause them to be at a high risk of exposure to biothreats.

We have established marketing and sales offices in Munich, Germany and Singapore to target sales of biodefense products to foreign governments. We have augmented our international efforts by engaging third party marketing representatives to identify potential opportunities to sell BioThrax in the Middle East, India, Australia, and several countries in Southeast Asia and Europe, and anticipate engaging additional representatives.

We expect to increase our sales and marketing resources 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, especially in situations in which the collaborator has particular expertise or resources for the commercialization of our products or product candidates or access to 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. Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Novartis and Wyeth generated over 90% of the total worldwide vaccine revenues in 2007. 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 narrowly focused companies, including Aeras, Crucell, Cangene, Human Genome Sciences, Soligenix, Dynport Vaccine Company LLC, Elusys, Bavarian Nordic, Panacea and PharmAthene, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or through significant development or procurement contracts with governmental agencies or philanthropic organizations.

Our biodefense product candidates face significant competition for U.S. government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. 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. Our opportunity to succeed in this industry 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.

Any product candidate that we successfully develop and commercialize is likely to compete with currently marketed products, such as vaccines and antibody therapies, including antibiotics, and with other product candidates that are in development for the same indications. Specifically, the competition for BioThrax and our product candidates includes the following:

- *BioThrax*. Although BioThrax is the only product approved by the FDA for human use for the prevention of anthrax infection, we face significant potential competition for the supply of anthrax vaccines to the U.S. government. Various agencies of the U.S. government are providing funding to our competitors for development of an anthrax vaccine based on recombinant protective antigen. In addition, the United Kingdom Health Protection Agency, or HPA, manufactures an anthrax vaccine for use by the government of the United Kingdom. Other countries as well may have anthrax vaccines for use by or in development for their own internal purposes.



- *rPA vaccine*. PharmAthene is currently developing a recombinant protective antigen based anthrax vaccine. BARDA has awarded a modification to an existing development contract to PharmAthene to fund the development of their rPA vaccine. Panacea is also developing an rPA vaccine.
- *BioThrax related programs and double-mutant rPA vaccine*. PharmAthene is currently developing a recombinant protective antigen based anthrax vaccine as well as a third-generation anthrax vaccine.
- *Anthrax immune globulin and monoclonal antibody therapeutic*. Cangene is currently developing an anthrax immune globulin therapeutic based on plasma collected from military personnel who have been vaccinated with BioThrax; Human Genome Sciences is developing a monoclonal antibody to *Bacillus anthracis*, referred to as ABthrax™, as a post-exposure therapeutic for anthrax infection; Elusys Therapeutics is developing a monoclonal antibody to *Bacillus anthracis*, known as Anthim™, as a pre-exposure and post-exposure prophylaxis against anthrax infection, as well as an active treatment of disease; and PharmAthene and Medarex are collaborating to develop a human antibody to *Bacillus anthracis*, known as Valortim™, to protect human cells from damage by anthrax toxins. The FDA has granted Fast Track designation and orphan drug status for ABthrax and Valortim. HHS awarded development and procurement contracts to Human Genome Sciences and Cangene to supply their anthrax therapeutics for evaluation of efficacy as a post-exposure therapeutic for anthrax infection.
- *Typhella (typhoid vaccine live oral ZH9)*. One oral typhoid vaccine and one type of 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. Vi-conjugable injectable vaccines are also in development.
- *Tuberculosis vaccine*. The Aeras Global Tuberculosis Vaccine Foundation is developing or supporting the development of five tuberculosis vaccine product candidates, one of which is in a Phase II clinical trial, and the rest of which are either in Phase I clinical trials or close to commencing Phase I clinical trials. The Aeras Global Tuberculosis Vaccine Foundation is also the sponsor of the Phase IIb clinical trial of our tuberculosis vaccine product candidate.
- *Influenza vaccine*. Seasonal and pandemic influenza vaccines produced using conventional egg-based manufacturing methodologies have been licensed and are being sold in both the United States and internationally by GlaxoSmith Kline, Novartis, MedImmune and others. Several flu vaccine manufacturers are transitioning the production of their seasonal and pandemic vaccines from egg-based processes to cell culture in an effort to increase supply of these products. These cell culture-based products are in various stages of advanced development. New influenza vaccines containing hemagglutinin (HA) antigens and/or other flu antigens produced using recombinant DNA technology and/or incorporate adjuvants are also under development. Some of these second generation flu vaccine candidates are in clinical development.
- *Chlamydia vaccine*. There is no vaccine currently on the market for chlamydia. Although we are not aware of any competing chlamydia vaccine product candidate in clinical development, competitors may have chlamydia vaccine product candidates in preclinical development. Screening tests and targeted antibiotic treatments have been effective at containing chlamydia in the United States and Europe, which may have the effect of decreasing demand for a vaccine.

### **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 February 26, 2010, we owned or licensed exclusively a total of 20 U.S. patents and 34 U.S. patent applications relating to our biodefense and commercial product candidates, 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 own or exclusively licensed from USAMRIID relating to our rPA vaccine product candidate and from OETC relating to our tuberculosis vaccine product candidate to be important.

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

- *Typhella (typhoid vaccine)*. We hold four U.S. patents relating to Typhella. These patents have claims to the composition of matter of the vaccine product candidate and methods of use of live 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 Typhella. Our issued U.S. patents expire, and, if issued, our U.S. patent applications would expire, between 2015 and 2020. We hold 107 foreign counterpart patents to our issued U.S. patents relating to Typhella, including counterparts under the European Patent Convention and in Japan, that expire, and 14 foreign patent applications that, if issued, would expire, between 2015 and 2020. Additional patents relating to Typhella and delivery of vaccine antigens are discussed below under “STM technology.”
- *STM technology*. We own four U.S. 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 product candidate. In addition, we have one pending U.S. patent application with additional claims to methods for identifying virulence genes using our STM technology. We also own 50 foreign counterpart patents, including counterparts under the European Patent Convention and in Japan. These patents relating to the STM method will expire in 2015. We also hold 14 foreign patent applications that, if issued would expire in 2015. Our rights under these patents are licensed on a limited non-exclusive basis to third parties to practice the STM method with respect to specific microorganisms, not including *Salmonella typhi* or hepatitis virus.

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. We may become subject to patent interference proceedings or claims that our products infringe or violate the intellectual property rights of third parties. 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 or for the label expansions and improvements that we are pursuing for BioThrax, our only intellectual property protection for BioThrax, aside from the BioThrax trademark, 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 employees, consultants, scientific advisors 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.

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 own 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 USAMRIID and OETC, which are described below. We also have a license agreement with the Bavarian State Ministry of the Environment and Public Health, or StMUG, relating to our MVA vector technology that we may use in the development of future product candidates, which is also described below.

*USAMRIID agreement.* In connection with our acquisition of our rPA vaccine product candidate in May 2008, we became a licensee under an October 2003 agreement with USAMRIID pursuant to which we have exclusive worldwide rights under the licensed patent technology to develop, manufacture and commercialize product candidates for human use as a vaccine for the prevention or treatment of anthrax infection. The licensed patent technology includes two U.S. patents with claims to the strain of *B. anthracis* used to prepare our rPA vaccine product candidate and methods of making a recombinant protective antigen vaccine. The patents expire in 2014. There are no foreign counterpart patents or applications.

Under the license agreement, we are required to pay USAMRIID a small annual license fee, aggregate payments of up to \$535,000 upon the achievement of specified development and regulatory milestones and mid single-digit royalties on sales of licensed products to non-U.S. government customers. Our obligation to pay royalties continues 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. In addition, we are required to pay USAMRIID a specified fee per dose for any sales by us to a U.S. government agency.

The license agreement requires us to expend reasonable efforts and resources to carry out the development and marketing of the inventions described and claimed in the licensed patent technology, and once licensed products are being utilized and have been made available to the public, to continue to make those licensed products available to the public. We also bear responsibility for the preparation, filing, prosecution and maintenance of patent applications and patents included in the licensed patent technology.

USAMRIID may terminate the license agreement if necessary to meet requirements for public use specified by government regulations that we do not reasonably satisfy. We may terminate the license agreement at any time upon 90 days advance written notice. Each party has the right to terminate the license agreement following the occurrence of a material breach by the other party, subject to USAMRIID's ability to cure any breach.

*OETC agreement.* In July 2008, we entered into a technology license agreement with OETC pursuant to which we obtained rights to develop, manufacture and commercialize product candidates containing MVA85A for the prevention or treatment of *Mycobacterium tuberculosis* in humans. Generally, our rights to manufacture the licensed product and to commercialize it in developed countries are exclusive. The licensed patent portfolio includes one U.S. patent application, which if issued as a patent would expire in 2025. The licensed patent portfolio also includes five foreign patents and 26 foreign patent applications, which if issued as patents would expire in 2025.

Under the license agreement, we paid OETC an initial signing fee of \$750,000 and are required to make aggregate payments of up to \$89.5 million upon the achievement of specified development, regulatory and sales milestones and pay escalating mid single-digit to low double-digit royalties on sales of the licensed product in developed countries. Our obligation to pay royalties continues on a product-by-product and country-by-country basis until the later of ten years from first commercial sale of the first licensed product in that country and the expiration of the last-to-expire valid claim of the licensed patent application in that country. We also reimbursed patent costs of approximately \$120,000 incurred by the University of Oxford and Isis Innovation Limited prior to entering into the license agreement and have agreed to reimburse OETC for future patent costs in specified developed countries. In addition, we have agreed that to retain our commercial license rights, if the planned Phase IIB clinical trial of the licensed product in infants is successful, we will fund and undertake a Phase III clinical trial of the licensed product in infants.

Under the OETC license agreement, we are generally required to use reasonable efforts to obtain regulatory approvals for an infant indication, and, if so approved, an adolescent indication, and thereafter an indication for HIV infected adults; develop a scaled-up manufacturing process that is cell-based and capable of achieving minimum dose quantities; market a licensed product in countries in the developed world for each indication for which regulatory approval has been received; and attain a minimum level of annual sales of the licensed product in the developed world.

The term of the license agreement lasts until the later of 20 years from the grant of the first marketing approval for a licensed product and the expiration of the last-to-expire valid claim of the licensed patent application. We may terminate the license agreement upon 30 days advance written notice if regulatory approval is not obtained to commence the planned Phase IIB clinical trial of the licensed product in infants by December 1, 2009 or if no subjects in such trial have been dosed by May 31, 2010; following receipt of the final report from the Phase IIB clinical trial of the licensed product in infants, a bridging study and an age de-escalation study, whichever is later; or if OETC terminates its underlying license agreement with Isis Innovation Limited for a material breach of that agreement.

We may terminate the license agreement upon 60 days advance written notice if any clinical trial of the licensed product is suspended or terminated for safety reasons or upon 90 days advance written notice if a clinical trial for an infant indication within the development plan agreed by the parties does not meet predetermined criteria for success. We may terminate the license agreement upon 12 months advance written notice at any time after we receive the final results in writing from the Phase IIB clinical trial of the licensed product in infants. We and OETC each have the right to terminate the license agreement following the occurrence of a material uncured breach by the other party.

*MVA platform technology.* In July 2006, in connection with our acquisition of ViVacs GmbH, or ViVacs, a German limited liability company, we acquired a license agreement with StMUG that provides us the non-exclusive, worldwide right to develop and produce viruses and viral products, including recombinant viral vectors, using MVA. Under the license agreement, we are required to pay StMUG low single digit royalties based on the net amounts or license fees that we receive from third-party licensees who use MVA to develop products that are used for research or diagnostic purposes and a mid-teens royalty based on 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. In addition, StMUG may terminate the license agreement upon the insolvency or liquidation of our wholly owned subsidiary, Emergent Product Development GmbH, formerly ViVacs GmbH. Our MVA 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 using recombinant technology. We are currently exploring potential product candidates based on our MVA platform, including a broadly cross protective influenza vaccine candidate.

## **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 products, including drugs and biological products. These agencies and other federal, state and local entities regulate the 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 product and product candidates.

### **U.S. Government Regulation**

In the United States, BioThrax and our product candidates are regulated by the FDA as biological products. Biological products 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 of development may result in various adverse consequences, including delay in approving or refusal to approve a product. Violations of regulatory requirements after product approval also may result in enforcement actions, including withdrawal of product approval, labeling restrictions, seizure of products, fines, injunctions and civil and 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:

- laboratory and preclinical tests, including animal testing;
- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before clinical trials may begin;
- completion of human clinical trials and other studies evaluating the safety and efficacy of the proposed product for each intended use;
- FDA inspection of facilities in which the product is manufactured, processed, filled, packed and held to determine compliance with cGMP; and
- submission to the FDA and approval of an NDA, in the case of a drug, or a BLA containing, among other things, preclinical, nonclinical and clinical data; proposed labeling; and information to demonstrate that the product will be safe and effective (in the case of an NDA) or safe, pure and potent (in the case of a BLA), and 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 and the IND**

Preclinical studies include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to begin to assess its potential safety and efficacy. We submit the results of the preclinical studies, together with manufacturing information, analytical data, relevant literature, and any available clinical data or experience in humans to the FDA as part of an IND, which must become effective before we may begin human clinical trials. The IND submission also contains one or more clinical trial protocols and an investigation plan, 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, or IRB, 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 a clinical trial. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various ground, including a finding that the study subjects are being exposed to an unacceptable health risk or that the proposed clinical trials will not yield sufficient data to support licensure or approval of the product.

## Clinical Trials

Human clinical trials are typically conducted in three sequential phases, some of which may overlap or be omitted in some cases:

- 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, distribution, metabolism 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, and preliminary information related to the efficacy of the product for specific targeted diseases, 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 has the potential to be effective and appears to potentially have 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 the dosage amount(s), clinical efficacy, and safety. Prior to commencing Phase III clinical trials, many sponsors elect to meet with FDA officials to discuss the conduct and design of the proposed trial or trials.

Clinical trials must be conducted in compliance with good clinical practice, or GCP, requirements, which, among other things, provide standards for the protection of human subjects. In addition, federal law now requires the listing, on a publicly-available website, of registry and results information for most clinical trials that we conduct. The federal requirements for submission of results information will continue to be phased-in over the next year. Some states have similar or more supplemental clinical trial reporting laws.

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,” under some circumstances approval of such products 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 drug or 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 requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

## Marketing Approval

In the United States, if a 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 biological product, the purity and potency of the product candidate. Both NDAs and BLAs must contain 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 an inspection of 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 or processes fail to pass the FDA inspection, we may not receive approval to market these products. The FDA may also conduct an audit of the clinical trial data used to support the NDA or BLA.

The FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or if the FDA believes that additional clinical data is necessary. Even if additional clinical data are 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 evaluation and mitigation strategy, or REMS, or otherwise limit the scope of any approval or limit labeling. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems, including concerns about the safety or effectiveness of the product, occur after the product reaches the market. In addition, in certain circumstances the FDA may require additional testing and surveillance programs for approved products that have been commercialized. The FDA has the power to prevent or limit further marketing or distribution of a product based on the results of these post-marketing studies or programs.

### **Fast Track Designation**

In February 2007, the FDA granted Fast Track designation for BioThrax as a post-exposure prophylaxis against anthrax infection. The FDA's Fast Track designation program is designed to facilitate the development and review of new drugs, including biological products that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for the conditions. Fast Track designation applies to a combination of the product and the specific indication for which it is being studied. Thus, it is the development program for a specific drug for a specific indication that receives Fast Track designation. The sponsor of a product designated as being in a Fast Track drug development program may engage in early communication with the FDA, including timely meetings and early feedback on clinical trials, and may submit portions of an application on a rolling basis rather than waiting to submit a complete application. Products in Fast Track drug development programs also may receive priority review or accelerated approval, under which an application may be reviewed within six months after a complete NDA or BLA is accepted for filing or sponsors may rely on a surrogate endpoint for approval, respectively. The FDA may notify a sponsor that its program is no longer classified as a Fast Track development program if the Fast Track designation is no longer supported by emerging data or the designated drug development program is no longer being pursued.

### **Post-Marketing Regulation**

Any products manufactured or distributed by us pursuant to FDA licenses 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 product; and
- advertising and promotion restrictions.

As a condition of NDA or BLA approval, the FDA may require post-approval testing and surveillance to monitor a product's safety or efficacy. The FDA also may impose other conditions, including labeling restrictions which can materially impact the potential market and profitability of a product.

The FDCA and the FDA's rules for advertising and promotion require, among other things, 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 certain planned changes to the approved product, product labeling or manufacturing process.

Drug manufacturers, distributors and their subcontractors are required to register their establishments with the FDA and state agencies. The cGMP requirements for biological products in particular are extensive and compliance with them requires considerable time, resources and ongoing investment. 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. For all drugs and biological products, the regulations require investigation and correction of any deviations from cGMP requirements 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 all cGMP requirements. 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.

We, our collaborators or our 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 or Untitled Letters from the FDA asking us, our collaborators or third party contractors to take or refrain from taking certain actions;
- withdrawal of the product from the market;
- FDA's 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.

### **BioThrax Lot Release and FDA Review**

Because of the complex manufacturing processes for most biological products, the FDA requires that each product lot of an approved biological product, including vaccines, undergo thorough testing for purity, potency, identity and sterility. Before a lot of BioThrax can be used, we must submit a sample of the vaccine lot and a lot release protocol to the FDA. The lot release protocol documents reflect the results of our tests for potency, safety, sterility, any additional assays mandated by our BLA for BioThrax and a summary of relevant manufacturing details. The FDA reviews the manufacturing and testing information provided in the lot release protocol and may elect to perform confirmatory testing on lot samples that we submit. We cannot distribute a lot of BioThrax until the FDA releases it. The length of the FDA review process depends on a number of 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.

### **Regulation of Immune Globulin Products**

Products derived from humans, including our anthrax immune globulin therapeutic candidate, 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 IRB 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.



## **Legislation and 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 legislation and regulation described below.

### **Project BioShield**

The Project BioShield Act of 2004, or Project BioShield, provides expedited procedures for bioterrorism related procurement 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, or FAR, for procuring 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.

Under Project BioShield, the Secretary of HHS, with the concurrence of the Secretary of the Department of Homeland Security, or DHS, and upon the approval of the President, can contract to purchase unapproved countermeasures for the SNS in specified circumstances. The U.S. Congress is notified of a recommendation for a stockpile purchase after Presidential approval. Project BioShield specifies that a company supplying the countermeasure to the SNS 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; and
- there is no adequate alternative to the product that is approved and available.

Although this provision permits the Secretary of HHS to circumvent the FDA approval process, its use would be limited to rare circumstances.

### **Safety Act**

The Support Anti-Terrorism by Fostering Effective Technologies Act, or 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, or PREP Act, enacted by Congress in 2005 provides immunity to manufacturers from all claims under state or federal law for “loss” arising out of the administration or use of a “covered countermeasure.” However, injured persons may still bring a suit for “willful misconduct” against the manufacturer under some circumstances. “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 October 2008, the Secretary of HHS issued a declaration that BioThrax and our anthrax immune globulin therapeutic have been included as covered countermeasures under the PREP Act. We cannot predict whether Congress will fund the relevant PREP Act compensation programs or whether the necessary prerequisites for immunity would be triggered with respect to our product or product candidates.

## **Changing Legal and Regulatory Landscape**

Periodically legislation is introduced in the U.S. Congress that could change the statutory provisions governing the approval, manufacturing and marketing of drugs, including biological products. For example, previous Congresses have considered, and the current Congress is considering, among other things, comprehensive health reform legislation and proposed legislation to permit the marketing of biosimilar biological products that rely on data submitted in an innovator’s application to support their approval or licensure. It is not possible to predict whether and when such legislative changes will be enacted or what those changes would entail, including whether the changes would provide innovators with a period of data exclusivity or the length of any such exclusivity period.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and products. We cannot predict whether or when legislation impacting our business will be enacted, what FDA regulations, guidance or interpretations may change, or what the impact of such changes, if any, may be in the future.

## **Foreign Regulation**

In addition to regulations in the United States, we may 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 usually 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 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, in the European Union, 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/mutual recognition 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, neurodegenerative disorder, diabetes, auto-immune diseases and other immune dysfunctions or 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/mutual recognition procedures provide for mutual recognition of national approval decisions. Under these procedures, the holder of a national marketing authorization may submit an application to a member state of its choice (the reference member state, or RMS) and identify other member states in which it also wishes to seek approval (concerned member states, or CMS). The RMS reviews the application and circulates an assessment report to each CMS, which must then decide whether to accept the RMS determination. If a member state does not accept the RMS position, the disputed points are referred to the Committee for Medicinal Products for Human Use, or CHMP, within the European Medicines Agency, or EMEA. The CHMP adopts an opinion, which the European Commission uses as a basis for a decision that is binding on all member states.

European Union member states generally do not have separate rules or review procedures for biological products 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 WHO 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**

In the United States, under the Orphan Drug Act, special incentives exist for sponsors to develop drug and biological 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 or one that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the drug for the disease or condition will be recovered from sales of the drug 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. Requests for orphan drug designation must be submitted prior to submission of an application for marketing authorization for a rare disease or condition. 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 of the drug for the designated orphan disease or condition. 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 applicant, however, 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 a similar system to encourage the development and marketing of medicinal products for rare diseases. Applications for orphan designations are submitted to the EMEA and reviewed by a Committee on Orphan Medicinal Products, or COMP, comprising representatives of the member states, patient groups and other persons. The final decision is made by the European Commission.

In the European Union, a product can be designated as an orphan drug if it is intended for either (i) a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union when the application is made; or (ii) a serious and chronic condition in the European Union for which, without incentives, it is unlikely that the marketing of the product in the European Union 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 Union or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition. The COMP assesses the orphan status at both the time of first designation and also in parallel with the review of every marketing authorization application for an orphan medicine.

After a marketing authorization has been granted in the European Union 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 even if they are similar, if they are safer, more effective or otherwise clinically superior to it.

Our anthrax immune globulin therapeutic product candidate has been granted orphan drug status in the United States and the European Union, and our tuberculosis vaccine product candidate has been granted orphan drug status in the European Union.

### **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 medicinal 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 increasing focus on drug and biologic pricing in recent years. There are currently no direct government price controls over private sector purchases in the United States. However, the Veterans Health Care Act establishes mandatory price discounts for certain federal purchasers, including the U.S. Department of Veterans Affairs, the U.S. Department of Defense, or DoD, and the U.S. Public Health Service; the discounts are based on prices charged to other customers.

Under the Medicaid program, a joint federal/state program that provides medical coverage to certain low income families and individuals, pharmaceutical manufacturers must pay prescribed rebates on specified drugs, including biological products, to enable them to be eligible for reimbursement. Vaccines are generally exempt from these rebate requirements, and vaccines for Medicaid-eligible children are primarily provided through the Vaccines for Children Program. Medicare, the federal program that provides medical coverage for the elderly and disabled, generally reimburses for physician-administered drugs, including biological products, on the basis of the product's average sales price, although the principal vaccines that are reimbursed under Part B, Influenza, Pneumococcal and Hepatitis B, are reimbursed based on average wholesale price. Outpatient drugs and other vaccines may be reimbursed under Medicare Part D. Part D is administered through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. Various states have adopted further mechanisms that seek to control drug 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 and exerts additional downward pressure on the prices of pharmaceutical products.

Public and private health care payors control costs and influence drug and biologic pricing through a variety of mechanisms, including negotiating discounts with the manufacturers and 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 conditions or 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 certain specified 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 PHSA. Federal and state governments purchase the majority of all pediatric vaccines produced in the United States, primarily through the Vaccines for Children Program implemented by the U.S. Congress in 1994. The Vaccines 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 Union, 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 FAR 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 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 and accounting systems, 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, or 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 certain vaccines to go through the compensation program, as administered by the U.S. Court of Federal Claims, before pursuing other 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 of a covered vaccine may be found liable in a civil action. The Vaccine Injury Act may not reduce or limit our liability arising out of product liability claims.

## **Hazardous Materials and Select Agents**

Our development and manufacturing processes may 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, U.S. Department of Agriculture, or USDA, 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 USDA 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 inspections 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 subject to regulation by various federal, state and local authorities. In the United States, in addition to the FDA, such authorities, include 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 and the False Claims Act, with the privacy provisions of the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act, and with 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. In addition, 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 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 U.S. Department of the Treasury, the antiboycott provisions of the Export Administration Act and the Internal Revenue Code and the Foreign Corrupt Practices Act. Outside the United States, advertising and promotion of medicinal products, along with associated commercial practices, are often subject to significant government regulation by local authorities.

## **Personnel**

As of December 31, 2009, we had 652 employees, including 172 employees engaged in product development, 310 employees engaged in manufacturing, 11 employees engaged in sales and marketing and 159 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 are represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

## **Available Information**

We maintain a website at [www.emergentbiosolutions.com](http://www.emergentbiosolutions.com). We make available, free of charge on our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the Securities and Exchange Commission, or SEC.

We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. In addition, we intend to make available on our website all disclosures that are required to be posted by applicable law, the rules of the SEC or the New York Stock Exchange listing standards regarding any amendment to, or waiver of, our code of business conduct and ethics. The information contained on, or that can be accessed through, our website is not a part of, or incorporated by reference, in this annual report on Form 10-K.

**ITEM 1A. RISK FACTORS**

**Risks Related to Our Dependence on U.S. Government Contracts**

*We have derived substantially all of our revenue from sales of BioThrax under contracts with HHS or the DoD. If HHS or DoD demand for BioThrax is reduced, 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 only marketed product, to the U.S. government. We are currently party to two contracts with the U.S. Department of Health and Human Services, or HHS, to supply doses of BioThrax for placement into the Strategic National Stockpile, or SNS. We are not currently party to a procurement contract with the U.S. Department of Defense, or DoD, which currently procures doses of BioThrax directly from the SNS. If the SNS priorities change, or if the DoD dose requirements from the SNS are reduced, our revenues could be substantially reduced.

Our existing and prior contracts with HHS and the DoD 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 price per dose, the number of doses and the timing of deliveries for BioThrax sales to the U.S. government.

*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;
- that we may be ineligible to respond to a request for proposal issued by the government;
- that third parties could submit protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- that we may incur or could suffer expenses or delays if our competitors protest or challenge contract awards made to us pursuant to competitive bidding and that any such protest or challenge would 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 December 2009, BARDA cancelled a previously issued procurement RFP for an rPA vaccine for the SNS in favor of BAA for rPA vaccine development. We submitted a proposal responding to the BAA in January 2010 to develop our rPA vaccine product. Additionally, 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 ongoing funding decisions by the government. Reduced or discontinued funding of these contracts could cause our financial condition and operating results to suffer materially.***

Our principal customer for BioThrax is the U.S. government. In addition, we anticipate that the U.S. government will be the principal customer for any other biodefense products that we successfully develop. Over its lifetime, a U.S. government program may be implemented through the award of many different individual contracts and subcontracts. The funding of some government programs is subject to Congressional appropriations, generally made on a fiscal year basis even though a program may continue for several years. Our government customers are subject to stringent budgetary constraints and political considerations. For example, the sale of most supplied doses under our most recent contract with HHS is subject to the annual appropriations process. If 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 regulations and obligations under our U.S. government contracts and various federal statutes and regulations.***

Our business with the U.S. government is subject to specific procurement regulations and a variety of other legal compliance obligations. These laws and rules 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 perform those contracts. If our estimates are not accurate, we may not be able to earn an adequate return or may incur a loss under these contracts.***

Our existing and prior contracts for the supply of BioThrax with HHS and the DoD have been fixed price contracts. We expect that our future contracts with the U.S. government for BioThrax as well as contracts for biodefense product candidates that we successfully develop also 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 to absorb any costs in excess of the fixed price. Estimating costs that are related to performance in accordance with contract specifications is difficult, particularly where the period of performance is over several years. 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, some of which may be customary, 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;
- unilaterally reduce or modify contracts or subcontracts, including equitable price adjustments;
- 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, if any, specified in a contract;
- decline to exercise an option to purchase the maximum amount, if any, specified in a contract;
- claim rights to products, including intellectual property, developed under the contract;
- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- 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 HHS 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.

***Legal proceedings challenging the U.S. government's use of BioThrax may be costly to defend and could limit future purchases of BioThrax by the U.S. government.***

Legal proceedings could be costly to defend, and the results could reduce demand for BioThrax by the U.S. government. For example, a group of unnamed military personnel filed a lawsuit in 2003 seeking to enjoin the DoD from administering BioThrax on a mandatory basis without informed consent of the recipient or a Presidential waiver, and a federal court issued the requested injunction in 2004. In 2005, the FDA issued an order affirming the BioThrax license, and, as a result, an appellate court ruled in February 2006 that the injunction was dissolved. In October 2006, the DoD announced that it was resuming a mandatory vaccination program for BioThrax for designated personnel and contractors. In December 2006, the same counsel who brought the prior lawsuit filed a new lawsuit contending that the FDA's 2005 final order should be set aside and that BioThrax is not properly approved for use in the DoD's vaccination program. In February 2008, the federal district court in which that case was pending dismissed the action, concluding that the FDA did not make a clear error of judgment in reaffirming the safety and efficacy of BioThrax. On September 29, 2009, the United States Court of Appeals for the District of Columbia Circuit issued its opinion in *Rempfer v. Torti*, affirming the February 29, 2008 finding of the District Court that the FDA did not violate the Administrative Procedure Act in connection with its December 19, 2005 Final Order classifying BioThrax as safe and effective. The plaintiffs' petition for writ of certiorari in the United States Supreme Court was denied on March 1, 2010.

Although we are not a party to any lawsuits challenging the DoD's mandatory use of BioThrax, if a court were to again enjoin the DoD's use of BioThrax on a mandatory basis, the amount of future purchases of BioThrax by the U.S. government could be affected. Furthermore, contractual indemnification provisions and statutory liability protections may not fully protect us from all related liabilities, and statutory liability protections could be revoked or amended to reduce the scope of liability protection. For example, although we have invoiced the DoD for reimbursement of our costs incurred with respect to 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 for defense costs associated with those claims. In addition, lawsuits brought directly against us by third parties, even if not successful, would require us to spend time and money defending the related litigation that may not be reimbursed by insurance carriers or covered by indemnification under existing contracts.

### **Risks Related to Our Financial Position and Need for Additional Financing**

*We may not maintain profitability in future periods or on a consistent basis.*

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 five fiscal years, we have not been profitable for every quarter during that time. Our profitability is substantially dependent on revenues from BioThrax product sales. Revenues from BioThrax product sales have fluctuated significantly in recent quarters, and we expect that they will continue to fluctuate significantly from quarter to quarter based on several factors, including the timing of our fulfilling orders from the U.S. government. Additionally, our profitability may be adversely affected as we progress through various stages of ongoing or planned clinical trials for our product candidates. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

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

As of December 31, 2009, we had \$65.7 million principal amount of debt outstanding. We may seek to raise substantial external debt financing to provide additional financial flexibility. 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. In addition, the covenants under our existing debt instruments and the pledge of our existing assets as collateral limit our 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. We also expect our 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 may undertake additional facility projects in the future.

As of December 31, 2009, we had \$102.9 million of cash and cash equivalents. Our future capital requirements will depend on many factors, including:

- the level and timing of BioThrax product sales and cost of product sales;
- the acquisition of, and capital improvements to, new facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to our manufacturing facility in Lansing, Michigan, the build out of our new manufacturing facility in Baltimore, and any other new facilities;
- 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 extent to which we lend money to third parties;
- 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 companies, 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.

Our committed external sources of funds consist of the borrowing availability under our revolving line of credit with Fifth Third Bank and grant and development funding of some of our candidates. 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. Difficult economic conditions may make it difficult to obtain financing on attractive terms or at all. Lenders may be able to impose covenants on us that could be difficult to satisfy, which could put us at increased risk of defaulting on debt. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

Our ability to borrow additional amounts under our loan agreement 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 are in the process of expanding our manufacturing facilities and entering into arrangements with contract manufacturing organizations. Delays in completing facilities, or delays or failures in obtaining regulatory approvals for new manufacturing facility projects or new contract manufacturing partners, could limit our potential revenues and growth.***

We continually evaluate alternatives for the manufacture of various product candidates. We may seek to acquire one or more additional facilities or sign agreements with contract manufacturing organizations. We have constructed a 50,000 square foot manufacturing facility on our Lansing, Michigan campus, which is designed to produce multiple fermentation-based vaccines, subject to developing, obtaining approval of, implementing and complying with appropriate change-over procedures. Additionally, in 2009 we acquired a facility in Baltimore, Maryland that we expect to utilize for certain product development or manufacturing projects. In order to do so, we anticipate that we will be required to make certain capital expenditures to upgrade and maintain this facility.

Constructing, preparing and maintaining a facility for manufacturing purposes is a significant project. For example, for our new facility in Lansing, the process for qualifying and validating for FDA licensure will be costly and time consuming, may result in unanticipated delays and may cost more than expected due to a number of factors, including regulatory requirements. The costs and time required to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements for sales of our products outside the U.S., may be significant. If our qualification and validation activities are delayed, we may not be able to meet our obligations to our customers, which may limit our opportunities for growth. Costs associated with constructing, qualifying and validating manufacturing facilities could require us to raise additional funds from external sources, and we may not be able to do so on favorable terms or at all.

We may seek permission from the FDA to use our new manufacturing facility in Lansing for the manufacture of both BioThrax and our rPA vaccine product candidate. This could require approval from the FDA of change-over procedures. If approval of such change-over procedures is delayed or not obtained, we may not be able to utilize this facility for the manufacture of both BioThrax and our rPA vaccine product candidate, which may limit our ability to grow our revenues.

***BioThrax and our vaccine and therapeutic product candidates are complex to manufacture and ship, which could cause us to experience delays in revenues or 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 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 maintaining master seed banks and preventing drift, obtaining materials, seed growth, fermentation, filtration, filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures or manufacturing shut-down, delay in the release of lots, product recalls, spoilage or regulatory action. Success rates can vary dramatically at different stages of the manufacturing process, which can lower yields and increase costs. From time to time we experience deviations in the manufacturing process that may take significant time and resources to resolve and if unresolved may affect manufacturing output and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation or regulatory action against us, or cause the FDA to cease releasing product until the deviations are explained and corrected, any of which could be costly to us and negatively impact our business.

We also depend on certain single-source suppliers for materials and services necessary for the manufacture of our product and product candidates. A disruption in the availability of such materials or services from these suppliers could require us to qualify and validate alternative suppliers. If we are unable to locate or establish alternative suppliers, our ability to manufacture our products could be adversely affected and also could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

FDA approval is required for the release of each lot of BioThrax. We will not be able to sell any lots that fail to satisfy the release testing specifications. We must provide the FDA with the results of potency testing before lots are released for sale. We have one mechanism for conducting this potency testing that is reliant on a unique animal strain for which we have no alternative. In developing alternatives, we may face significant regulatory hurdles. In the event of a problem with this strain, if we have not developed alternatives, we would not be able to provide the FDA with required potency testing.

In addition, under our contracts with HHS to deliver doses of BioThrax, we are responsible for shipping BioThrax and our product candidates must be maintained at a prescribed temperature range during shipping, and variations from that temperature range could result in loss of product and could adversely affect our profitability. Delays, lot failures, shipping deviations, spoilage or other loss during shipping could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

***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 or slow downs;
- protests, including by animal rights activists;
- damage to or destruction of the facility;
- regional power shortages; or
- product tampering.

As our equipment ages, it will need to be replaced. Replacement of equipment has the potential to introduce variations in the manufacturing process that may result in lot failures or manufacturing shut-down, delay in the release of lots, product recalls, spoilage or regulatory action.

In addition, providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. For example, the U.S. government has designated our Lansing facility as a facility requiring additional security to protect against potential terrorist threats to the facility. 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.

***If the company on which 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, or Hollister-Stier. Our contract with Hollister-Stier expires on December 31, 2010. We have not established internal redundancy for our filling functions, however, we have identified and contracted with an additional provider that we believe can handle our filling needs. Before this party may perform filling services for us, it must be qualified and licensed by the FDA. Such qualification and licensure may require use of a significant number of doses of BioThrax for consistency lots and stability testing that we may not be able to sell in the future once testing is complete. If Hollister-Stier is unable to perform filling services for us, we would need to obtain FDA approval of our potential substitute filler, engage, qualify and license an alternative filling company or develop our own filling capabilities. Any new contract filling company or filling capabilities that we acquire or develop will need to be approved by the FDA. Identifying and engaging a new contract filling company or developing our own filling capabilities and obtaining FDA approval could involve significant time and cost. As a result, we might not be able to deliver BioThrax orders on a timely basis and our revenues could decrease.

***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, 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, or choose to commercialize products for which the market is smaller than we anticipate, we could incur significant unrecoverable costs from creating excess capacity. 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.

***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, or plan to rely, on third parties to manufacture the supplies of our vaccine and therapeutic product candidates that we require for preclinical and clinical development, including our anthrax immune globulin therapeutic, anthrax monoclonal therapeutic, Typhella vaccine, tuberculosis vaccine and chlamydia vaccine product candidates. Any significant delay in obtaining adequate supplies of our product candidates could adversely affect our ability to develop or commercialize these product candidates. For example, in 2008 the initial manufacturer of our anthrax monoclonal therapeutic informed us it was discontinuing contract manufacturing operations and we were forced to secure alternative manufacturing resources.

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 and contract fill and finish operations and we rely on those manufacturers to comply with a wide variety of rules and regulations. If our contract manufacturers are unable to scale-up production to generate enough materials for commercial launch, if manufacturing is of insufficient quality, or if the costs of manufacturing are prohibitively high, the success of those products may be jeopardized. For example, we are currently evaluating manufacturing alternatives for Typhella in countries in which we believe manufacturing costs will be economical. 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.

Third party manufacturers under 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 or develop our own manufacturing capabilities to satisfy our requirements.

If alternative suppliers are not available or are delayed in fulfilling our requirements, or if we are unsuccessful in developing our own manufacturing capabilities, we may not be able to obtain adequate supplies of our product candidates on a timely basis. A change of manufacturers would require review and approval from the FDA and the applicable foreign regulatory agencies. 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 U.S. 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. We are also subject to a variety of environmental laws in Michigan regarding underground storage tanks. One such tank on our Lansing campus has leaked in the past. The State of Michigan removed the tank, continues to monitor the situation and has agreed to indemnify us for any resulting liabilities. In the event that the State of Michigan does not indemnify us, or if our insurance does not cover the exposure of any remediation that may be necessary, we may be required to spend significant amounts on remediation efforts. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the Centers for Disease Control and Prevention, or 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 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. These laws and regulations may limit the countries in which we may conduct development and manufacturing activities. 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 or we could be suspended from the right to do business with the U.S. government.



***Our insurance policies may not adequately compensate us for all liabilities that we may incur in the event of unanticipated costs, exposing us to potential expense and reduced profitability.***

We hold a number of insurance policies in an effort to protect ourselves against extraordinary or unanticipated costs. Our general liability and excess insurance policies provide for coverage up to annual aggregate limits of \$12 million, with coverage of \$1 million per occurrence and \$2 million in the aggregate for general liability and \$10 million per occurrence and in the aggregate for excess liability. Both policies 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 facility with coverage of \$1 million per occurrence and \$2 million annual aggregate limit and a \$25,000 per claim deductible. We hold product liability and clinical trial liability insurance policies for our commercial products and each clinical trial we are conducting in amounts we deem appropriate.

These policies are subject to deductibles, exclusions and coverage limitations. Circumstances may arise where we face liabilities that are not covered by these policies, or where our coverage is not adequate, which may expose us to significant liabilities and significantly and adversely affect our business or financial position.

### **Risks Related to Product Development**

***Our business depends significantly on our success in completing development and commercialization of our product candidates at acceptable costs. If we are unable to commercialize these product candidates, or experience significant delays or unanticipated costs 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 vaccines and therapeutic product candidates. In addition to BioThrax product sales, our ability to generate near term revenue is dependent on the success of our development programs, on the U.S. government's interest in providing development funding for or procuring our product candidates, on the interest of non-governmental organizations in providing grant funding for development of our product candidates and on the commercial viability of those product candidates. The commercial success of our product candidates will depend on many factors, including accomplishing the following in an economical manner:

- successful development, formulation and cGMP scale-up of biological manufacturing that meets FDA requirements;
- successful development of animal models by the U.S. government;
- successful completion of non-clinical development, including studies in approved animal models;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- 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 SNS prior to FDA approval;
- establishing commercial manufacturing processes of our own or arrangements with contract manufacturers;
- manufacturing stable commercial supplies of product candidates, including materials based on recombinant technology;
- 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.

If, as a result of the foregoing factors or otherwise, we are prevented from developing and commercializing a product candidate in an economically acceptable manner, that product program may be adversely affected and the commercial success of the product candidate may be harmed. For example, we recently agreed with Talecris Biotherapeutics, Inc. to extend the commencement date of the commercial term for manufacture of our anthrax immune globulin product candidate. We are currently in negotiations with Talecris for a longer-term resolution regarding commercial production; however, in the event that we are not able to negotiate a satisfactory resolution we may be required to explore other options for our anthrax immune globulin program that could result in less favorable commercial success for this product candidate, or no commercial success at all.

***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 studies and clinical trials to establish proof of concept, safety and efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete, and the outcome of such trials is uncertain. 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.

For example, in December 2008, we and Sanofi Pasteur determined that the joint efforts of our collaboration had not identified a viable product candidate, which effectively ended most material development activities under our meningitis B product development program. Additionally, our flu and chlamydia vaccine product candidates are still in preclinical stages of development, and if we are unable to successfully complete these development efforts and commence clinical trials for these product candidates, our business and opportunities for growth could be materially harmed.

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

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 could escalate and become cost prohibitive;

- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials; 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.

For example, the standard of care for the treatment of patients infected with hepatitis B impacted our ability to recruit participants for our Phase II clinical trial in the United Kingdom and Serbia because we administered our product candidate as a monotherapy, causing us to cease enrollment in this trial. If we are required to cease enrollment in other product candidate clinical trials or are not able to commence such trials in a region in which our enrollment efforts are successful, we will be unable to progress the clinical programs for such product candidates. In addition, because some of our current and future vaccine product candidates contain live attenuated viruses, our testing of these vaccine product candidates is subject to additional risk. For example, there have been reports of serious adverse events following administration of live vaccine products in clinical trials conducted by other vaccine developers. Also, for some of our current and future vaccine product candidates, we expect to conduct clinical trials in chronic carriers of the disease that our product candidate seeks to prevent. There have been reports of disease flares in chronic carriers following administration of live vaccine products.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if our clinical trials are not well designed, 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.

Our product development costs will also increase if we experience delays in testing, are required to conduct additional testing, or experience delays in product approval. 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 the Project BioShield Act, the Secretary of HHS can contract to purchase countermeasures for the SNS 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 might not be selected by the Secretary under this authority. Moreover, this authority could result in increased competition for our products and product candidates.

### **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 foreign governments and state and local governments, which we expect will be interested in BioThrax to protect emergency 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 undeveloped, and we may not be successful in generating meaningful sales of BioThrax to these potential customers. To date, we have made only modest sales to these customers. In particular, we have supplied small amounts of BioThrax directly to several foreign governments. In 2007, 2008 and 2009, our sales of BioThrax to customers other than the U.S. government represented a small portion 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 may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, many foreign governments require licensure of BioThrax in their jurisdiction before they will consider procuring doses. Additionally, 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 and related technology, 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 prohibitions could limit our sales of BioThrax to foreign governments and other foreign customers. In addition, U.S. government demand for anthrax vaccine may limit supplies of BioThrax available for sale to non-U.S. government customers. 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 doses that we do not currently anticipate. Furthermore, the DoD's sale of BioThrax to foreign governments under the Foreign Military Sales program has and may continue to have an adverse effect on our ability to sell BioThrax internationally.

Our ability to meet any potential 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 primary manufacturing facility in Lansing, Michigan to manufacture BioThrax for current sales to U.S. government customers. Additionally, we have constructed another manufacturing facility at our Lansing campus that is available for production of BioThrax, subject to final qualification and validation activities. To prepare for the event that we obtain significant orders for BioThrax from customers other than the U.S. government that cannot be accommodated by our existing facilities, we may explore additional manufacturing alternatives that would enable us to increase our manufacturing capacity and, as a result, allow us to increase sales of BioThrax to customers other than the U.S. government. If we are successful in this effort, it could be several years until a facility is qualified and validated and able to produce saleable vaccine. If we are unsuccessful in this effort, our opportunities for growth could be limited.

***Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.***

As we continue to expand our operations outside of the United States, we must comply with numerous laws and regulations relating to international business operations. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice. The Securities Exchange Commission, or SEC, is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical studies and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. China is an example of one jurisdiction in which we are contemplating future expansion where we will need to exercise caution to ensure our compliance with the FCPA.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expanding presence outside of the United States will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on United States exchanges for violations of the FCPA's accounting provisions.

***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 vaccine and therapeutic 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.

In addition, notwithstanding favorable findings regarding the safety and efficacy of BioThrax by the FDA in its final ruling in December 2005, the 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 then-licensed 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 against inhalational anthrax. Continued reiteration of these concerns could have a detrimental effect on the market acceptance of BioThrax.

The use of vaccines carries a risk of adverse health effects. The adverse reactions that have been associated with the administration of BioThrax 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 adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event. Serious adverse events, including diabetes, heart attacks, autoimmune diseases, including Guillian Barre syndrome, lupus, 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 from sales of 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;
- the 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
- the sufficiency of coverage or reimbursement by third parties.

***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 2006, members of the military and various activist groups who oppose mandatory inoculation with BioThrax petitioned the FDA and the federal courts to revoke the license for BioThrax and to terminate the DoD program for the mandatory administration of BioThrax to military personnel. Although the DoD has prevailed in those challenges to date, the actions of these groups have created negative publicity about BioThrax.

Additional lawsuits, publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of, and thereby limit the demand for, BioThrax and our biodefense product candidates. In such event, our ability to market and sell such products may be hindered and the commercial success of BioThrax and other products we develop will be harmed, thereby reducing our revenues.

***We have a small sales and marketing 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 through a small, targeted sales and marketing 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, which will be expensive and time consuming.

We may not be able to attract, hire, train and retain qualified sales and marketing personnel to build a significant or effective sales and marketing 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. 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 vaccine and therapeutic products 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 vaccine and therapeutics are a number of pharmaceutical companies that have vaccine programs, including Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Pfizer, and Novartis, as well as smaller more focused companies engaged in vaccine and therapeutic development, such as Aeras, Crucell, Cangene, Human Genome Sciences, Soligenix, Dynport Vaccine Company, Elusys, Bavarian Nordic and PharmAthene.

Any vaccine and therapeutic product candidate that we successfully develop and commercialize is likely to compete with currently marketed products, including antibiotics and antiviral drugs, 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 intend to seek marketing approval.

Although BioThrax is the only anthrax vaccine approved by the FDA for the prevention of anthrax infection, the government is funding the development of new products that could compete with BioThrax, and could eventually procure those new products in addition to, or instead of, BioThrax, potentially reducing our BioThrax revenues. We also face competition for our biodefense product candidates. For example, HHS has awarded a development and SNS procurement contract to a competitor for an anthrax immune globulin therapeutic and is assisting this company in its production efforts by providing it with BioThrax doses that we delivered for placement into the SNS so that it can immunize donors and obtain plasma for its anthrax immune globulin therapeutic product candidate. HHS has awarded another development and SNS procurement contract to another competitor for an anthrax monoclonal antibody as a post-exposure therapeutic for anthrax infection. One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the U.S. and Europe. The Aeras Global Tuberculosis Vaccine Foundation is developing or supporting the development of five tuberculosis vaccine product candidates in addition to ours, any of which could present competitive risks. Numerous companies have vaccine product candidates in development that would compete with any of our commercial product candidates for which we are seeking to 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 competing for government funding and 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 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 U.S. government 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, or PREP Act, which was signed into law in December 2005, creates immunity for manufacturers of biodefense countermeasures when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is meant to provide 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 protection under the PREP Act in cases of willful misconduct. Upon a declaration by the Secretary of HHS, 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. Therefore, 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. In October 2008, the Secretary of HHS issued a PREP Act declaration identifying BioThrax and our anthrax immune globulin therapeutic candidate as covered countermeasures. We do not know, however, whether the PREP Act will provide adequate protection or survive anticipated legal challenges to its validity.

In August 2006, the Department of Homeland Security approved our application under the Support Anti-Terrorism by Fostering Effective Technology Act, or 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 U.S. 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 prior contracts with the DoD and HHS provided that the U.S. government would indemnify us for any damages resulting from product liability claims, our current contracts with HHS do not contain such indemnification, and we may not be able to negotiate similar indemnification provisions in future contracts.

***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. For example, we have been a defendant in lawsuits filed on behalf of military personnel who alleged that they were vaccinated with BioThrax by the DoD and claimed damages resulting from personal injuries allegedly suffered because of the vaccinations. The plaintiffs in these lawsuits claimed different injuries and sought varying amounts of damages. Although we successfully defended these lawsuits, we cannot ensure that we will be able to do so in the future.



Under our prior BioThrax contracts with the DoD and HHS, the U.S. government indemnified 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 the DoD for uninsured costs incurred in defending these claims; however, the DoD has not acted on our requests for reimbursement. The collection process can be lengthy and complicated, and there is no guarantee that we will be able to recover these amounts from the U.S. government.

If we cannot successfully defend ourselves against future claims that our product or product candidates caused injuries and if we are not entitled to indemnity by the U.S. government, or if the U.S. government does not honor its indemnification obligations, we will incur substantial liabilities. Regardless of merit or eventual outcome, product 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 currently have product liability insurance for coverage up to a \$15 million annual aggregate limit with a deductible of \$75,000 per claim up to \$375,000 in aggregate. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Product liability insurance is difficult to obtain and 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 large scale deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on statutory protections in addition to insurance to mitigate our liability exposure 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 U.S. 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 product 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 U.S., 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 non-governmental, charitable or philanthropic organizations fund the cost of vaccines.

Medicare Part B reimburses for physician-administered drugs and biologics based on the product's "average sales price." This reimbursement methodology went into effect in 2005 and has generally led to lower Medicare reimbursement levels than under the reimbursement methodology in effect prior to that time. The Medicare Part D outpatient prescription drug benefit went into effect in January 2006. Coverage under Medicare Part D is provided primarily through private entities, which act as plan sponsors and negotiate price concessions from pharmaceutical manufacturers.

In addition, Congress is considering various legislative proposals to reform the U.S. health care system. These legislative proposals generally are intended to expand health care coverage to currently uninsured Americans and to limit the rate of increase in health care spending. Such legislation, if enacted, could decrease the price we receive or our sales volume for any approved products which, in turn, could adversely affect our operating results and our overall financial condition.

***Certain products we may develop may 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 Medicaid 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 our 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 U.S., which may include re-importation from foreign countries where the drugs are sold at lower prices than in the U.S. 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 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, chairman of our Board of Directors and our chief executive officer, and Daniel J. Abdun-Nabi, a member of our Board of Directors and our president and chief operating officer, to be key to our BioThrax operations and our efforts to develop and commercialize our product candidates. Both of these key employees are at will employees and can terminate their employment at any time. 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 is subject to audit by the U.S. government and a negative audit could adversely affect our business.***

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 conducting 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 conduct 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 the FCPA;
- 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. Although we ultimately prevailed in this litigation, we spent significant time and money defending the litigation. U.S. 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 conduct business and, in some instances, impose additional 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 U.S. government in the manufacturing process for BioThrax.***

We have the right to use certain property and equipment that is owned by the U.S. government, referred to as government furnished equipment, or GFE, at our Lansing, Michigan site in the manufacture of BioThrax. We have the option to purchase all or part of the existing GFE from the U.S. government on terms to be negotiated with the U.S. government. If the U.S. government modifies the terms under which we use the GFE in a manner that is unfavorable to us, including substantially increasing the usage fee, or we are unable to reach an agreement with the U.S. government concerning the terms of the purchase of that part of the GFE necessary for our business, our business could be harmed. If the U.S. government were to terminate or fail to extend all BioThrax supply contracts with us, we potentially could be required to rent or purchase that part of the GFE necessary for the continued production of BioThrax in our current manufacturing 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 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 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 our product candidates, 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 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. However, our biodefense product candidates require slightly different treatment. Specifically, because humans are rarely exposed to anthrax 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. This is known as the FDA's animal rule.

We intend to use the animal rule in pursuit of FDA approval for BioThrax as a post-exposure prophylaxis, our anthrax immune globulin therapeutic candidate, our rPA anthrax vaccine, our anthrax monoclonal antibody therapeutic, our BioThrax dual adjuvant vaccine, and our double mutant rPA vaccine. We cannot guarantee that the FDA will permit us to proceed with licensure of any of our BioThrax related programs or our other product candidates under the animal rule. Even if we are able to proceed pursuant to the animal rule, the FDA may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products.

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 the regulatory review for a 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 vaccine and therapeutic 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. 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 or prior notice 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. In March 2007, the FDA notified us that our manufacturing facility license is no longer subject to the notice of intent to revoke.

After approving the renovated Lansing facilities in December 2001, the FDA conducted routine, biannual inspections of the Lansing facilities in September 2002, May 2004, May 2006 and March 2008. Following each of these inspections, the FDA issued inspectional observations on Form FDA 483, some of which were significant. We responded to the FDA regarding the inspectional observations relating to each inspection and, where necessary, implemented corrective action. All observations from each of those inspections were successfully closed out. In December 2005, the FDA stated in its final order on BioThrax that at that time we were in substantial 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.

The FDA conducted a routine, biannual inspection of the Lansing facility in December 2009. Following this inspection, the FDA issued inspectional observations on Form FDA 483. We are in the process of implementing corrective action where necessary and anticipate that all observations from the 2009 inspection will be successfully closed out in the near future. If in connection with this inspection or with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, or if the FDA is not satisfied with the corrective actions we take in connection with any such inspection, 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;
- shut down, or substantial limitations of the operations in, manufacturing facilities;
- refusal to permit the import or export of products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

***If our competitors are able to obtain orphan drug exclusivity for their products that are the same as our products, we may be precluded from selling or obtaining approval of our competing products by the applicable regulatory authorities for a significant period of time.***

If one of our competitors 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 or the FDA determines that the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the drug. We have obtained orphan drug status from the FDA and in the European Union for our anthrax immune globulin therapeutic product candidate and in the European Union for our tuberculosis vaccine product candidate; however, none of our other products or product candidates has been designated as an orphan drug and there is no guarantee that the FDA will grant such designation in the future. 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 may have obtained will not block the approval of that competitive product.

***The Fast Track designation for our product candidates may not actually lead to a faster development, regulatory review or approval.***

We have obtained a Fast Track designation from the FDA for BioThrax as a post-exposure prophylaxis against anthrax infection and for our anthrax immune globulin therapeutic product candidate. However, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw a Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical development program. Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the FDA's expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

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

We intend to have some or all of 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 obtain regulatory 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 commercialize our product candidates domestically and internationally.***

For each of our product candidates, we plan to evaluate the merits of retaining commercialization rights or entering into collaboration arrangements with leading pharmaceutical or biotechnology companies or non-governmental organizations. We 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 for accessing 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, or the arrangements that we establish may not turn out to be productive or beneficial for us. The terms of any collaboration or other arrangements that we establish may not be favorable to us.

Any collaboration that we enter into may not be successful. For example, based on preclinical studies performed under a license agreement that we entered into with Sanofi Pasteur, both parties determined that the joint efforts had not identified a promising meningitis B vaccine product candidate and we mutually terminated the collaboration. Additionally, 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.

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 may 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;
- 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; or
- our collaborators may decide not to continue to work with us in the development of product candidates.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Such terminations or expirations could adversely affect us financially and could harm our business reputation.

***If third parties on whom we rely for clinical or non-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 as a result, our business may suffer.***

We do not have the ability to independently conduct the clinical or non-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 and non-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 and non-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, 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.

We expect to rely on data from clinical trials conducted by third parties 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 results of a clinical trial conducted by the CDC. 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.



## **Risks Related to Our Intellectual Property**

***Protection of our intellectual property rights could be costly, and if we fail to protect them, our business could be harmed.***

Our success, particularly with respect to our commercial business, will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property covering or incorporated into our technology and products. This protection is very costly. The patentability of technology in the field of vaccine and therapeutic development 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 duration 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 U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, or result in costly defense measures.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the U.S. 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 may 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.

For example, we licensed an oligonucleotide adjuvant, CpG 7909, for use in our double mutant rPA product candidate and our BioThrax dual adjuvant vaccine product candidate from Coley Pharmaceutical Group, Inc. Coley, which was subsequently acquired by Pfizer Inc., is responsible for prosecuting, maintaining and defending these licensed patent rights. Coley notified us that a patent interference had been declared in the U.S. Patent and Trademark Office between our licensed patent and a third party patent application, which could result in revocation of the patent we have licensed. We may not know the outcome for a considerable period of time.

***If we are unable to in-license any intellectual property necessary to develop, manufacture or sell any of our product candidates, we will not be successful in developing or commercializing such product candidate.***

We expect that we may need to in-license various components or technologies, including, for example, adjuvants and novel delivery systems, for some of our current or future product candidates. We may be unable to obtain the necessary licenses on acceptable terms, or at all. If we are unable to obtain such licenses, we could be prevented or delayed from continuing further development or from commercially launching the applicable product candidate.

***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 and expect to enter into additional license agreements in the future. For example, we consider our license from the Oxford-Emergent Tuberculosis Consortium to our tuberculosis vaccine product candidate to be material to our business. 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 or the label expansions and improvements that we are pursuing for BioThrax, our only intellectual property protection for BioThrax, other than the BioThrax trademark, 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. Additionally, third parties may be successful in obtaining patent protection for technologies that cover development and commercialization activities in which we are already engaged. Third parties may own or control these patents and intellectual property rights in the U.S. 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 non-exclusive, 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 or if an injunction is granted against us. 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, Bavarian Nordic sued Acambis for patent infringement and other claims arising out of Acambis' importation of an MVA-based smallpox vaccine for biodefense use by the U.S. government. Bavarian Nordic claimed that its patents broadly covered the manufacture of MVA-based biological products and that Bavarian Nordic had rights in the biological materials used by Acambis. The Acambis strain has a distinct lineage from the strains used by us. That litigation was terminated by a settlement and consent order. Bavarian Nordic subsequently sued Oxford BioMedica PLC, Oxford BioMedica Ltd. and Biomedica Inc., collectively Oxford BioMedica, alleging that Oxford BioMedica has infringed certain Bavarian Nordic U.S. patents by making, using, and importing, and inducing others to use Oxford BioMedica's experimental drug TroVax<sup>®</sup>, which is an MVA-based therapeutic cancer vaccine. The Oxford BioMedica strain also has a distinct lineage from the strain used by us. The lawsuit was settled by agreement between the parties. While the terms of the settlement have not been published, the parties have announced that Oxford BioMedica received a license for TroVax under Bavarian Nordic's MVA patents, and in return Bavarian Nordic received a license under Oxford BioMedica's patents on heterologous prime boost technology and a sublicense under certain patents licensed by Sanofi to Oxford BioMedica. Typically, patent infringement settlements are structured to specifically cover the alleged infringing product, and the settlement has no direct impact on other products in the field. Accordingly, we do not believe that the Acambis or Oxford BioMedica settlements will have any adverse effect on our plans for commercialization of our tuberculosis vaccine or our MVA platform. Bavarian Nordic also filed legal proceedings against the Bavarian State Ministry of the Environment and Public Health, or StMUG, in which Bavarian Nordic questioned StMUG's rights to convey MVA strains to third parties. This lawsuit was dismissed and an appeal by Bavarian Nordic was withdrawn in June 2009. We have licensed from StMUG rights to materials and technology related to MVA. Our MVA platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based in part on these rights.

Our ability to use our MVA platform technology, or to develop and manufacture MVA-based products such as our tuberculosis product candidate, could be negatively affected by pending or future patent infringement litigation or other legal actions brought by Bavarian Nordic or other parties challenging our rights to use MVA materials or technology. To protect our interests, we have filed oppositions in the European Patent Office against four of Bavarian Nordic's patents covering certain aspects of the MVA technology. The European Patent Office has called for hearings in one of these oppositions to be held in June 2010 and in an additional two of these proceedings in October 2010. We are also a party to a trademark invalidation proceeding in the U.S. and certain foreign trademark offices. In addition, we may in the future become party to additional trademark invalidation or interference proceedings. 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.***

Since our inception we have pursued an acquisition strategy to build our business. 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 a portion of our pipeline of vaccine and therapeutic product candidates through our acquisition of Microscience Limited in a share exchange in 2005 and our acquisitions of substantially all of the assets, for cash, of Antex Biologics, Inc. in 2003 and of ViVacs GmbH in 2006.

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 vaccine and therapeutic 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 vaccine and therapeutic field to increase, which may result in 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;
- prioritizing product portfolios;
- disruption of our ongoing business;
- difficulty and expense in assimilating and integrating 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;
- challenges and costs associated with reductions in work force; and
- subsequent loss of key personnel.

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

### **Risks Related to Our Common Stock**

***Fuad El-Hibri, chief executive officer and chairman of our Board of Directors, has substantial control over us, 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.***

Mr. El-Hibri has the ability to control the election of the members of our Board of Directors through his ownership interests among our significant stockholders. As of February 26, 2010, Mr. El-Hibri was the beneficial owner of approximately 39% of our outstanding common stock. Because Mr. El-Hibri has significant influence over 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 us 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 changes in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their 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;
- 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.

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. 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.

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% or more 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 us.

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

Under a rights agreement that establishes our stockholder rights plan, we issue to each of 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 of \$150 in cash, subject to adjustments.

Our stockholder rights plan is intended to protect stockholders in the event of an unfair or coercive offer to acquire us 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.

***Our stock price is volatile and purchasers of our common stock could incur substantial losses.***

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through December 31, 2009, our common stock has traded as high as \$27.00 per share and as low as \$4.40 per share. 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. 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 U.S. 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 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. Our current and 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 the sole source of gain for our stockholders for the foreseeable future.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. For example, we have filed a registration statement that would permit us to issue up to \$100 million in common stock. Moreover, holders of an aggregate of approximately 11.2 million shares of our common stock outstanding as of February 26, 2010 have the right to require us to register these shares of common stock under specified circumstances.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

The following table sets forth general information regarding our materially important properties:

<b>Location</b>	<b>Use</b>	<b>Segment</b>	<b>Approximate square feet</b>	<b>Owned/leased</b>
Lansing, Michigan	Manufacturing operations facilities, office space and laboratory space	Biodefense	214,000	Owned
Baltimore, Maryland	Future manufacturing facilities and office and laboratory space	Biodefense/Commercial	56,000	Owned
Gaithersburg, Maryland	Office and laboratory space	Biodefense/Commercial	48,000	Owned
Wokingham, England	Office and laboratory space	Commercial	29,000	Leases expire 2016
Rockville, Maryland	Office space	Biodefense/Commercial	23,000	Lease expires 2016
Munich, Germany	Office and laboratory space	Commercial	16,000	Lease expires 2015
Frederick, Maryland	Held for sale	Biodefense/Commercial	290,000	Owned

*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. It also includes our new 50,000 square foot manufacturing facility which we financed in part with a term loan from a commercial lender. 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. In December 2001, the FDA approved a supplement to our manufacturing facility license for the manufacture of BioThrax at the renovated facilities.

*Baltimore, Maryland.* We own a 56,000 square foot manufacturing facility in Baltimore, Maryland. We expect to use this facility to support our future product development and manufacturing needs, and we are currently renovating and improving this facility so that it will be capable of supporting development of our pipeline product candidates. Our specific plans for this facility will be contingent on the progress of our existing development programs and the outcome of our efforts to acquire new product candidates.

*Other.* We own or lease three separate product development facilities. Our facility in Gaithersburg, Maryland, which we purchased in November 2009, is approximately 48,000 square feet and contains a combination of laboratory and office space. Our facility in Wokingham, England consists of approximately 29,000 square feet in two buildings, and contains a combination of laboratory and office space. Our facility in Munich, Germany is approximately 16,000 square feet and contains a combination of laboratory and office space. Our facility in Rockville, Maryland contains approximately 23,000 square feet of office space, including our executive offices.

We own two buildings of approximately 145,000 square feet each on a 15-acre site in Frederick, Maryland. We are actively seeking to sell these facilities. Accordingly, we have classified these buildings as held for sale in our balance sheet, and have recorded an impairment expense of approximately \$7.3 million in 2009 related to costs previously capitalized based on the difference between the carrying value of the assets and their estimated fair value less costs to sell.

### ITEM 3. LEGAL PROCEEDINGS

*Litigation Against Protein Sciences Corporation.* We are currently pursuing three legal actions against PSC and its senior management arising out of a letter of intent, a loan and security agreement and related promissory note, and an asset purchase agreement between us and PSC that were entered into in 2008. Under those agreements, we agreed to acquire substantially all of PSC's assets and to provide funding to PSC to enable it to continue operations through the anticipated closing date of the asset purchase transaction. Between March 2008 and June 2008, we provided PSC with \$10 million in funding under the loan and security agreement and related promissory note. PSC's obligations to us under these agreements is secured by substantially all of PSC's assets, including PSC's intellectual property. The note accrued interest at an annual rate of 8% through December 31, 2008, a default rate of 11% through May 31, 2009, and a default rate of 14% since June 1, 2009. PSC has not repaid any portion of the loan. As of December 31, 2009, \$10 million of principal was outstanding and \$1.8 million of interest was accrued and unpaid.

On June 8, 2009, after the expiration of a five-month forbearance period on the loan, we initiated legal proceedings in the Superior Court of the State of Connecticut, Judicial District of New Haven, to acquire possession of the collateral by foreclosing on PSC's physical assets that secure the loan. In addition, we and several other creditors of PSC filed a federal involuntary bankruptcy petition against PSC on June 22, 2009 in the United States Bankruptcy Court for the District of Delaware. In September 2009, the bankruptcy court concluded that PSC was insolvent and that PSC's debt to us was valid and not subject to a bona fide dispute, but the bankruptcy court declined to force PSC into involuntary bankruptcy, finding that the foreclosure proceeding, not the bankruptcy action, was the proper mechanism of recovery. We intend to continue to pursue the Connecticut action for possession of its physical assets in an effort to recover amounts due to us. PSC has filed a motion to stay the Connecticut action for possession pending a decision in the New York litigation against PSC, which is described below. Such motion has been briefed and argued and we are awaiting a decision from the Connecticut state court.

In addition to the action seeking possession of the physical assets, we continue to pursue two separate lawsuits that we filed regarding this matter: one against PSC on July 9, 2008, and the other against PSC's executive management team, which consists of Daniel D. Adams, PSC's Chief Executive Chairman, and Manon M.J. Cox, PSC's President and Chief Executive Officer, on October 3, 2008. The lawsuit against PSC is pending in the Supreme Court of the State of New York and includes, among other things, claims for fraud, breach of contract, breach of the duty of good faith and fair dealing, unjust enrichment and unfair business practices. The lawsuit against Mr. Adams and Ms. Cox is pending in the United States District Court for the District of Connecticut and alleges, among other things, that these individuals engaged in fraudulent conduct in connection with their efforts to obtain \$10 million in bridge financing from us. PSC has moved to dismiss the New York action, and that motion remains pending. Mr. Adams and Ms. Cox moved to dismiss the Connecticut action, and the court denied that motion with respect to the fraud claims and granted it with respect to unfair business practice claims. In our lawsuits against PSC and PSC's executive management team, we seek monetary damages of no less than \$13 million, punitive damages, declaratory judgment, injunctive relief to protect the collateral for the loan, and other appropriate relief. PSC, Mr. Adams, and Ms. Cox have not yet asserted any counterclaims in either lawsuit, but PSC has stated that it may assert counterclaims for "among other things, breach of contract, intentional misrepresentations, tortious interference with business relations and unfair trade practices."

We intend to pursue full repayment of the loan, as well as other relief as described in our pleadings in the pending lawsuits against PSC and PSC's executive management.



*BioThrax product liability litigation.* Between 2001 and 2003, over 100 individual plaintiffs filed a series of lawsuits in which they claimed damages resulting from personal injuries allegedly caused by vaccination with BioThrax by the DoD. In April 2006, the U.S. District Court for the Western District of Michigan entered summary judgment in our favor in four consolidated lawsuits brought by approximately 120 claimants. The District Court's ruling in these consolidated cases was based on two grounds. First, the District Court found that we were 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 were 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 risks arising from the use of the product. The District Court found that we established each of those factors.

In 2005 and 2006, we were named as a defendant in three federal lawsuits, each filed on behalf of a single plaintiff, claiming different injuries caused by DoD's immunization with BioThrax. Each plaintiff sought a different amount of damages. The plaintiff in the first case alleged that the vaccine caused erosive rheumatoid arthritis and requested damages in excess of \$1 million. The plaintiff in the second case alleged that the vaccine caused Bell's palsy and other related conditions and requested damages in excess of \$75,000. The plaintiff in the third case alleged 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 requested damages in excess of \$10 million. Each of these lawsuits has been dismissed with prejudice, and no BioThrax product liability cases remain pending.

*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 Lansing Inc., or EBOL, 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. EBOL is currently a named defendant in 38 lawsuits pending in two jurisdictions: one in California and 37 in Illinois. The products at issue in these lawsuits are pediatric vaccines. 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. We no longer manufacture any products that contain thimerosal.

**ITEM 4. REMOVED AND RESERVED**

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### Market Information and Holders

Our common stock trades on the New York Stock Exchange under the symbol "EBS". The following table sets forth the high and low sales prices per share of our common stock during each quarter of the years ended December 31, 2009 and 2008:

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
<b>Year Ended December 31, 2009</b>				
High	\$ 27.00	\$ 15.31	\$ 19.95	\$ 18.25
Low	\$ 12.23	\$ 9.15	\$ 12.09	\$ 12.36
<b>Year Ended December 31, 2008</b>				
High	\$ 9.17	\$ 11.14	\$ 15.17	\$ 26.40
Low	\$ 4.93	\$ 8.22	\$ 9.62	\$ 11.22

As of February 26, 2010, the closing price per share of our common stock on the New York Stock Exchange was \$14.66 and we had 22 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

#### Dividend Policy

We have not declared, or paid any cash dividends on our common stock since becoming a publicly traded company in November 2006. 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.

#### Recent Sales of Unregistered Securities

None.

#### Use of Proceeds

Not applicable.

#### Purchases of Equity Securities

Not applicable.

**ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA**

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes included in this annual report on Form 10-K and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this annual report.

We have derived the consolidated statement of operations data for the years ended December 31, 2009, 2008 and 2007 and the consolidated balance sheet data as of December 31, 2009 and 2008 from our audited consolidated financial statements, which are included in this annual report on Form 10-K. We have derived the consolidated statements of operations data for the years ended December 31, 2006 and 2005 and the consolidated balance sheet data as of December 31, 2007, 2006 and 2005 from our audited consolidated financial statements, which are not included in this annual report on Form 10-K. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

(in thousands, except share and per share data)	Year Ended December 31,				
	2009	2008	2007	2006	2005
<b>Statements of operations data:</b>					
Revenues:					
Product sales	\$ 217,172	\$ 169,124	\$ 169,799	\$ 147,995	\$ 127,271
Contracts and grants	17,614	9,430	13,116	4,737	3,417
Total revenues	234,786	178,554	182,915	152,732	130,688
Operating expenses (income):					
Cost of product sales	46,262	34,081	40,309	24,125	31,603
Research and development	74,588	59,470	53,958	45,501	18,381
Selling, general & administrative	73,786	55,076	55,555	44,601	42,793
Purchased in-process research and development	-	-	-	477	26,575
Litigation settlement	-	-	-	-	(10,000)
Total operating expenses	194,636	148,627	149,822	114,704	109,352
Income from operations	40,150	29,927	33,093	38,028	21,336
Other income (expense):					
Interest income	1,418	1,999	2,809	846	485
Interest expense	(7)	(47)	(71)	(1,152)	(767)
Other income (expense), net	(50)	134	156	293	55
Total other income (expense)	1,361	2,086	2,894	(13)	(227)
Income before provision for income taxes	41,511	32,013	35,987	38,015	21,109
Provision for income taxes	14,966	12,055	13,051	15,222	5,325
Net income	\$ 26,545	\$ 19,958	\$ 22,936	\$ 22,793	\$ 15,784
Net loss attributable to noncontrolling interest	4,599	724	-	-	-
Net income attributable to Emergent BioSolutions Inc.	\$ 31,144	\$ 20,682	\$ 22,936	\$ 22,793	\$ 15,784
Earnings per share — basic	\$ 1.02	\$ 0.69	\$ 0.79	\$ 0.99	\$ 0.77
Earnings per share — diluted	\$ 0.99	\$ 0.68	\$ 0.77	\$ 0.93	\$ 0.69
Weighted average number of shares — basic	30,444,485	29,835,134	28,995,667	23,039,794	20,533,471
Weighted average number of shares — diluted	31,375,305	30,458,098	29,663,127	24,567,302	22,751,733

(in thousands)	As of December 31,				
	2009	2008	2007	2006	2005
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 102,924	\$ 91,473	\$ 105,730	\$ 76,418	\$ 36,294
Working capital	139,113	98,866	88,649	82,990	29,023
Total assets	344,689	290,788	273,508	238,255	100,332
Total long-term liabilities	46,173	37,418	46,688	35,436	10,502
Total stockholders’ equity	243,815	199,349	171,159	138,472	59,737

## ITEM 7. 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 annual report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report on Form 10-K, 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 "Special Note Regarding Forward Looking Statements" and "Risk Factors" sections of this annual report 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**

#### **Product Portfolio**

We are a biopharmaceutical company focused on the development, manufacture and commercialization of vaccines and antibody therapies that assist the body's immune system to prevent or treat disease. For financial reporting purposes, we operate in two business segments, biodefense and commercial.

Our biodefense segment focuses on vaccines and antibody therapies for use against biological agents that are potential weapons of bioterrorism or biowarfare. Our product candidates in this segment are focused on anthrax. We manufacture and market BioThrax<sup>®</sup> (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. In addition to BioThrax, we are developing a recombinant protective antigen, or rPA, anthrax vaccine, an anthrax immune globulin therapeutic, an anthrax monoclonal antibody therapeutic, a BioThrax dual adjuvant vaccine, and an advanced double-mutant protective antigen anthrax vaccine.

Our commercial segment focuses on vaccines and antibody therapies for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. Our product candidates in this segment include a tuberculosis vaccine, a typhoid vaccine, an influenza vaccine and a chlamydia vaccine.

Our biodefense segment has generated net income for each of the last five fiscal years. Our commercial segment has generated revenue through development contracts and grant funding. None of our commercial product candidates has received marketing approval and, therefore, our commercial segment has not generated any product sales revenues. As a result, our commercial segment has incurred a net loss for each of the last five fiscal years.

#### **Product Sales**

We have derived substantially all of our product sales revenues from BioThrax sales to the U.S. Department of Health and Human Services, or HHS, and the U.S. Department of Defense, or DoD, and expect for the foreseeable future to continue to derive substantially all of our product sales revenues from the sales of BioThrax to the U.S. government. Our total revenues from BioThrax sales were \$217.2 million and \$169.1 million for years ended December 31, 2009 and 2008, respectively. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers domestically and internationally and pursuing label expansions and improvements for BioThrax.

#### **Contracts and Grants**

We seek to advance development of our product candidates through external funding arrangements. We may slow down development programs or place them on hold during periods that are not covered by external funding. We have received external funding awards for the following development programs:

- BioThrax post-exposure prophylaxis
- BioThrax dual adjuvant vaccine
- Anthrax immune globulin therapeutic
- Anthrax monoclonal antibody therapeutic
- Advanced double-mutant protective antigen
- Recombinant botulinum vaccine
- Typhella (typhoid vaccine live oral ZH9)

Additionally, our tuberculosis vaccine product candidate is indirectly supported by grant funding provided to The University of Oxford by The Wellcome Trust and Aeras Global Tuberculosis Vaccine Foundation.

We continue to actively pursue additional government sponsored development contracts and grants and to encourage both governmental and non-governmental agencies and philanthropic organizations to provide development funding or to conduct clinical studies of our product candidates.

### **Manufacturing Infrastructure**

We conduct our primary vaccine manufacturing operations at a multi-building campus on approximately 12.5 acres in Lansing, Michigan. To augment our existing manufacturing capabilities, we have constructed a 50,000 square foot manufacturing facility on our Lansing campus. We have incurred costs of approximately \$79 million through December 2009 for the building and associated capital equipment, as well as for validation and qualification activities required for regulatory approval and initiation of manufacturing. We suspended the completion of those activities for approximately one year as we commenced a change-over process to plan for the potential use of the facility for the manufacture of our rPA anthrax vaccine product candidate under an anticipated HHS contract for the development of a recombinant anthrax vaccine. This change-over process was successfully completed. During the fourth quarter of 2009, we recommenced qualification and validation activities for the commercial manufacture of BioThrax. We designed this facility to be campaignable subject to complying with appropriate change-over procedures, and we may seek permission from the FDA to use the facility for the manufacture of both BioThrax and our rPA anthrax vaccine product candidate. In the event we do not manufacture our rPA anthrax vaccine product candidate in this building, we intend to use the facility for the manufacture of BioThrax and potentially for additional products.

In November 2009, we paid approximately \$8.2 million to purchase a building in Baltimore, Maryland for product development and manufacturing purposes, and have begun renovation and improvement of this facility. Our specific plans for this facility will be contingent on the progress of our existing development programs and the outcome of our efforts to acquire new product candidates. As we proceed with this project, we expect the costs to be substantial and will likely seek external sources of funds to finance the project.

In October 2009, we paid approximately \$6.4 million to purchase the product development facility in Gaithersburg, Maryland that we previously leased. We are in the process of developing plans and cost estimates for renovations and improvements to the facility. These plans will be contingent on the progress of our existing development programs.

We also own two buildings in Frederick, Maryland that we currently expect to sell. Accordingly, we have classified these buildings as held for sale in our balance sheet, and recorded an impairment expense of approximately \$7.3 million in 2009 related to costs previously capitalized, based on the difference between the carrying value of the assets and their estimated fair value less costs to sell. We continue to actively seek to sell these buildings.

## **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 U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, fair value of 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 that require no continuing performance on our part if four basic criteria have been met:

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

We have generated BioThrax sales revenues under U.S. government contracts with HHS and the DoD. Under our current contract with HHS, we invoice HHS and recognize the related revenues upon acceptance by the government at the delivery site, at which time title to the product passes to HHS.

From time to time, we are awarded reimbursement contracts for services and development grant contracts with government entities and non-government and philanthropic organizations. Under these contracts, we typically are reimbursed for our costs as we perform specific development activities, and we may also be entitled to additional fees. We recognize revenue upon incurring accepted reimbursable costs. The amounts that we receive under these contracts vary greatly from quarter to quarter, depending on the scope and nature of the work performed. We record the reimbursement of our costs and any associated fees as contracts and grants revenue and the associated costs as research and development expense.

### **Accounts Receivable**

Accounts receivable are stated at invoice amounts and consist primarily of amounts due from HHS as well as amounts due under reimbursement contracts with other government entities and non-government and philanthropic organizations. Because the 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.

## **Income Taxes**

Under the asset and liability method of income tax accounting, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax basis of assets and liabilities and are measured using the tax rates and laws that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A net deferred tax asset or liability is reported on the balance sheet. 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 the financial reporting and tax basis of assets and liabilities.

We have historically incurred net operating losses for income tax purposes in some states, primarily Maryland, 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 Limited, or Microscience, and Antex Biologics, Inc., or 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.

Uncertainty in income taxes is accounted for using 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. We recognize in our 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.

## **Stock-based Compensation**

In accordance with stock-based compensation accounting guidance, all share-based payments to employees, including grants of employee stock options, are recognized in the income statement based on their estimated grant date fair values.

We value our share-based payment transactions using the Black-Scholes valuation model. We measure the amount of compensation cost based on the fair value of the underlying equity award on the date of grant. We recognize compensation cost over the period that an employee provides service in exchange for the award.

The effect of this accounting treatment on net income attributable to Emergent BioSolutions Inc. and earnings per share in any period 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.

## **Financial Operations Overview**

### **Revenues**

On September 25, 2007, we entered into an agreement with HHS to supply 18.75 million doses of BioThrax to HHS for placement into the Strategic National Stockpile, or the SNS. The term of the agreement is from September 25, 2007 through September 24, 2010. The firm fixed price for the 18.75 million doses, net of a discount for a portion of the doses, is \$400 million in the aggregate. In June 2009, we received FDA approval of our supplement to our biologics license application, or BLA, to extend the expiry dating of BioThrax from three years to four years. As a result of this approval, HHS agreed to increase the price per dose under the agreement by eliminating the discount for the final 13.25 million doses sold, up to a total of approximately \$34 million. In conjunction with this approval, we billed HHS approximately \$34 million for doses delivered through July 31, 2009. Under this agreement, we provided all shipping services related to delivery of doses into the SNS over the term of the agreement, for which HHS paid us approximately \$2 million. We invoiced HHS for each delivery upon acceptance of BioThrax doses delivered into the SNS. In July 2009, we completed delivery of the doses under this agreement. The agreement also provided for HHS to pay us up to \$11.5 million in milestone payments in connection with us advancing a program to obtain a post-exposure prophylaxis indication for BioThrax. These funds are payable upon achievement of specific program milestones. In October 2007, we achieved the initial milestone and received payment from HHS of \$8.8 million.

On September 30, 2008, we entered into an agreement with HHS to supply up to 14.5 million doses of BioThrax to HHS for placement into the SNS. The term of the agreement is from September 30, 2008 through September 30, 2011. Delivery of doses under the agreement commenced in September 2009 and will continue through September 2011. Funds for the procurement of the first 10.2 million doses of BioThrax have been committed. Procurement of the remaining 4.3 million doses will be funded through the annual appropriations process for the SNS. Four-year expiry dated product will be invoiced at a higher price than three-year expiry dated product. The total purchase price for the 14.5 million doses will be up to approximately \$400 million, assuming the delivery of four-year expiry dated product. Through December 31, 2009, we have delivered approximately 2.7 million doses under this agreement. We have agreed to provide all shipping services related to delivery of doses into the SNS over the term of the agreement, for which HHS has agreed to pay us approximately \$1.9 million. We invoice HHS under the agreement upon acceptance of each delivery of BioThrax doses to the SNS.



We have received contract and grant funding from NIAID and BARDA for the following development programs:

Product Candidate	Funding Source	Award Date	Amount (Up to)	Performance Period
Anthrax immune globulin therapeutic	NIAID	September-2007	\$9.5 million	9/2007 — 12/2011
Recombinant botulinum vaccine	NIAID	June-2008	\$1.8 million	6/2008 — 5/2011
BioThrax dual adjuvant vaccine	NIAID	July-2008	\$2.8 million	7/2008 — 6/2013
Anthrax monoclonal antibody therapeutic	NIAID/BARDA	September-2008	\$24.3 million	9/2008 — 8/2012
BioThrax dual adjuvant vaccine	NIAID/BARDA	September-2008	\$29.7 million	9/2008 — 9/2011
Double-mutant protective antigen anthrax vaccine	NIAID	September-2009	\$4.9 million	9/2009 — 8/2011

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 and work done under new and existing contracts and grants.

### 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 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.

We determine the cost of product sales for doses sold during a reporting period based on the average manufacturing cost per dose in the period those doses were manufactured. We calculate the average manufacturing cost per dose in the period of manufacture by dividing the actual costs of manufacturing in such 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 the period of production.

### 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, preclinical and analytical testing, independently monitoring our clinical trials and acquiring and evaluating data from our clinical trials and non-clinical studies;
- costs of contract manufacturing services for clinical trial material;
- 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 operating costs of facilities and the legal costs of pursuing patent protection of our intellectual property.

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 expect that development spending for our product pipeline will increase as our product development activities continue based on ongoing advancement of our product candidates, and as we prepare for regulatory submissions and other regulatory activities. 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 programs that we may initiate, costs associated with manufacturing our product candidates on a large scale basis for later stage clinical trials, and our ability to use or rely on data generated by government agencies, such as studies with BioThrax conducted by the Centers for Disease Control and Prevention, or CDC.

In July 2008, we entered into a joint venture with the University of Oxford, or Oxford, and certain Oxford researchers to conduct clinical trials in the advancement of a vaccine product candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium, or OETC. We have a 51% equity interest in OETC and control the OETC Board of Directors. In addition, we have certain funding and service obligations of up to approximately \$20 million related to our investment through 2011 to support further development of the vaccine product candidate and a Phase IIb proof of concept study in humans, primarily in the form of services to be performed by our personnel on behalf of the joint venture. As part of this arrangement, we have entered into a license agreement with the joint venture pursuant to which we obtained rights to develop, manufacture and commercialize pharmaceutical compositions intended to prevent or treat tuberculosis in humans in developed countries. Oxford's contributions include support from the Wellcome Trust and the Aeras Global Tuberculosis Vaccine Foundation for the Phase IIb clinical trial in the form of cash and services.

### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, sales and marketing, 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 currently market and sell BioThrax directly to HHS with a small, targeted marketing and sales group. 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 primarily of interest income and interest expense. We earn interest income on our cash, cash equivalents and a note receivable, and we incur interest expense on our indebtedness. We capitalize interest based on the cost of major ongoing projects which have not yet been placed in service, such as new manufacturing facilities. 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**

### **Year Ended December 31, 2009 Compared to Year Ended December 31, 2008**

#### ***Revenues***

Product sales revenues increased by \$48.0 million, or 28%, to \$217.2 million for 2009 from \$169.1 million for 2008. This increase in product sales revenues was primarily due to payments from HHS of approximately \$34.0 million related to the approval of four-year expiry dating for BioThrax, obtained in June 2009, coupled with an 8% increase in the number of doses sold in 2009. Product sales revenues in 2009 consisted of BioThrax sales to HHS of \$216.4 million and aggregate international and other sales of \$703,000. Product sales revenues in 2008 consisted of BioThrax sales to HHS of \$167.6 million and aggregate international and other sales of \$1.5 million.

Contracts and grant revenues increased by \$8.2 million, or 87%, to \$17.6 million in 2009 from \$9.4 million in 2008. Contracts and grants revenues for 2009 consisted of \$17.4 million in development contract revenue from NIAID and BARDA and \$211,000 from Sanofi Pasteur under a collaboration agreement with Sanofi Pasteur, which was terminated in December 2008. Contracts and grants revenues for 2008 consisted of \$4.4 million from the Sanofi Pasteur collaboration, related to recognition upon termination of the collaboration in December 2008 of deferred revenue associated with the upfront payment received in 2006 as well as development service revenue, \$3.2 million in development contract and grant revenue from NIAID and other governmental agencies, and \$1.8 million from the sale of technology rights and related materials and documentation pertaining to our Pertussis technology.

#### ***Cost of Product Sales***

Cost of product sales increased by \$12.2 million, or 36%, to \$46.3 million for 2009 from \$34.1 million for 2008. This increase was attributable to the 8% increase in the number of BioThrax doses sold and an increase in average cost per dose sold associated with reduced production yield in the period during which the doses sold were produced.

#### ***Research and Development Expenses***

Research and development expenses increased by \$15.1 million, or 25%, to \$74.6 million for 2009 from \$59.5 million for 2008. This increase reflects higher contract service costs, and includes increased expenses of \$16.6 million on product candidates that are categorized in the biodefense segment, decreased expenses of \$7.1 million on product candidates categorized in the commercial segment, and increased expenses of \$5.7 million in other research and development, which are in support of technology platforms and central research and development activities.

The increase in spending on biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials, coupled with increased spending on product candidates that we acquired in 2008. The increase in spending for BioThrax related programs was due to the preparation for and conduct of clinical and non-clinical feasibility, efficacy and stability studies to support applications for marketing approval of these programs, along with formulation development and manufacture of clinical material. The increase in spending for the recombinant protective antigen anthrax vaccine was related primarily to costs incurred to respond to a request for proposal from BARDA and the continued advancement of the product candidate. The decrease in spending for our double mutant protective antigen vaccine resulted from the timing of feasibility and stability studies. The increase in spending for our anthrax immune globulin therapeutic candidate was primarily due to the commencement of clinical and non-clinical studies during 2009. The increase in spending for the anthrax monoclonal therapeutic candidate was primarily for manufacture of a working cell bank, formulation development and the conduct of non-clinical studies. The increase in spending for our botulinum vaccine product candidates resulted from conducting non-clinical studies and the manufacture of master and working cell banks. We expect that spending for our botulinum vaccine candidates will decrease in the future, due primarily to reduced interest in and funding for these product candidates by the U.S. government.

The decrease in spending on commercial product candidates, detailed in the table below, was primarily attributable to the timing of development efforts and to the termination or scaling back of certain programs. The increase in spending for our tuberculosis vaccine product candidate is related to the formation of our joint venture with the University of Oxford in July 2008, the procurement of licenses, and preparation for and conduct of a Phase IIb clinical trial, which commenced in April 2009. The spending for Typhella in 2008 resulted from the manufacture of clinical material and conducting a Phase IIb clinical trial in the United States. These activities did not continue in 2009, resulting in the decrease in spending. The increase in spending for our influenza vaccine product candidate is related to preparation for and conduct of feasibility and immunogenicity studies. The spending for our hepatitis B therapeutic vaccine product candidate was related to our Phase II clinical trial in the United Kingdom and Serbia and other development activities. We have significantly reduced ongoing spending with regard to this product candidate while we investigate options to sell or outlicense the related technology, and expect that future spending will be reduced. The decrease in spending for our group B streptococcus vaccine product candidate resulted from our decision not to proceed with Phase I clinical trials for two of the protein components of the vaccine product candidate. We expect that spending for our group B streptococcus vaccine product candidate will continue to be minimal in the future. The decrease in spending for our chlamydia candidate, which is in preclinical development, is related to a decrease in development activities while seeking external funding. The decrease in spending for our meningitis B vaccine product candidate resulted from the termination of our collaboration with Sanofi-Pasteur in December 2008.

The increase in other research and development expenses was primarily attributable to spending associated with the development activities targeting our two technology platforms, MVA and *spi*-VEC, and central research and development activities.

We continue to assess, and may alter, our future development plans for our products based on the interest of the U.S. government or non-governmental and philanthropic organizations in providing funding for further development or procurement.

Our principal research and development expenses for 2009 and 2008 are shown in the following table:

(in thousands)	Year ended December 31,	
	2009	2008
<b>Biodefense:</b>		
BioThrax related programs	\$ 15,748	\$ 7,159
Recombinant protective antigen anthrax vaccine	8,450	6,563
Double mutant protective antigen vaccine	560	2,540
Anthrax immune globulin therapeutic	6,890	6,126
Anthrax monoclonal therapeutic	7,215	1,062
Botulinum vaccines	4,011	2,871
Total biodefense	42,874	26,321
<b>Commercial:</b>		
Tuberculosis vaccine	11,711	2,145
Typhella	5,083	15,431
Influenza vaccine	2,822	1,511
Hepatitis B therapeutic vaccine	3,521	3,010
Group B streptococcus vaccine	202	6,539
Chlamydia vaccine	567	1,220
Meningitis B vaccine	158	1,313
Total commercial	24,064	31,169
Other	7,650	1,980
<b>Total</b>	<b>\$ 74,588</b>	<b>\$ 59,470</b>

### ***Selling, General and Administrative Expenses***

Selling, general and administrative expenses increased by \$18.7 million, or 34%, to \$73.8 million for 2009 from \$55.1 million for 2008. This increase includes approximately \$5.0 million in increased litigation services and other professional services, a \$7.3 million impairment charge associated with our Frederick, Maryland facilities and a \$1.4 million charge associated with acquisitions that were in progress but not completed as of December 31, 2008, as well as increased personnel costs related to the growth of our business. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses increased by \$5.9 million, or 14%, to \$48.8 million for 2009 from \$43.0 million for 2008. Selling, general and administrative expenses related to our commercial segment increased by \$12.8 million, or 105%, to \$25.0 million for 2009 from \$12.2 million for 2008, reflecting increased litigation services, along with the charges discussed above related to the Frederick facilities and acquisitions in progress.

### ***Total Other Income (Expense)***

Total other income decreased by \$725,000, or 35%, to \$1.4 million for 2009 from \$2.1 million for 2008. This decrease resulted primarily from a decrease in interest income of \$581,000 primarily as a result of lower investment return on average invested cash balances related to a decline in interest rates.

### ***Income Taxes***

Provision for income taxes increased by \$2.9 million, or 24%, to \$15.0 million for 2009 from \$12.1 million for 2008. The provision for income taxes for 2009 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of \$46.1 million and an effective annual tax rate of approximately 32%. The provision for income taxes for 2008 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of \$32.7 million and an effective annual tax rate of approximately 37%. The decrease in the effective tax rate was primarily due to the benefit of certain costs capitalized for book purposes that are deductible for tax purposes. The provision for income taxes also reflects research and development tax credits of \$835,000 for 2009 and \$819,000 for 2008.

### ***Net Loss Attributable to Noncontrolling Interest***

Net loss attributable to noncontrolling interest increased by \$3.9 million to \$4.6 million for 2009 from \$724,000 for 2008. The increase resulted from increased development activities and related expenses incurred by our joint venture with the University of Oxford, which was established in July 2008. These amounts represent the portion of the loss incurred by the joint venture for 2009 and 2008, respectively, that is attributable to Oxford.

## **Year Ended December 31, 2008 Compared to Year Ended December 31, 2007**

### ***Revenues***

Product sales revenues decreased by \$675,000, or 0.4%, to \$169.1 million for 2008 from \$169.8 million for 2007. This decrease in product sales revenues was primarily due to a 16% decrease in the number of doses of BioThrax delivered, offset by a 18% increase in the average sales price per dose attributable to a discounted price provided to HHS due to the limited remaining shelf life for certain doses delivered in the third and fourth quarters of 2007. Product sales revenues in 2008 consisted of BioThrax sales to HHS of \$167.6 million and aggregate international and other sales of \$1.5 million. Product sales revenues in 2007 consisted of BioThrax sales to HHS of \$141.6 million, sales to the DoD of \$26.2 million and aggregate international and other sales of \$2.0 million.

Contracts and grant revenues decreased by \$3.7 million, or 28%, to \$9.4 million in 2008 from \$13.1 million in 2007. Contracts and grants revenues for 2008 consisted of \$4.4 million from the Sanofi Pasteur collaboration, related to recognition upon termination of the collaboration in December 2008 of deferred revenue associated with the upfront payment received in 2006 as well as development service revenue, \$3.2 million in development contract and grant revenue from NIAID and other governmental agencies, and \$1.8 million from the sale of technology rights and related materials and documentation pertaining to our Pertussis technology. Contracts and grants revenues for 2007 consisted of a milestone payment of \$8.8 million from HHS in connection with our advancing a program to obtain a post-exposure prophylaxis indication for BioThrax, \$3.1 million from the Sanofi Pasteur collaboration, related to recognition of deferred revenue associated with the upfront payment received in 2006 as well as development service revenue, and \$1.2 million in grant revenue from the NIH and the Wellcome Trust.

### ***Cost of Product Sales***

Cost of product sales decreased by \$6.2 million, or 15%, to \$34.1 million for 2008 from \$40.3 million for 2007. This decrease was attributable to a 16% decrease in the number of doses of BioThrax delivered.

### ***Research and Development Expenses***

Research and development expenses increased by \$5.5 million, or 10%, to \$59.5 million for 2008 from \$54.0 million for 2007. This increase reflects additional personnel and contract service costs, and includes increased expenses of \$1.6 million on product candidates that are categorized in the biodefense segment, \$5.0 million on product candidates categorized in the commercial segment, partially offset by a decrease of \$1.1 million in other research and development expenses, which are in support of technology platforms and central research and development activities.

The increase in spending on biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials, coupled with increased spending on product candidates that we acquired during the year. The spending for BioThrax related programs was due to formulation development and preparing for and conducting clinical and non-clinical, feasibility efficacy and stability studies to support applications for marketing approval of these related programs. The spending for the recombinant protective antigen anthrax vaccine was related primarily to the purchase of this vaccine product candidate from VaxGen in May 2008 and continued advancement of this product candidate. The spending in our advanced anthrax vaccines program resulted from conducting feasibility studies. The decrease in spending in our anthrax immune globulin therapeutic candidate was primarily due to the timing of costs related to plasma collection. The spending for the anthrax monoclonal therapeutic candidate was primarily due to the purchase of this vaccine product candidate and related technology in March 2008 and continued advancement of this product candidate. The decrease in spending for our botulinum vaccine product candidates resulted from enhanced spending in 2007 to advance this program to the process development stage and the manufacture of clinical trial material, coupled with lower spending in 2008 and going forward as we have scaled back our development efforts on our botulinum toxoid vaccine product candidate pending the receipt of third party development funding.

The increase in spending on commercial product candidates, detailed in the table below, primarily reflects additional personnel and contracted services. The spending for our tuberculosis vaccine product candidate related to the formation of our joint venture with the University of Oxford in July 2008 and preparation for a Phase IIb clinical trial. The increase in spending for Typhella resulted from the manufacture of clinical material and initiating and conducting a Phase IIb study in the U.S., which commenced in the second quarter of 2008. The spending for our influenza vaccine product candidate was related to immunogenicity studies. The decrease in spending for our hepatitis B therapeutic vaccine product candidate resulted from the cessation of new patient enrollment from our ongoing Phase II clinical trial in the United Kingdom and Serbia as a result of patient recruiting difficulties because we administer our product candidate as a monotherapy. The spending for our group B streptococcus vaccine product candidate resulted from preparing for Phase I clinical trials for two of the protein components of the vaccine product candidate. We decided not to proceed with these trials and, as a result spending for our group B streptococcus vaccine product candidate will be significantly reduced in the future. The decrease in spending for our chlamydia vaccine product candidate, which is in preclinical development, was related to slowing development while seeking external funding.

The decrease in other research and development expenses was primarily attributable to spending associated with the development of our two technology platforms, MVA and *spi*-Vec.

We continue to assess, and may alter, our future development plans for our products based on the interest of the U.S. government or non-governmental and philanthropic organizations in providing funding for further development or procurement.

Our principal research and development expenses for 2008 and 2007 are shown in the following table:

(in thousands)	Year ended December 31,	
	2008	2007
<b>Biodefense:</b>		
BioThrax related programs	\$ 7,159	\$ 5,175
Recombinant protective antigen anthrax vaccine	6,563	-
Advanced anthrax vaccines	2,540	2,719
Anthrax immune globulin therapeutic	6,126	7,717
Anthrax monoclonal therapeutic	1,062	-
Botulinum vaccines	2,871	9,133
Total biodefense	26,321	24,744
<b>Commercial:</b>		
Tuberculosis vaccine	2,145	-
Typhella	15,431	9,641
Influenza vaccine	1,511	-
Hepatitis B therapeutic vaccine	3,010	5,370
Group B streptococcus vaccine	6,539	6,790
Chlamydia vaccine	1,220	3,146
Meningitis B vaccine	1,313	1,212
Total commercial	31,169	26,159
Other	1,980	3,055
<b>Total</b>	<b>\$ 59,470</b>	<b>\$ 53,958</b>

#### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses decreased by \$479,000, or 1%, to \$55.1 million for 2008 from \$55.6 million for 2007. The decrease in selling, general and administrative expenses was driven by the recovery of approximately \$2.1 million from the DoD and our insurance company in previously expensed legal fees associated with BioThrax litigation, partially offset by an increase of approximately \$1.8 million in our headquarters and staff organization to support the overall growth of our business. The increase related to the growth of our business is primarily attributable to the addition of personnel and increased legal and other professional services for our headquarters organization. The majority of the expense is attributed to the biodefense segment, in which selling, general and administrative expenses for 2008 remained consistent with 2007 at \$43.0 million. Selling, general and administrative expenses related to our commercial segment decreased by \$330,000, or 3%, to \$12.2 million for 2008 from \$12.5 million for 2007.

#### *Total Other Income (Expense)*

Total other income decreased by \$806,000, or 28%, to income of \$2.1 million for 2008 from income of \$2.9 million for 2007. This increase resulted primarily from a decrease in interest income of \$810,000 as a result of lower investment return on average invested cash balances related to a decline in interest rates.

### ***Income Taxes***

Provision for income taxes decreased by \$1.0 million, or 8%, to \$12.1 million for 2008 from \$13.1 million for 2007. The provision for income taxes for 2008 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of \$32.7 million and an effective annual tax rate of 37%. The provision for income taxes for 2007 resulted primarily from our income before provision for income taxes of \$36.0 million and an effective annual tax rate of 36%. The increase in the effective annual tax rate is due primarily to a reduction in state valuation allowances in 2007 related to the expected utilization of net operating losses, partially offset by a reduction in state and local taxes in 2008. The provision for income taxes also reflects research and development tax credits of \$819,000 for 2008 and \$880,000 for 2007.

### ***Net Loss Attributable to Noncontrolling Interest***

Net loss attributable to noncontrolling interest of \$724,000 in 2008 resulted from the formation of our joint venture with the University of Oxford in July 2008. This amount represents the portion of the loss incurred by the joint venture in 2008 that is attributable to Oxford.

### **Liquidity and Capital Resources**

#### ***Sources of Liquidity***

We have funded our cash requirements from inception through 2009 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases, development funding from government entities and non-government and philanthropic organizations, the net proceeds from our initial public offering and from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the five years ended December 31, 2009.

As of December 31, 2009, we had cash and cash equivalents of \$102.9 million. Additionally, at December 31, 2009, our accounts receivable balance was \$54.9 million.

#### ***Cash Flows***

The following table provides information regarding our cash flows for the years ended December 31, 2009, 2008 and 2007.

<b>(in thousands)</b>	<b>Year ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Net cash provided by (used in):			
Operating activities(1)	\$ 29,894	\$ 7,588	\$ 54,790
Investing activities	(33,287)	(30,813)	(43,969)
Financing activities	14,844	8,968	18,491
<b>Total net cash provided (used in)</b>	<b>\$ 11,451</b>	<b>\$ (14,257)</b>	<b>\$ 29,312</b>

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



Net cash provided by operating activities of \$29.9 million in 2009 was due principally to our net income attributable to Emergent BioSolutions Inc. of \$31.1 million, a net increase in deferred income taxes related to timing differences of \$7.6 million, and non-cash charges of \$7.2 million for development expenses from our joint venture with the University of Oxford, \$7.3 million related to the impairment of our Frederick facilities, \$5.0 million for depreciation and amortization and \$5.0 million for stock-based compensation, partially offset by a \$30.0 million increase in accounts receivable related to amounts billed in the fourth quarter of 2009 for which payment was not received until January 2010.

Net cash provided by operating activities of \$7.6 million in 2008 resulted principally from our net income of \$20.7 million, partially offset by an increase in accounts receivable of \$6.0 million due to amounts billed primarily to HHS in December 2008 that were collected in 2009 and a decrease in income taxes payable of \$6.7 million due to the timing of payment of our 2007 income tax liability and estimated tax payments related to our 2008 income tax liability.

Net cash provided by operating activities of \$54.8 million in 2007 resulted principally from our net income of \$22.9 million, a decrease in accounts receivable of \$24.5 million due to amounts billed primarily to HHS in December 2006 that were collected in 2007, partially offset by amounts billed in December 2007 and outstanding at year end, a decrease in inventory of \$9.3 million related to increased product sales in 2007, and \$4.8 million from the impact of non-cash depreciation and amortization, partially offset by a decrease in income taxes payable of \$5.2 million due to the timing of payment of the 2006 income tax liability offset by the pending payable for 2007 income taxes.

Net cash used in investing activities for the years ended December 31, 2009, 2008 and 2007 resulted principally from the purchase of property, plant and equipment and, in 2008, the issuance of a note receivable in the amount of \$10 million. Capital expenditures in 2009 include \$8.2 million for the purchase of our Baltimore facility, \$6.4 million for the purchase of our Gaithersburg facility, \$7.6 million in construction and related costs for our new manufacturing facility in Lansing, Michigan and approximately \$11.1 million in infrastructure investments and other equipment. Capital expenditures in 2008 relate primarily to \$13.1 million in construction and related costs for our new manufacturing facility in Lansing, Michigan and approximately \$7.7 million in infrastructure investments and other equipment. Capital expenditures in 2007 relate primarily to \$30.3 million for construction of our new building in Lansing, and approximately \$13.7 million in infrastructure investments and other equipment.

Net cash provided by financing activities of \$14.8 million in 2009 resulted primarily from \$57.2 million in proceeds from indebtedness, including borrowings under our revolving line of credit with Fifth Third Bank of \$45.0 million and \$12.2 million in loans related to the financing of the purchases of our Baltimore and Gaithersburg facilities coupled with \$4.5 million in proceeds from the exercise of stock options. These cash inflows were partially offset by \$48.6 million in principal payments on indebtedness, including \$45.0 million in payments on our revolving line of credit with Fifth Third Bank.

Net cash provided by financing activities of \$9.0 million in 2008 resulted primarily from \$60.0 million in proceeds from borrowings under our revolving line of credit with Fifth Third Bank, \$5.0 million from the release of restricted cash related to our continuing compliance with the debt covenants specified in our HSBC term loan, \$1.3 million related to excess tax benefits from the exercise of stock options, and \$3.4 million in proceeds from stock option exercises, partially offset by \$60.8 million in principal payments on indebtedness, including \$56.8 million in payments on our revolving line of credit with Fifth Third Bank.

Net cash provided by financing activities of \$18.5 million in 2007 resulted primarily from \$15.3 million in additional proceeds from a term loan with HSBC related to financing a portion of the costs related to the construction of our new building in Lansing, \$17.9 million in proceeds from borrowings under our revolving line of credit with Fifth Third Bank, \$6.0 million related to excess tax benefits from the exercise of stock options, and \$2.5 million in proceeds from stock option exercises, partially offset by \$18.0 million in principal payments on long-term indebtedness, including \$15.0 million in payments on our revolving line of credit with Fifth Third Bank, and restricted cash deposits in 2007 consisting of \$5.0 million in restricted cash in conjunction with our June 2007 HSBC term loan.

### ***Contractual Obligations***

The following table summarizes our contractual obligations at December 31, 2009:

<b>(in thousands)</b>	<b>Payments due by period</b>						
	<b>Total</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>After 2014</b>
<b>Contractual obligations:</b>							
Long-term indebtedness	\$ 50,718	\$ 5,791	\$ 14,724	\$ 2,331	\$ 2,331	\$ 25,541	\$ -
Operating lease obligations	11,950	1,817	1,800	1,767	1,786	1,806	2,974
Contractual settlement liabilities	-	-	-	-	-	-	-
<b>Total contractual obligations</b>	<b>\$ 62,668</b>	<b>\$ 7,608</b>	<b>\$ 16,524</b>	<b>\$ 4,098</b>	<b>\$ 4,117</b>	<b>\$ 27,347</b>	<b>\$ 2,974</b>

There are a number of uncertainties that we face in the development of new product candidates that prevent us from making a reasonable estimate of the cash obligations under our material license and collaboration agreements. Because of these uncertainties, the preceding table excludes contingent contractual payments that we may become obligated to make under such agreements. These agreements typically provide for the payment of milestone fees upon achievement of specified research, development and commercialization milestones, such as the commencement of clinical trials, the receipt of funding awards, the receipt of regulatory approvals, and the achievement of sales milestones. The amount of contingent contractual milestone payments that we may become obligated to make is variable based on the actual achievement and timing of the applicable milestones and the characteristics of any products or product candidates that are developed, including factors such as number of products or product candidates developed, type and number of components of each product or product candidate, ownership of the various components and the specific markets affected, and the aggregate payments could be as much as approximately \$160 million. The success of our efforts to commercialize our product candidates depends on many factors, including those set forth in “*Risk Factors—Our business depends significantly on our success in completing development and commercialization of our product candidates at acceptable costs.*” and is highly uncertain. Even if these efforts are successful, the timing of success is highly unpredictable and variable. The same is true for any contingent contractual royalty payments that we may be obligated to make upon successful commercialization of these product candidates. We do not expect that any such payments would have an adverse effect on our financial position, operations and capital resources because, if payable, we expect that the benefits associated with the achievement of the relevant milestones or the achievement of revenue would offset the burden of making these payments. We are not obligated to pay any minimum royalties under our existing contracts.

### ***Debt Financing***

As of December 31, 2009, we had \$65.7 million principal amount of debt outstanding, comprised primarily of the following:

- \$2.5 million outstanding under a loan from the Department of Business and Economic Development of the State of Maryland used to finance eligible costs incurred to purchase our first facility in Frederick, Maryland;
- \$6.0 million outstanding under a mortgage loan from PNC Bank used to finance the remaining portion of the purchase price for our first Frederick facility;

- \$7.3 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance the purchase price for our second facility on the Frederick site;
- \$22.8 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;
- \$7.0 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance the purchase of our facility in Baltimore, Maryland;
- \$5.1 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance the purchase of our facility in Gaithersburg, Maryland; and
- \$15.0 million outstanding under a \$15.0 million revolving line of credit with Fifth Third Bank, the balance of which we repaid in January 2010.

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

- Under our 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. Our plans for this facility have changed, and we currently plan to sell both Frederick buildings. As such we have not met the requirements for the loan to be forgivable as of December 31, 2009. We have reached an agreement with the State of Maryland to repay the loan in full by September 30, 2010, with an earlier repayment due upon sale of the building.
- Under our mortgage loan from PNC 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 term loan with HSBC Realty Credit Corporation to finance a portion of the costs of our facility expansion in Lansing, Michigan, we are required to maintain on an annual basis a book leverage ratio of less than 1.00. In addition, we are required to maintain on a quarterly basis a debt coverage ratio of not less than 1.25 to 1.00.
- Under our mortgage loan with HSBC Realty Credit Corporation for our Gaithersburg facility, we are required to maintain on an annual basis a book leverage ratio of less than 1.00. In addition, we are required to maintain on a quarterly basis a debt coverage ratio of not less than 1.25 to 1.00.
- Under our mortgage loan with HSBC Realty Credit Corporation for our Baltimore facility, we are required to maintain on an annual basis a book leverage ratio of less than 1.00. In addition, we are required to maintain on a quarterly basis a debt coverage ratio of not less than 1.25 to 1.00.
- Under our revolving 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 with HSBC Realty Credit Corporation limits the ability of Emergent BioDefense Operations to incur indebtedness and liens, sell assets, make loans, advances or guarantees, enter into mergers 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 mergers or similar transactions, enter into transactions with affiliates and amend the terms of any government contract.

The facilities, software and other equipment that we purchased with the proceeds of our loans from PNC Bank, the State of Maryland and HSBC Realty Credit Corporation serve as collateral for these loans. Our line of credit with Fifth Third Bank is secured by accounts receivable under our HHS and DoD contracts. Our term loan with HSBC Realty Credit Corporation is secured by substantially all of Emergent BioDefense Operations' assets, other than accounts receivable under our HHS and DoD 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 PNC Bank, we began 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 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 to purchase our second facility in Frederick, Maryland, we are required to make monthly principal payments. A residual principal repayment of approximately \$7.0 million is due upon maturity in April 2011. Interest is payable monthly and accrues at an annual rate equal to the three month LIBOR plus 3.00%.

Under our term loan with HSBC Realty Credit Corporation, which we refinanced in December 2009, we are required to make monthly principal payments. A residual principal payment of \$15.2 million is due upon maturity in December 2014. Interest is payable monthly and accrues at an annual rate equal to the three month LIBOR plus 3.25%.

Under our mortgage loan from HSBC Realty Credit Corporation to purchase our Gaithersburg facility, we are required to make monthly principal payments. A residual principal repayment of approximately \$3.5 million is due upon maturity in November 2014. Interest is payable monthly and accrues at an annual rate equal to the three month LIBOR plus 3.25%.

Under our mortgage loan from HSBC Realty Credit Corporation to purchase our Baltimore facility, we are required to make monthly principal payments. A residual principal repayment of approximately \$4.7 million is due upon maturity in November 2014. Interest is payable monthly and accrues at an annual rate equal to the three month LIBOR plus 3.25%.

Under our revolving line of credit with Fifth Third Bank, any outstanding principal is due upon maturity in June 2010. The principal amount outstanding at any time under the line of credit may not exceed 75% of total eligible accounts receivable under our HHS and DoD contracts. Consistent with the terms of this agreement, we repaid \$15.0 million of outstanding principal under the line of credit in January 2010. 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.

### ***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, beginning in 2006. These tax benefits are primarily based on our investment in our Lansing facility. In addition, we must maintain a specified number of employees in Lansing to continue to qualify for these tax benefits.

### ***Funding Requirements***

We expect to continue to fund our anticipated operating expenses, capital expenditures and debt service requirements from existing cash and cash equivalents, revenues from BioThrax product sales and other committed sources of funding. There are numerous risks and uncertainties associated with BioThrax product sales and with the development and commercialization of our product candidates.

We may seek additional external debt financing to provide additional financial flexibility. Our committed external sources of funds consist of the borrowing availability under our revolving line of credit with Fifth Third Bank and grant and development funding of some of our product candidates. Our ability to borrow additional amounts under our loan agreement 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 acquisition of, and capital improvements to new facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to our manufacturing facility in Lansing, Michigan and, any new facilities;
- 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 extent to which we lend money to third parties;
- 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.

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.

### ***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 January 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-06, which amended Accounting Standards Codification, or ASC, Topic 820 regarding improving disclosures about fair value measurements. The amendments in ASU No. 2010-06 will provide more robust disclosures about (1) the different classes of assets and liabilities measured at fair value, (2) the valuation techniques and inputs used, (3) the activity in Level 3 fair value measurements, and (4) the transfers between Levels 1, 2, and 3. This amendment is effective for financial statements issued for interim and annual periods ending after December 15, 2010. We do not anticipate this amendment will have a material impact on our financial statements.

In January 2010, the FASB issued ASU No. 2010-02, which amended ASC Topic 810 regarding accounting and reporting for decreases in ownership of a subsidiary. The amendments in ASU No. 2010-02 clarifies what type of subsidiaries or asset groups the scope of the decrease in ownership applies. These amendments also clarify that the decrease in ownership guidance does not apply to certain transactions even if they involve businesses. This amendment is effective for financial statements issued for interim and annual periods beginning on or after December 15, 2009 for entities that have adopted the pending content that links to ASC 10-10-65-1. We do not anticipate this amendment will not have a material impact on our financial statements.

In January 2010, the FASB issued ASU No. 2010-01, which amended ASC Topic 505 regarding distributions to shareholders with components of stock and cash. The amendments in ASU No. 2010-01 clarify that the stock portion of a distribution to shareholders that allows them to elect to receive cash or stock, with a potential limitation on the total amount of cash that all shareholders can elect to receive in the aggregate, is considered a share issuance that is reflected in earnings per share prospectively and is not a stock dividend for purposes of applying ASC Topics 505 and ASC Topic 260. This amendment is effective for financial statements issued for interim and annual periods ending after December 15, 2009. We do not anticipate this amendment will have a material impact on our financial statements.

In December 2009, the FASB issued ASU No. 2009-17, which amended ASC Topic 810 regarding variable interest entities. The amendments in ASU No. 2009-17 replace the quantitative-based risks and rewards calculation for determining which reporting entity, if any, has a controlling financial interest in a variable interest entity with an approach focused on identifying which reporting entity has the power to direct the activities of a variable interest entity that most significantly impact the entity's economic performance and (1) the obligation to absorb losses of the entity or (2) the right to receive benefits from the entity. The amendments also require additional disclosures about a reporting entity's involvement in variable interest entities, which will enhance the information provided to users of financial statements. This amendment is effective as of the beginning of each reporting entity's first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. We do not expect that the adoption of this amendment will have a material impact on our financial statements.

In October 2009, the FASB issued ASU No. 2009-13, which amended ASC Topic 605 regarding multiple-deliverable revenue arrangements. The amendments in ASU No. 2009-13 establish a selling price hierarchy for determining the selling price of a deliverable. In addition, this amendment replaces the term "fair value" in the revenue allocation guidance with "selling price". ASU No. 2009-13 will eliminate the residual method of allocation and require that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method and will require that an entity determine its best estimate of selling price in a manner that is consistent with that used to determine the price to sell the deliverable on a standalone basis. ASU No. 2009-13 will significantly expand the disclosures related to an entity's multiple-deliverable revenue arrangements. In the year of adoption, entities will be required to disclose information that enables the users of financial statements to understand the effect of adopting ASU No. 2009-13.

This amendment is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. If early adoption is elected and the period of adoption is not the beginning of the entity's fiscal year, the entity will be required to apply the amendments in ASU No. 2009-13 retrospectively from the beginning of the entity's fiscal year. The adoption of this amendment will have an impact on our financial statements to the extent we are a party to multiple-deliverable revenue arrangements.

In June 2009, the FASB issued ASU No. 2009-01, *The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles — a replacement of FASB Statement No. 162*, an amendment to ASC Topic 105, *Generally Accepted Accounting Principles*. The FASB ASC will be the source of authoritative U.S. generally accepted accounting principles, or GAAP, recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission, or SEC, under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The ASC supersedes all then-existing non-SEC accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the ASC will become non-authoritative. ASU No. 2009-01 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. This statement did not have a material impact on our financial statements.

In June 2009, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 167, *Amendments to FASB Interpretation No. 46(R)*, or SFAS No. 167, included in ASC Topic 810. SFAS No. 167 amends Interpretation 46(R) to replace the quantitative-based risks and rewards calculation for determining which enterprise, if any, has a controlling financial interest in a variable interest entity with an approach focused on identifying which enterprise has the power to direct the activities of a variable interest entity that most significantly impact the entity's economic performance and (1) the obligation to absorb losses of the entity or (2) the right to receive benefits from the entity. SFAS No. 167 requires an additional reconsideration event when determining whether an entity is a variable interest entity when any changes in facts and circumstances occur such that the holders of the equity investment at risk, as a group, lose the power from voting rights or similar rights of those investments to direct the activities of the entity that most significantly impact the entity's economic performance. It also requires ongoing assessments of whether an enterprise is the primary beneficiary of a variable interest entity. SFAS No. 167 amends FASB Interpretation No. 46(R) to require additional disclosures about an enterprise's involvement in variable interest entities. We adopted the provisions of SFAS No. 167 effective January 1, 2009. Earlier application is prohibited. We do not anticipate this statement will have a material impact on our financial statements.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events*, or SFAS No. 165, which was later included in ASC Topic 855. SFAS No. 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. In particular, SFAS No. 165 sets forth: (1) the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements; (2) the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements; and (3) the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. We have adopted SFAS No. 165 during the three months ended September 30, 2009. The provisions of SFAS No. 165 will impact our financial statements to the extent that we have material subsequent events.

In April 2009, the FASB issued FASB Staff Position, or FSP, SFAS No. 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies*, or FSP SFAS No. 141(R)-1, which was later included in ASC Topic 805. FSP SFAS No. 141(R)-1 amends the initial recognition and measurement, subsequent measurement and accounting, and disclosure of assets and liabilities arising from contingencies in a business combination. We adopted FSP SFAS No. 141(R)-1 effective January 1, 2009, and it will impact our financial statements to the extent that we are a party to a business combination.

**ITEM 7A. 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, and our long-term indebtedness. We currently do not hedge interest rate exposure or interest on foreign currency exchange exposure, and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations. 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 a significant impact on the realized value of our investments, but would likely increase the interest expense associated with our debt.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders of Emergent BioSolutions Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. and Subsidiaries as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. 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. An audit 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, 2009 and 2008, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Emergent BioSolutions Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 5, 2010 expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

McLean, Virginia  
March 5, 2010



**Emergent BioSolutions Inc. and Subsidiaries**  
**Consolidated Balance Sheets**  
(in thousands, except share and per share data)

	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 102,924	\$ 91,473
Accounts receivable	54,872	24,855
Inventories	13,521	18,325
Note receivable	10,000	10,000
Deferred tax assets, net	1,870	-
Income tax receivable, net	2,574	-
Restricted cash	215	208
Prepaid expenses and other current assets	7,838	8,026
Total current assets	<u>193,814</u>	<u>152,887</u>
Property, plant and equipment, net	131,834	124,656
Assets held for sale	13,960	-
Deferred tax assets, net	3,894	12,073
Other assets	1,187	1,172
Total assets	<u>\$ 344,689</u>	<u>\$ 290,788</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 17,159	\$ 18,254
Accrued expenses and other current liabilities	1,570	1,399
Accrued compensation	14,926	11,380
Indebtedness under line of credit	15,000	15,000
Long-term indebtedness, current portion	5,791	6,248
Income taxes payable	-	951
Deferred tax liabilities, net	-	557
Deferred revenue	255	232
Total current liabilities	<u>54,701</u>	<u>54,021</u>
Long-term indebtedness, net of current portion	44,927	35,935
Other liabilities	1,246	1,483
Total liabilities	<u>100,874</u>	<u>91,439</u>
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock, \$0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2009 and 2008, respectively	-	-
Common stock, \$0.001 par value; 100,000,000 shares authorized, 30,831,360 and 30,159,546 shares issued and outstanding at December 31, 2009 and 2008, respectively	31	30
Additional paid-in capital	120,492	109,170
Accumulated other comprehensive loss	(1,476)	(859)
Retained earnings	122,152	91,008
Total Emergent BioSolutions Inc. stockholders' equity	<u>241,199</u>	<u>199,349</u>
Noncontrolling interest in subsidiary	2,616	-
Total stockholders' equity	<u>243,815</u>	<u>199,349</u>
Total liabilities and stockholders' equity	<u>\$ 344,689</u>	<u>\$ 290,788</u>

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

**Emergent BioSolutions Inc. and Subsidiaries**  
**Consolidated Statements of Operations**  
(in thousands, except share and per share data)

	<b>Year Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>Revenues:</b>			
Product sales	\$ 217,172	\$ 169,124	\$ 169,799
Contracts and grants	17,614	9,430	13,116
<b>Total revenues</b>	<b>234,786</b>	<b>178,554</b>	<b>182,915</b>
<b>Operating expense:</b>			
Cost of product sales	46,262	34,081	40,309
Research and development	74,588	59,470	53,958
Selling, general and administrative	73,786	55,076	55,555
<b>Income from operations</b>	<b>40,150</b>	<b>29,927</b>	<b>33,093</b>
<b>Other income (expense):</b>			
Interest income	1,418	1,999	2,809
Interest expense	(7)	(47)	(71)
Other income (expense), net	(50)	134	156
<b>Total other income (expense)</b>	<b>1,361</b>	<b>2,086</b>	<b>2,894</b>
Income before provision for income taxes	41,511	32,013	35,987
Provision for income taxes	14,966	12,055	13,051
Net income	26,545	19,958	22,936
Net loss attributable to noncontrolling interest	4,599	724	-
Net income attributable to Emergent BioSolutions Inc.	<b>\$ 31,144</b>	<b>\$ 20,682</b>	<b>\$ 22,936</b>
<b>Earnings per share - basic</b>	<b>\$ 1.02</b>	<b>\$ 0.69</b>	<b>\$ 0.79</b>
<b>Earnings per share - diluted</b>	<b>\$ 0.99</b>	<b>\$ 0.68</b>	<b>\$ 0.77</b>
<b>Weighted-average number of shares - basic</b>	<b>30,444,485</b>	<b>29,835,134</b>	<b>28,995,667</b>
<b>Weighted-average number of shares - diluted</b>	<b>31,375,305</b>	<b>30,458,098</b>	<b>29,663,127</b>

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

**Emergent BioSolutions Inc. and Subsidiaries**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	<b>Year Ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities:</b>			
Net income	\$ 26,545	\$ 19,958	\$ 22,936
Adjustments to reconcile to net cash provided by operating activities:			
Stock-based compensation expense	5,007	2,510	2,541
Depreciation and amortization	4,999	4,964	4,817
Deferred income taxes	7,604	2,006	5,589
Non-cash development expenses from joint venture	7,215	724	-
Loss (gain) on disposal of property and equipment	61	(135)	24
Provision for impairment of long-lived assets	7,328	-	-
Excess tax benefits from stock-based compensation	(1,852)	(1,336)	(6,003)
Changes in operating assets and liabilities:			
Accounts receivable	(30,017)	(6,038)	24,514
Inventories	6,207	(1,428)	9,337
Income taxes	(3,525)	(6,714)	(5,169)
Prepaid expenses and other assets	(1,230)	(4,949)	(2,828)
Accounts payable	(1,334)	(457)	(12)
Accrued expenses and other liabilities	(66)	(523)	(1,557)
Accrued compensation	3,546	1,878	2,312
Deferred revenue	23	(3,143)	(1,054)
Net cash provided by operating activities	<u>30,511</u>	<u>7,317</u>	<u>55,447</u>
<b>Cash flows from investing activities:</b>			
Purchases of property, plant and equipment	(33,287)	(20,813)	(43,969)
Issuance of note receivable	-	(10,000)	-
Net cash used in investing activities	<u>(33,287)</u>	<u>(30,813)</u>	<u>(43,969)</u>
<b>Cash flows from financing activities:</b>			
Restricted cash release (deposit)	(7)	4,992	(5,008)
Proceeds from borrowings on long-term indebtedness and line of credit	57,183	60,000	33,195
Issuance of common stock subject to exercise of stock options	4,464	3,391	2,471
Principal payments on long-term indebtedness and line of credit	(48,648)	(60,751)	(18,015)
Excess tax benefits from stock-based compensation	1,852	1,336	6,003
Debt issuance costs	-	-	(155)
Net cash provided by financing activities	<u>14,844</u>	<u>8,968</u>	<u>18,491</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(617)</u>	<u>271</u>	<u>(657)</u>
Net increase (decrease) in cash and cash equivalents	11,451	(14,257)	29,312
Cash and cash equivalents at beginning of year	91,473	105,730	76,418
Cash and cash equivalents at end of year	<u>102,924</u>	<u>91,473</u>	<u>105,730</u>
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid during the year for interest	\$ 1,627	\$ 3,216	\$ 3,094
Cash paid during the year for income taxes	\$ 15,155	\$ 16,788	\$ 14,329
<b>Supplemental information on non-cash investing and financing activities:</b>			
Purchases of property, plant and equipment unpaid at year end	\$ 2,749	\$ 2,510	\$ 4,056

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

**Consolidated Statement of Changes in Stockholders' Equity**  
(in thousands, except share and per share data)

	<u>\$0.001 Par Value Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Noncontrolling Interest in Subsidiary</u>	<u>Retained Earnings</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>					
Balance at December 31, 2006	27,596,249	\$ 28	\$ 90,920	\$ (473)	\$ -	\$ 47,997	\$ 138,472
Exercise of stock options	2,153,988	2	2,469	-	-	-	2,471
Stock-based compensation expense	-	-	2,541	-	-	-	2,541
Cumulative effect of change in accounting principle (FIN 48)	-	-	-	-	-	(607)	(607)
Excess tax benefits from exercises of stock options	-	-	6,003	-	-	-	6,003
Net income	-	-	-	-	-	22,936	22,936
Foreign currency translation	-	-	-	(657)	-	-	(657)
Comprehensive income	-	-	-	-	-	-	22,279
Balance at December 31, 2007	29,750,237	\$ 30	\$ 101,933	\$ (1,130)	\$ -	\$ 70,326	\$ 171,159
Exercise of stock options	409,309	-	3,391	-	-	-	3,391
Stock-based compensation expense	-	-	2,510	-	-	-	2,510
Excess tax benefits from exercises of stock options	-	-	1,336	-	-	-	1,336
Net income	-	-	-	-	-	20,682	20,682
Foreign currency translation	-	-	-	271	-	-	271
Comprehensive income	-	-	-	-	-	-	20,953
Balance at December 31, 2008	30,159,546	\$ 30	\$ 109,170	\$ (859)	\$ -	\$ 91,008	\$ 199,349
Exercise of stock options	671,814	1	4,463	-	-	-	4,464
Stock-based compensation expense	-	-	5,007	-	-	-	5,007
Excess tax benefits from exercises of stock options	-	-	1,852	-	-	-	1,852
					7,215		7,215

Non-cash development expenses from joint venture								
Net loss attributable to noncontrolling interest	-	-	-	-	(4,599)	-	(4,599)	
Net income	-	-	-	-	-	31,144	31,144	
Foreign currency translation	-	-	-	(617)	-	-	(617)	
Comprehensive income	-	-	-	-	-	-	30,527	
Balance at December 31, 2009	<u>30,831,360</u>	<u>\$ 31</u>	<u>\$ 120,492</u>	<u>\$ (1,476)</u>	<u>\$ 2,616</u>	<u>\$ 122,152</u>	<u>\$ 243,815</u>	

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

## **Emergent BioSolutions Inc. and Subsidiaries**

### **Notes to consolidated financial statements**

#### **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 vaccines and antibody therapies. The Company is developing products to be offered both to the biodefense and commercial markets. 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. 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”).

As a result of the Reorganization, BioPort became a wholly owned subsidiary of the Company. The Company has renamed BioPort as Emergent BioDefense Operations Lansing Inc. (“Emergent BioDefense Operations”). The Company acquired a portion of its portfolio of vaccine and therapeutic product candidates through an acquisition of Microscience Limited (“Microscience”) in a share exchange in June 2005, and acquisitions of substantially all of the assets, for cash, of Antex Biologics Inc. (“Antex”) in May 2003 and ViVacs GmbH, Germany (“ViVacs”) in July 2006. The Company has renamed Microscience as Emergent Product Development UK Limited. The assets acquired from Antex were incorporated as Emergent Product Development Gaithersburg Inc., and the assets acquired from ViVacs were incorporated as Emergent Product Development Germany GmbH.

#### **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 and majority-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation. For investments in variable interest entities, the Company consolidates when it is determined to be the primary beneficiary.

##### **Use of estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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. 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.

##### **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 fair value of the Company’s long-term indebtedness is estimated based on the quoted prices for the same or similar issues or on the current rates offered to the Company for debt of the same remaining maturities. The carrying value and fair value of long-term indebtedness were \$50.7 million and \$50.0 million, respectively, at December 31, 2009 and \$42.2 million and \$42.0 million, respectively, at December 31, 2008.

### **Restricted cash**

Restricted cash at December 31, 2009 and 2008 includes a certificate of deposit held by a bank as collateral for a letter of credit acting as a security deposit on a loan. As of December 31, 2009 and 2008 the Company had restricted cash of \$215,000 and \$208,000, respectively.

### **Significant customers and accounts receivable**

For the years ended December 31, 2009, 2008 and 2007, the Company's primary customers were the U.S. Department of Health and Human Services ("HHS") and the U.S. Department of Defense (the "DoD"). For the years ended December 31, 2009 and 2008, revenues from HHS and HHS agencies comprised 99.6% and 95.7%, respectively, of total revenues. For the year ended December 31, 2007, revenues from the DoD, HHS and HHS agencies comprised 97.2%, of total revenues. As of December 31, 2009 and 2008, the Company's receivable balances were comprised of 99.4% and 97.7%, respectively, from these customers. Unbilled accounts receivable, included in accounts receivable, totaling \$3.1 million and \$1.9 million as of December 31, 2009 and 2008, respectively, relate to various service contracts for which work has been performed, though invoicing has not yet occurred. Accounts receivable are stated at invoice amounts and consist primarily of amounts due from HHS and the DoD 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, 2009 and 2008, an allowance for doubtful account, was not recorded as the collection history from those customers indicated collection was probable.

### **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.

## Note receivable

In 2008, the Company entered into a loan and security agreement with Protein Sciences Corporation (“PSC”) to loan PSC up to \$10 million in conjunction with an agreement pursuant to which the Company would acquire substantially all of the assets of PSC. The loan is secured by substantially all of PSC’s assets, including PSC’s intellectual property. Under this loan agreement and a related promissory note, \$10 million of principal is outstanding as of December 31, 2009, and the Company has recorded this as a note receivable. By its original terms, the note accrued interest at an annual rate of 8% and was due and payable no later than December 31, 2008. Thereafter, the note accrued interest at a default rate of 11%. In early 2009, the Company entered into a forbearance agreement with PSC. Under the terms of the forbearance agreement, the note continued to accrue interest at an annual rate of 11%, and became due and payable on May 31, 2009. The Company also agreed not to foreclose on the collateral for the loan prior to May 31, 2009. Since the expiration of the forbearance agreement, the note has accrued interest at a default rate of 14%. As of December 31, 2009, the Company has recorded accrued interest on the note receivable of \$1.8 million, included in prepaid expenses and other current assets.

In 2008, the Company initiated litigation against PSC and its senior management alleging fraud and breach of contract, among other claims. In June 2009, after the expiration of a five-month forbearance period on the loan, the Company initiated proceedings to acquire possession of its physical assets by foreclosing. In addition, the Company and several other creditors of PSC filed a federal involuntary bankruptcy petition against PSC in June 2009 in United States Bankruptcy Court for the District of Delaware. In September 2009, the bankruptcy court concluded that PSC was insolvent and that PSC’s debt to the Company was valid and not subject to a bona fide dispute. However, the bankruptcy court declined to force PSC into bankruptcy, finding that foreclosure proceedings, not the bankruptcy action, were the proper mechanism of recovery. The Company intends to continue to pursue foreclosure on PSC’s assets and to pursue the two pending lawsuits against PSC and its management. The Company has concluded that the \$10 million note receivable is not impaired as of December 31, 2009, and therefore has not recorded a reserve against this note. This conclusion is based on the Company’s belief that it will recover all amounts recorded, either by repayment from PSC or through foreclosure on PSC’s assets. In the event that PSC does not voluntarily repay the amounts due, the Company believes that the value of its collateral as a secured creditor is in excess of the note and related interest and that a loss is not probable.

## 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	31-39 years
Building improvements	10-39 years
Furniture and equipment	3-7 years
Software	Lesser of 3-5 years or product life
Leasehold improvements	Lesser of the asset life or lease term

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.

## 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's ability to realize deferred tax assets depends upon future taxable income as well as the limitations discussed below. 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. 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 more likely than not to realize more than the recorded amounts of net deferred tax assets in the future, the Company will reverse all or a portion of the valuation allowance established against its deferred tax assets, resulting in a decrease to the provision for income taxes in the period in which the determination is made. Likewise, if the Company determines that it is not more likely than not to realize all or part of the net deferred tax asset in the future, the Company will establish a valuation allowance against deferred tax assets, with an offsetting increase to the provision for income taxes, in the period in which the determination is made.

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 and the Company's initial public offering, the Company believes the use of the operating losses will be significantly limited.

### **Revenue recognition**

The Company recognizes 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 previous contracts with HHS, the Company invoiced HHS and recognized the related revenues upon delivery of the product to the government carrier, at which time title to the product passed to HHS. Under the Company's current contracts with HHS, the Company invoices HHS and recognizes the related revenue upon acceptance by the government at delivery site, at which time title to the product passes to HHS.

Under the Company's previous contracts with the DoD, title to the product passed to the DoD upon submission of the first invoice. The earnings process was considered complete upon FDA release of the product for sale and distribution. Following FDA release of the product, the product was segregated for later shipment, and all deferred revenue related to the released product was recognized in accordance with "bill and hold" requirements.

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 ("SNS"). This interpretation provides for revenue recognition for specifically identified products purchased for the SNS in the event that all requirements for revenue recognition are not met. While the Company's contracts with HHS are for qualifying sales of vaccine for placement into the SNS, the Company meets all requirements for revenue recognition upon delivery of product to HHS, and therefore has not applied this guidance.

Collaborative research and development agreements can provide for one or more of up-front license fees, research payments, and milestone payments. Agreements with multiple components (“deliverables” or “items”) are evaluated to determine if the deliverables can be divided into more than one unit of accounting. An item can generally be considered a separate unit of accounting if all of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis; (2) there is objective and reliable evidence of the fair value of the undelivered item(s); and (3) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in control of the Company. Items that cannot be divided into separate units are combined with other units of accounting, as appropriate. Consideration received is allocated among the separate units based on their respective fair values or based on the residual value method and is recognized in full when the criteria above are met. The Company deems service to have been rendered if no continuing obligation exists on the part of the Company.

Revenue associated with non-refundable up-front license fees under arrangements where the license fees and research and development activities cannot be accounted for as separate units of accounting is deferred and recognized as revenue on a straight-line basis over the expected term of the Company’s continued involvement in the research and development process. Revenues from the achievement of research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved, and the milestone payments are due and collectible. If not deemed substantive, the Company would recognize such milestone as revenue on a straight-line basis over the remaining expected term of continued involvement in the research and development process.

Milestones are considered substantive if all of the following conditions are met; (1) the milestone is non-refundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone and any ongoing research and development or other services are priced at fair value. Payments received in advance of work performed are recorded as deferred revenue.

The Company generates contract and grant revenue from cost-plus-fee contracts. Revenues are recognized to the extent of costs incurred plus an estimate of the applicable fees earned. The Company considers fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. The Company analyzes each cost for contracts and reimbursable grants to ensure reporting of revenues gross versus net is appropriate based on the guidance in the American Institute of Certified Public Accountants Federal Government Contractors Guide or Financial Accounting Standards Board (“FASB”) guidance for accounting revenue recognition, whichever is most appropriate. For each of the three years in the period ended December 31, 2009, the costs incurred under the contracts and grants approximated the revenue earned.

### **Impairment of long-lived assets**

The Company assesses the recoverability of its long-lived assets for which an indicator of impairment exists by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If the Company concludes that the carrying value will not be recovered, the Company measures the amount of such impairment by comparing the fair value to the carrying value. The Company recorded an impairment charge of \$7.3 million in 2009 related to its two Frederick, Maryland facilities, described more fully in Note 14 — Assets Held for Sale. The Company recorded no impairment losses for the years ended December 31, 2008 and 2007.

### **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.

## **Comprehensive income**

Comprehensive income is comprised of net income and other changes in equity that are excluded from net income. 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.

## **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.

## **Capitalized interest**

The Company capitalizes interest based on the cost of major ongoing capital projects which have not yet been placed in service. For the years ended December 31, 2009, 2008 and 2007, the Company incurred interest of \$1.8 million, \$3.0 million and \$3.2 million, respectively. Of these amounts, the Company capitalized \$1.8 million, \$3.0 million and \$3.1 million, respectively.

## **Certain risks and uncertainties**

The Company has derived substantially all of its revenue from sales of BioThrax under contracts with HHS and the DoD. The Company's ongoing U.S. government contract does 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 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 have received regulatory approval.

## **Earnings per share**

Basic net income per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income by the weighted average number of shares outstanding for the period. Diluted net income 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:

(in thousands, except share and per share data)	Year Ended December 31,		
	2009	2008	2007
Numerator:			
Net income	\$ 31,144	\$ 20,682	\$ 22,936
Denominator:			
Weighted-average number of shares—basic	30,444,485	29,835,134	28,995,667
Dilutive securities—stock options	930,820	622,964	667,460
Weighted-average number of shares—diluted	31,375,305	30,458,098	29,663,127
Earnings per share-basic	\$ 1.02	\$ 0.69	\$ 0.79
Earnings per share-diluted	\$ 0.99	\$ 0.68	\$ 0.77

For the years ending December 31, 2009, 2008 and 2007, outstanding stock options to purchase approximately 1.4 million, 183,000 and 211,000 shares, respectively, of common stock are not considered in the diluted earnings per share calculation because the exercise price of these options is greater than the average per share closing price during the year.

### Accounting for stock-based compensation

As of December 31, 2009, the Company has two stock-based employee compensation plans, the Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the “2006 Plan”) and the Emergent BioSolutions Employee Stock Option Plan (the “2004 Plan”), described more fully in Note 8 — Stockholders’ Equity.

The Company recognizes stock-based compensation net of an estimated forfeiture rate. Based on options granted to employees as of December 31, 2009, total compensation expense not yet recognized related to unvested options is approximately \$4.8 million, after tax. The Company expects to recognize that expense over a weighted average period of 1.7 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 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,		
	2009	2008	2007
Expected dividend yield	0%	0%	0%
Expected volatility	55%	65%	50%
Risk-free interest rate	1.32-1.72%	1.63-2.75%	2.99-5.09%
Expected average life of options	3.3 years	3.0 years	3.0 years

- 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 analyzed the volatility used by similar companies at a similar stage of development to estimate expected volatility. The volatility used by these similar companies ranged from 40% to 80%, with an average estimated volatility of 55%. The Company used a rate of 55% for grants made in 2009, approximately the mid-point of this range.
- Risk-free interest rate — This is the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date 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 Company’s expectation of optionee exercise behavior subsequent to vesting of options.

Pursuant to accounting guidance related to stock compensation, the Company classifies the cash flows resulting from the tax benefits of deductions in excess of the compensation cost recognized for options exercised (excess tax benefits from stock-based compensation) as financing cash flows.

### **Reclassifications**

Certain amounts classified as inventory in the consolidated balance sheet as of December 31, 2008 have been reclassified as other current assets to conform with current period presentation.

### **Subsequent events**

The Company has evaluated subsequent events through the time of filing these financial statements.

### **Recent accounting pronouncements**

In January 2010, the FASB issued Accounting Standards Update (“ASU”) No. 2010-06 which amended Accounting Standards Codification (“ASC”) Topic 820 regarding improving disclosures about fair value measurements. The amendments in ASU No. 2010-06 will provide more robust disclosures about (1) the different classes of assets and liabilities measured at fair value, (2) the valuation techniques and inputs used, (3) the activity in Level 3 fair value measurements, and (4) the transfers between Levels 1, 2, and 3. This amendment is effective for financial statements issued for interim and annual periods ending after December 15, 2010. The Company anticipates that the adoption of this amendment will not have a material impact on its financial statement.

In January 2010, the FASB issued Accounting Standards Update ASU No. 2010-02 which amended ASC Topic 810 regarding accounting and reporting for decreases in ownership of a subsidiary. The amendments in ASU No. 2010-02 clarifies what type of subsidiaries or asset groups the scope of the decrease in ownership applies. The amendments in this Update also clarify that the decrease in ownership guidance does not apply to certain transactions even if they involve businesses. This amendment is effective for financial statements issued for interim and annual periods beginning on or after December 15, 2008 for entities that have not adopted the pending content that links to ASC 10-10-65-1. This amendment is effective for financial statements issued for interim and annual periods beginning on or after December 15, 2009 for entities that have adopted the pending content that links to ASC 10-10-65-1. The Company anticipates that the adoption of this amendment will not have a material impact on its financial statement.

In January 2010, the FASB issued ASU No. 2010-01 which amended ASC Topic 505 regarding distributions to shareholders with components of stock and cash. The amendments in ASU No. 2010-01 clarify that the stock portion of a distribution to shareholders that allows them to elect to receive cash or stock, with a potential limitation on the total amount of cash that all shareholders can elect to receive in the aggregate, is considered a share issuance that is reflected in earnings per share prospectively and is not a stock dividend for purposes of applying ASC Topics 505 and ASC Topic 260. This amendment is effective for financial statements issued for interim and annual periods ending after December 15, 2009. The Company anticipates that the adoption of this amendment will not have a material impact on its financial statement.

In December 2009, the FASB issued Accounting Standards Update ASU No. 2009-17 which amended ASC Topic 810 regarding variable interest entities. The amendments in ASU No. 2009-17 replace the quantitative-based risks and rewards calculation for determining which reporting entity, if any, has a controlling financial interest in a variable interest entity with an approach focused on identifying which reporting entity has the power to direct the activities of a variable interest entity that most significantly impact the entity’s economic performance and (1) the obligation to absorb losses of the entity or (2) the right to receive benefits from the entity. The amendments also require additional disclosures about a reporting entity’s involvement in variable interest entities, which will enhance the information provided to users of financial statements. This amendment is effective as of the beginning of each reporting entity’s first annual reporting period that begins after November 15, 2009, for interim periods within that first annual reporting period, and for interim and annual reporting periods thereafter. The adoption of this amendment will not have a material impact on the Company’s financial statements. The Company does not expect the adoption of this amendment to have a material impact on its financial statements.

In October 2009, FASB issued ASU No. 2009-13 which amended ASC Topic 605 regarding multiple-deliverable revenue arrangements. The amendments in ASU No. 2009-13 establish a selling price hierarchy for determining the selling price of a deliverable. In addition, this amendment replaces the term “fair value” in the revenue allocation guidance with “selling price”. ASU No. 2009-13 will eliminate the residual method of allocation and require that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method and will require that an entity determine its best estimate of selling price in a manner that is consistent with that used to determine the price to sell the deliverable on a standalone basis. ASU No. 2009-13 will significantly expand the disclosures related to an entity’s multiple-deliverable revenue arrangements. In the year of adoption, entities will be required to disclose information that enables the users of financial statements to understand the effect of adopting ASU No. 2009-13. This amendment is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. If early adoption is elected and the period of adoption is not the beginning of the entity’s fiscal year, the entity will be required to apply the amendments in ASU No. 2009-13 retrospectively from the beginning of the entity’s fiscal year. The adoption of this amendment will have an impact on the Company’s financial statements to the extent the Company is a party to multiple-deliverable revenue arrangements.

In June 2009, the FASB issued ASU No. 2009-01, *The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles — a replacement of FASB Statement No. 162*, an amendment to ASC Topic 105, *Generally Accepted Accounting Principles*. The ASC will be the source of authoritative U.S. generally accepted accounting principles (“GAAP”) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission (“SEC”) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The ASC supersedes all then-existing non-SEC accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the ASC will become non-authoritative. ASU No. 2009-01 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Company does not expect the adoption of this amendment to have a material impact on its financial statements.

In June 2009, the FASB issued Statement of Financial Accounting Standards (“SFAS”) No. 167, *Amendments to FASB Interpretation No. 46(R)* (“SFAS No. 167”) which was later superseded by the FASB ASC and included in ASC Topic 810. SFAS No. 167 amends FASB Interpretation 46(R) to replace the quantitative-based risks and rewards calculation for determining which enterprise, if any, has a controlling financial interest in a variable interest entity, with an approach focused on identifying which enterprise has the power to direct the activities of a variable interest entity that most significantly impact the entity’s economic performance and (1) the obligation to absorb losses of the entity or (2) the right to receive benefits from the entity. SFAS No. 167 requires an additional reconsideration event when determining whether an entity is a variable interest entity when any changes in facts and circumstances occur such that the holders of the equity investment at risk, as a group, lose the power from voting rights or similar rights of those investments to direct the activities of the entity that most significantly impact the entity’s economic performance. It also requires ongoing assessments of whether an enterprise is the primary beneficiary of a variable interest entity. SFAS No. 167 amends FASB Interpretation 46(R) to require additional disclosures about an enterprise’s involvement in variable interest entities. SFAS No. 167 shall be effective for the Company as of January 1, 2009. Earlier application is prohibited. The Company does not expect the adoption of this amendment to have a material impact on its financial statements.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events* (“SFAS No. 165”) which was later superseded by the FASB ASC and included in ASC Topic 855. SFAS No. 165 establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. In particular, SFAS No. 165 sets forth: (1) the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements; (2) the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements; and (3) the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. The Company adopted SFAS No. 165 during the three months ended June 30, 2009. The provisions of SFAS No. 165 will impact the Company’s financial statements to the extent that the Company has material subsequent events.

In April 2009, the FASB issued FASB Staff Position (“FSP”) SFAS No. 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies* (“FSP SFAS No. 141(R)-1”) which was later superseded by the FASB ASC and included in ASC Topic 805. FSP SFAS No. 141(R)-1 amends the initial recognition and measurement, subsequent measurement and accounting, and disclosure of assets and liabilities arising from contingencies in a business combination. FSP SFAS No. 141(R)-1 was adopted by the Company effective January 1, 2009, and will impact the Company’s financial statements to the extent that the Company is party to a business combination.

In December 2007, the FASB issued Statement of Financial Accounting Standards (“SFAS”) No. 141 (revised 2007), *Business Combinations* (“SFAS No. 141(R)”). SFAS 141(R) was subsequently codified into ASC Topic 805, *Business Combinations* (“ASC 805”). ASC 805 requires the expensing of acquisition-related costs as incurred. In accordance with the provisions of ASC 805, in January 2009 the Company expensed \$1.4 million in previously capitalized acquisition-related costs associated with acquisitions that were in progress but not complete as of December 31, 2008.

### 3. Accounts receivable

Accounts receivable consist of the following:

(in thousands)	December 31,	
	2009	2008
Billed	\$ 51,782	\$ 23,005
Unbilled	3,090	1,850
Total	\$ 54,872	\$ 24,855

### 4. Inventories

Inventories consist of the following:

(in thousands)	December 31,	
	2009	2008
Raw materials and supplies	\$ 1,565	\$ 1,352
Work-in-process	9,870	14,459
Finished goods	2,086	2,514
Total inventories	\$ 13,521	\$ 18,325

### 5. Property, plant and equipment

Property, plant and equipment consist of the following:

(in thousands)	December 31,	
	2009	2008
Land and improvements	\$ 2,932	\$ 5,050
Buildings, building improvements and leasehold improvements	18,661	28,119
Furniture and equipment	27,086	22,657
Software	6,833	6,423
Construction-in-progress	98,178	82,518
	153,690	144,767
Less: Accumulated depreciation and amortization	(21,856)	(20,111)
Total Property, plant and equipment, net	\$ 131,834	\$ 124,656

Depreciation and amortization expense was \$5.0 million, \$5.0 million and \$4.8 million for the years ended December 31, 2009, 2008 and 2007, respectively. For the years ended December 31, 2009, 2008 and 2007, depreciation and amortization expense included approximately \$0, \$0, and \$1.0 million, respectively, related to the amortization of internal-use software. As of December 31, 2009 and 2008, there was no unamortized internal use software-cost.

## 6. Long-term debt

The components of long-term debt are as follows:

(in thousands)	December 31,	
	2009	2008
Term loan dated December 2009; three month LIBOR plus 3.25%, due December 2014	\$ 22,750	\$ 25,500
Term loan dated November 2009; three month LIBOR plus 3.25%, due November 2014	6,981	-
Term loan dated November 2009; three month LIBOR plus 3.25%, due November 2014	5,134	-
Term loan dated April 2006; three month LIBOR plus 3.0%, due April 2011	7,308	7,809
Loan dated October 2004; 3.0%, due September 2010	2,500	2,500
Term loan dated October 2004; 6.625%, due October 2011	6,045	6,369
Other	-	5
Total long-term indebtedness	50,718	42,183
Less current portion of long-term indebtedness	(5,791)	(6,248)
Noncurrent portion of long-term indebtedness	\$ 44,927	\$ 35,935

In December 2009, the Company entered into a loan agreement with HSBC, under which HSBC provided the Company with a term loan of \$22.8 million. This loan replaced a prior loan arrangement with HSBC under which HSBC agreed to loan the Company \$30.0 million. Under the new loan agreement, the Company is required to make monthly payments in the amount of \$126,000 in principal plus accrued interest, with a residual principal payment due upon maturity in December 2014. Payment of the loan is secured by substantially all of the assets of Emergent BioDefense Operations, other than accounts receivable under BioThrax supply contracts with HHS and the DoD that are pledged as collateral to secure a \$15 million revolving line of credit with Fifth Third Bank. The assets that secure this loan total approximately \$150 million at December 31, 2009. The annual interest rate is based on the three month LIBOR plus 3.25% (3.50% as of December 31, 2009).

In November 2009, the Company completed the acquisition of a development and manufacturing facility in Baltimore, Maryland for \$8.2 million. The Company paid approximately \$1.2 million in cash and financed the remaining balance with a term loan from HSBC in the amount of \$7.0 million. This loan requires monthly principal payments of \$39,000 plus accrued interest from November 2009 through November 2014 with a balloon payment for the remaining unpaid principal and interest due in November 2014. The loan is collateralized by the facility. The annual interest rate is based on the three month LIBOR plus 3.25% (3.50% as of December 31, 2009).

In October 2009, the Company completed the acquisition of a research and development facility in Gaithersburg, Maryland for \$6.4 million. The Company paid \$1.2 million in cash and financed the remaining balance with a term loan from HSBC in the amount of \$5.2 million. This loan requires monthly principal payments of \$29,000 plus accrued interest from November 2009 through November 2014 with a balloon payment for the remaining unpaid principal and interest due in November 2014. The loan is collateralized by the facility. The annual interest rate is based on the three month LIBOR plus 3.25% (3.50% as of December 31, 2009).

In April 2006, the Company completed the acquisition of a 145,000 square foot facility in Frederick, Maryland for \$9.8 million. This facility was previously under a lease which contained an option to purchase the facility. The Company paid \$1.3 million in cash and financed the remaining balance with a bank loan with HSBC in the amount of \$8.5 million. This loan requires monthly principal and interest payments from May 2006 through April 2011 of \$72,000 with a balloon payment for the remaining unpaid principal and interest due in April 2011. The loan is collateralized by the facility. The annual interest rate is based on the three month LIBOR plus 3.0% (3.25% as of December 31, 2009).



Under the terms of the four loans we have with HSBC, the Company is required to maintain a book leverage ratio of less than 1.00. This ratio is calculated by dividing total liabilities, excluding deferred revenues specific to contracts with the U.S. government, by total net worth. In addition, the Company is required to maintain a debt coverage ratio of not less than 1.25 to 1.00. This ratio is calculated by dividing earnings before interest, taxes, depreciation and amortization for the most recent four quarters by 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. The Company is in compliance with these covenants as of December 31, 2009.

In October 2004, the Company entered into a Secured Conditional Loan with the Maryland Economic Development Assistance Fund ("MEDAF") 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 \$1.3 million letter of credit and a security interest in the building. The Company is required to pay an annual fee of 1.0% to maintain the letter of credit. The borrowing bears interest at 3.0% per annum, and the term of the loan ends March 31, 2013. The terms of the loan call for principal and related accrued interest to be forgiven if specified employment levels are achieved and maintained through December 2012, at least \$42.9 million in project costs are expended prior to December 2009, and the Company occupies the building through December 2012. As of December 31, 2009 the Company has not met the requirements for the loan to be forgivable, and in February 2010 reached an agreement with MEDAF to repay the loan in full by September 30, 2010, with an earlier repayment due upon sale of the building. The full \$2.5 million outstanding under this loan is included in current portion of long-term indebtedness at December 31, 2009, and the accrued interest is included in accrued expenses and other current liabilities.

In connection with the 2004 purchase of the building in Frederick, Maryland discussed above, the Company entered into a loan agreement for \$7.0 million with a bank to finance the remaining portion of the purchase price. The borrowing accrued interest at 6.625% per annum through October 2006. The Company was required to make interest only payments through that date. Beginning in November 2006, the Company began to make monthly payments of \$62,000, based upon a 15 year amortization schedule. In November 2009, the monthly payments will be adjusted based upon a 12 year amortization schedule. Beginning in November 2009, the loan will bear interest at a fixed rate equal to 3.2% over the yield on actively traded U.S. Government securities issues adjusted to a constant maturity of two years, rounded up to the nearest one-eighth of one percent (1/8 of 1%). 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 \$5.0 million and a debt coverage ratio of not less than 1.1 to 1. The Company is in compliance with these covenants as of December 31, 2009.

Scheduled principal repayments and maturities on long-term debt as of December 31, 2009 are as follows:

<b>(in thousands)</b>	
2010	\$ 5,791
2011	14,724
2012	2,331
2013	2,331
2014	25,541
2015 and beyond	-
	<u>\$ 50,718</u>

## 7. Line of credit

In June 2007, the Company entered into a loan agreement with Fifth Third Bank, whereby Fifth Third Bank agreed to extend to the Company a revolving line of credit up to \$15 million. The Company can borrow under this line of credit through June 2010, at which time the agreement expires. The line of credit is secured by accounts receivable under the Company's HHS contract and bears interest at a rate equal to the one month LIBOR plus 2% (2.23% as of December 31, 2009). The Company is subject to certain covenants, including maintenance of specified equity levels on a quarterly basis, and is currently in compliance with those covenants. For each of the years ended December 31, 2009 and 2008, \$15.0 million was outstanding under the line of credit. These amounts were repaid in January 2010 and February 2009, respectively.

## 8. Stockholders' equity

### Preferred stock

The Company is authorized to issue up to 15,000,000 shares of preferred stock, \$0.001 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 December 31, 2009 and 2008, no preferred stock has been issued.

### Common stock

The Company currently has one class of \$0.001 par value per share common stock ("Common Stock") authorized and outstanding. The Company is authorized to issue up to 100,000,000 shares of the Common Stock. Holders of Common Stock are entitled to one vote for each share of Common Stock held on all matters as may be provided by law.

### Stock options

As of December 31, 2009, the Company has two stock-based employee compensation plans, the 2006 Plan and the 2004 Plan (together, the "Emergent Plans"), under which the Company has granted options to purchase shares of Common Stock. The Emergent Plans have both incentive and non-qualified stock option features.

The 2006 Plan was amended and restated on May 21, 2009 at the Company's 2009 Annual Meeting of Stockholders to provide for, among other things, an increase in the number of shares of Common Stock authorized for issuance by 3.9 million shares. The amendment to the 2006 Plan also allowed for an additional 450,000 shares of Common Stock to be reserved for issuance effective July 1, 2009, as previously approved under the provisions of the 2006 Plan. Additionally, the amendment eliminates an "evergreen provision" contained in the original 2006 Plan that allowed for periodic increases in the number of shares authorized for issuance. As of December 31, 2009, an aggregate of 8,678,826 shares of Common Stock are authorized for issuance under the 2006 Plan, and a total of 4,586,304 shares of Common Stock remain available for future awards to be made to plan participants. The maximum number of shares subject to awards which that may be granted per year under the 2006 Plan to a single participant is 287,700. 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. Options granted under the 2006 Plan have a vesting period of no more than 5 years and a contractual life of no more than 10 years. The terms and conditions of stock options (including price, vesting schedule, term and number of shares) under the Emergent Plans are determined by the Company's compensation committee, which administers the Emergent Plans. Following the closing of the Company's initial public offering in November 2006, the Company no longer granted options pursuant to the 2004 Plan.

Each option granted under the Emergent Plans becomes exercisable as specified in the relevant option agreement, and no option can be exercised after ten years from the date of grant. The following is a summary of stock option plan activity:

	2006 Plan		2004 Plan		Aggregate Intrinsic Value
	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price	
Outstanding at December 31, 2008	2,466,519	\$ 8.76	438,628	\$ 5.52	51,826,012
Exercisable at December 31, 2008	487,148	\$ 10.00	383,486	\$ 4.68	16,063,651
Granted	1,514,437	18.00	-	-	
Exercised	(406,424)	8.53	(265,390)	3.76	
Forfeited	(89,033)	11.76	(43,156)	10.28	
Outstanding at December 31, 2009	3,485,499	12.72	130,082	7.52	11,178,792
Exercisable at December 31, 2009	936,933	9.56	130,082	7.52	4,768,507

The weighted average remaining contractual term of options outstanding as of December 31, 2009 and 2008 was 5.6 and 5.7 years, respectively. The weighted average remaining contractual term of options exercisable as of December 31, 2009 and 2008 was 4.8 and 4.5 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2009, 2008 and 2007 was \$7.16, \$3.53 and \$3.58, respectively. The total intrinsic value of options exercised during the years ended December 31, 2009, 2008 and 2007 was \$7.1 million, \$4.0 million and \$20.5 million, respectively. The total fair value of options vested during 2009, 2008 and 2007 was \$3.3 million, \$1.9 million and \$1.9 million, respectively.

Stock-based compensation expense was recorded in the following financial statement line items:

(in thousands)	Years Ended December 31,	
	2009	2008
Cost of sales	\$ 200	\$ 100
Research and development	1,103	520
General and administrative	3,704	1,890
Total stock-based compensation expense	\$ 5,007	\$ 2,510

A summary of the status of the Company's nonvested stock options at December 31, 2009 is presented below:

	2006 Plan		2004 Plan	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2008	1,979,371	\$ 3.57	55,142	\$ 4.24
Granted	1,514,437	18.00	-	-
Exercised	-	-	-	-
Vested	(856,209)	3.62	(40,757)	4.33
Forfeited	(89,033)	11.76	(14,385)	3.98
Nonvested at December 31, 2009	2,548,566	\$ 3.57	-	\$ -
Options expected to vest at December 31, 2009	1,703,399		-	

During the years ended December 31, 2009, 2008 and 2007, the Company received a tax benefit from stock options exercised of approximately \$1.9 million, \$1.3 million and \$6.0 million, respectively.

## 9. Income taxes

Significant components of the provision for income taxes attributable to operations consist of the following:

<b>(in thousands)</b>	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>Current</b>			
Federal	\$ 8,254	\$ 11,186	\$ 11,189
State	902	98	2,275
International	58	101	-
<b>Total current</b>	<b>9,214</b>	<b>11,385</b>	<b>13,464</b>
<b>Deferred</b>			
Federal	5,799	(1,174)	2,832
State	(47)	1,844	(3,245)
<b>Total deferred</b>	<b>5,752</b>	<b>670</b>	<b>(413)</b>
<b>Total provision for income taxes</b>	<b>\$ 14,966</b>	<b>\$ 12,055</b>	<b>\$ 13,051</b>

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

<b>(in thousands)</b>	<b>December 31,</b>	
	<b>2009</b>	<b>2008</b>
Net operating loss carryforward	\$ 10,304	\$ 8,458
Research and development carryforward	1,578	1,714
Stock compensation	1,358	730
Foreign deferrals	52,059	46,151
Other	(452)	1,902
Deferred tax asset	64,847	58,955
Fixed assets	(3,104)	(851)
Other	(2,783)	(2,051)
Deferred tax liability	(5,887)	(2,902)
Valuation allowance	(53,196)	(44,537)
<b>Net deferred tax asset</b>	<b>\$ 5,764</b>	<b>\$ 11,516</b>

Net operating loss carryforwards consist of approximately \$191.7 million for state jurisdictions and \$157.0 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 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:

<b>(in thousands)</b>	<b>Year ended December 31,</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
US	\$ 74,758	\$ 66,326	\$ 62,016
International	(28,648)	(33,589)	(26,029)
<b>Earnings before taxes on income</b>	<b>46,110</b>	<b>32,737</b>	<b>35,987</b>
Federal tax at statutory rates	\$ 16,138	\$ 11,458	\$ 12,595
State taxes, net of federal benefit	(1,172)	(2,118)	701
Impact of foreign operations	(7,156)	(8,384)	(7,106)
Change in valuation allowance	9,025	10,835	6,419
Effect of change in rates	-	-	493
Effect of foreign rates	(17)	(11)	154
Tax credits	(835)	(819)	(880)
Other differences	(2,056)	185	(617)
Permanent differences	1,039	909	1,292
<b>Provision for income taxes</b>	<b>\$ 14,966</b>	<b>\$ 12,055</b>	<b>\$ 13,051</b>

The effective annual tax rate for the years ended December 31, 2009, 2008 and 2007 was 32%, 37% and 36%, respectively. The decrease in the effective rate in 2009 from 2008 is due primarily to the benefit of certain costs capitalized for book purposes that are deductible for tax purposes.

In September 2006, the FASB issued guidance for accounting for uncertainty in income taxes. This guidance 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. In addition, this guidance requires that the Company recognize in its financial statements the impact of a tax position if that position is more likely than not to be sustained on audit based on the technical merits of the position and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure.

The Company recognizes interest in interest expense and recognizes potential penalties related to unrecognized tax benefits in selling, general and administrative expense. The Company accrued approximately \$23,000 and \$44,000, respectively, for the payment of interest and penalties as of December 31, 2009 and 2008. Of the total unrecognized tax benefits recorded at December 31, 2009 and 2008, \$175,000 and \$160,000, respectively is classified as a current liability and \$85,000 and \$110,000, respectively, is classified as a non-current liability on the balance sheet. As of December 31, 2009 and 2008, \$126,000 and \$0, respectively, of unrecognized tax benefits will reverse within the next twelve months.

The table below presents the gross unrecognized tax benefits activity for 2009, 2008 and 2007:

<b>(in thousands)</b>	
Gross unrecognized tax benefits at January 1, 2007	\$ 607
Increases for tax positions for prior years	262
Decreases for tax positions for prior years	(65)
Increases for tax positions for current year	100
Settlements	(201)
Lapse of statute of limitations	(426)
Gross unrecognized tax benefits at December 31, 2007	<u>277</u>
Increases for tax positions for prior years	28
Decreases for tax positions for prior years	-
Increases for tax positions for current year	-
Settlements	-
Lapse of statute of limitations	(35)
Gross unrecognized tax benefits at December 31, 2008	<u>270</u>
Increases for tax positions for prior years	15
Decreases for tax positions for prior years	(80)
Increases for tax positions for current year	55
Settlements	-
Lapse of statute of limitations	-
Gross unrecognized tax benefits at December 31, 2009	<u>\$ 260</u>

Substantially all of these reserves would impact the effective tax rate if released into income.

The Company's federal and state income tax returns for the tax years 2008 to 2006 remain open to examination. The Company's tax returns in the United Kingdom remain open to examination for the tax years 2008 to 2001, and tax returns in Germany remain open indefinitely.

A limited scope federal income tax audit of the Company's tax return for the 2006 tax year was completed in May 2009, without adjustment. A federal income tax audit of the Company's tax return for the 2005 tax year was completed in March 2008. As a result of that audit, the Company paid an assessment of \$450,000, including \$55,000 of interest. A federal income tax audit of the Company's tax return for the 2004 tax year was completed in March 2007. As a result of this audit, the Company paid an assessment of \$722,000, including \$96,000 of interest.

## 10. 401(k) savings plan

The Company has 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 currently provides for matching of qualified deferrals up to 50% of the first 6% of the employee's salary. During the years ended December 31, 2009, 2008 and 2007, the Company made matching contributions of approximately \$1.1 million, \$827,000 and \$682,000, respectively.

## 11. 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 Munich, Germany under a non-cancelable operating lease that expires in June 2015. The Company leases office and laboratory space in Wokingham, England under two coterminous non-cancelable operating leases that expire in November 2016. The Company leases office space in Rockville, Maryland under a non-cancelable operating lease that contains a 3% annual escalation clause over the ten year term of the lease, which expires in December 2016 and the Company has a five year renewal option at the end of the initial term. Prior to purchasing the building in October 2009, we also leased office and laboratory space in Gaithersburg, Maryland. For the years ended December 31, 2009, 2008 and 2007, total rent expense was \$3.2 million, \$3.7 million and \$3.4 million, respectively.

Future minimum lease payments under operating lease obligations as of December 31, 2009 are as follows:

<b>(in thousands)</b>	
2010	\$ 1,817
2011	1,800
2012	1,767
2013	1,786
2014	1,806
2015 and beyond	2,974
Total minimum lease payments	<u>\$ 11,950</u>

## 12. Litigation

*Litigation against Protein Sciences Corporation.* The Company is currently pursuing three legal actions against PSC and its senior management arising out of a letter of intent, a loan and security agreement and related promissory note, and an asset purchase agreement between the Company and PSC that were entered into in 2008. Under those agreements, the Company agreed to acquire substantially all of PSC's assets and to provide funding to PSC to enable it to continue operations through the anticipated closing date of the asset purchase transaction. Between March 2008 and June 2008, the Company provided PSC with \$10 million in funding under the loan and security agreement and related promissory note. PSC's obligations to the Company under these agreements are secured by substantially all of PSC's assets, including PSC's intellectual property. The note accrued interest at an annual rate of 8% through December 31, 2008, a default rate of 11% through May 31, 2009, and a default rate of 14% since June 1, 2009. PSC has not repaid any portion of the loan. As of December 31, 2009, \$10 million of principal was outstanding and \$1.8 million of interest was accrued and unpaid.

On June 8, 2009, after the expiration of a five-month forbearance period on the loan, the Company initiated legal proceedings in the Superior Court of the State of Connecticut, Judicial District of New Haven, to acquire possession of the physical assets by foreclosing on PSC's physical assets that secure the loan. In addition, the Company and several other creditors of PSC filed a federal involuntary bankruptcy petition against PSC on June 22, 2009 in the United States Bankruptcy Court for the District of Delaware. In September 2009, the bankruptcy court concluded that PSC was insolvent and that PSC's debt to the Company was valid and not subject to a bona fide dispute, but the bankruptcy court declined to force PSC into involuntary bankruptcy, finding that the foreclosure proceeding, not the bankruptcy action, was the proper mechanism of recovery. The Company intends to continue to pursue the Connecticut action for possession of its physical assets in an effort to recover amounts due to the Company. PSC has filed a motion to stay the Connecticut action for possession pending a decision in the New York litigation against PSC, which is described below. Such motion has been briefed and argued and the Company is awaiting a decision from the Connecticut state court.

In addition to the action seeking possession of the collateral, the Company continues to pursue two separate lawsuits filed regarding this matter: one against PSC on July 9, 2008 and the other PSC's executive management team, which consists of Daniel D. Adams, PSC's Chief Executive Chairman, and Manon M.J. Cox, PSC's President and Chief Executive Officer, on October 3, 2008. The lawsuit against PSC is pending in the Supreme Court of the State of New York and includes, among other things, claims for fraud, breach of contract, breach of the duty of good faith and fair dealing, unjust enrichment and unfair business practices. The lawsuit against Mr. Adams and Ms. Cox is pending in the United States District Court for the District of Connecticut and alleges, among other things, that these individuals engaged in fraudulent conduct in connection with their efforts to obtain \$10 million in bridge financing from us. PSC has moved to dismiss the New York action, and that motion remains pending. Mr. Adams and Ms. Cox moved to dismiss the Connecticut action, and the court denied that motion with respect to the fraud claims and granted it with respect to unfair business practice claims. In the Company's lawsuits against PSC and PSC's executive management team, the Company is seeking monetary damages of no less than \$13 million, punitive damages, declaratory judgment, injunctive relief to protect the collateral for the loan, and other appropriate relief. PSC, Mr. Adams, and Ms. Cox have not yet asserted any counterclaims in either lawsuit, but PSC has stated that it may assert counterclaims for "among other things, breach of contract, intentional misrepresentations, tortious interference with business relations and unfair trade practices."

The Company intends to pursue full repayment of the loan, as well as other relief as described in pleadings in the pending lawsuits against PSC and PSC's executive management.

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.

### **13. Oxford collaboration**

In July 2008, the Company entered into a collaboration with the University of Oxford ("Oxford") and certain University of Oxford researchers to conduct clinical trials in the advancement of a vaccine product candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium ("OETC"). The Company has a 51% equity interest in OETC and controls the OETC Board of Directors. In addition, the Company has certain funding and services obligations of up to \$20.3 million related to its investment. In accordance with accounting provisions related to the accounting for variable interest entities, the Company has evaluated its variable interests in OETC and has determined that it is the primary beneficiary as it will absorb the majority of expected losses. Accordingly, the Company consolidates the entity. As of December 31, 2009, assets of \$379,000 and liabilities of \$83,000 related to this entity are included within the Company's consolidated balance sheet. During the year ended December 31, 2009, the entity incurred a net loss of \$9.4 million, of which \$4.8 million is included in the Company's consolidated statement of operations.

In conjunction with the establishment of OETC, the Company granted a put option to Oxford and the Oxford researchers whereby the Company may be required to acquire all of the OETC shares held by Oxford and the Oxford researchers at fair market value of the underlying shares. This put option is contingent upon the satisfaction of a number of conditions that must exist or occur subsequent to the grant of a marketing authorization for a tuberculosis vaccine by the European Commission. The Company accounts for the put option in accordance with the accounting provision related to derivatives and distinguishing liabilities from equity. In accordance with this guidance, the Company has determined that the put option has a de minimus fair value as of December 31, 2009.

#### **14. Assets held for sale**

The Company currently owns two buildings in Frederick, Maryland that it is actively seeking to sell. In June 2009, the Company determined that these two buildings, along with associated improvements, would not be placed into service and committed to a plan to sell the facilities. Therefore, these buildings are classified on the Company's balance sheet as assets held for sale. Assets held for sale are recorded at the lower of the carrying amount or fair market value less costs to sell, and are no longer depreciated once classified as held for sale. The Company recorded the assets held for sale at fair market value, based on factors that include recent purchase offers less estimated selling costs, and recorded an impairment charge of \$7.3 million in 2009. This impairment charge is classified in the Company's statement of operations as selling, general and administrative expense, within the Company's commercial segment. The Company is continuing efforts to sell these buildings.

#### **15. Related party transactions**

The Company entered into an agreement in February 2009 with an entity controlled by family members of the Company's Chief Executive Officer. The agreement, to market and sell BioThrax, was effective as of November 2008 and requires payment based on a percentage of net sales of biodefense products of 17.5% in Saudi Arabia and 15% in Qatar and United Arab Emirates, and reimbursement of certain expenses. No payments under this agreement have been triggered for the years ended December 31, 2009 and 2008.

The Company has entered into a consulting arrangement with a member of the Company's Board of Directors. At December 31, 2009 and 2008, \$15,000 and \$0, respectively, remained in accounts payable for these services. For each of the years ended December 31, 2009 and 2008, the Company paid approximately \$180,000, under this agreement for strategic consultation and project support for the Company's marketing and communications group.

The Company has entered into a transportation arrangement with an entity owned by Company's Chief Executive Officer. At December 31, 2009 and 2008, \$3,000 remained in accounts payable for these services. During the years ended December 31, 2009 and 2008, the Company paid approximately \$32,000 and \$31,000, respectively, under this arrangement for transportation and logistical support.

#### **16. Segment information**

For financial reporting purposes, the Company reports financial information for two business segments: biodefense and commercial. In the biodefense segment, the Company develops, manufactures and commercializes vaccine and antibody therapies for use against biological agents that are potential weapons of bioterrorism or biowarfare. Revenues in this segment relate primarily to the Company's FDA-licensed product, BioThrax. In the commercial segment, the Company develops vaccines and antibody therapies for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. Revenues in this segment consist predominantly of milestone payments and development and grant revenues received under collaboration, development contracts and grant arrangements. The "All Other" segment relates to the general operating costs of the Company and includes costs of the centralized services departments, which are not allocated to the other segments, as well as spending on product candidates or activities that are not classified as biodefense or commercial. The assets in this segment consist primarily of cash and fixed assets.



(in thousands)	Reportable Segments			
	Biodefense	Commercial	All Other	Total
<b>Year Ended December 31, 2009</b>				
External revenue	\$ 234,574	\$ 212	\$ -	\$ 234,786
Intersegment revenue (expense)	-	-	-	-
Research and development	42,874	24,064	7,650	74,588
Interest revenue	-	-	1,418	1,418
Interest expense	-	-	(7)	(7)
Depreciation and amortization	3,867	852	280	4,999
Net income (loss)	87,850	(43,770)	(12,936)	31,144
Assets	215,786	25,350	103,553	344,689
Expenditures for long-lived assets	26,583	5,933	771	33,287
<b>Year Ended December 31, 2008</b>				
External revenue	\$ 174,061	\$ 4,346	\$ 147	\$ 178,554
Intersegment revenue (expense)	-	-	-	-
Research and development	26,321	31,169	1,980	59,470
Interest revenue	-	-	1,999	1,999
Interest expense	-	-	(47)	(47)
Depreciation and amortization	3,438	1,114	412	4,964
Net income (loss)	69,770	(41,313)	(7,775)	20,682
Assets	161,091	23,450	106,247	290,788
Expenditures for long-lived assets	20,014	64	735	20,813

#### 17. Quarterly financial data (unaudited)

Quarterly financial information for the years ended December 31, 2009 and 2008 is presented in the following tables:

(in thousands)	Three months ended			
	March 31,	June 30,	September 30,	December 31,
<b>Fiscal year 2009</b>				
Revenue	\$ 64,519	\$ 73,191	\$ 43,272	\$ 53,804
Income (loss) from operations	17,266	22,710	(3,951)	4,125
Net income	11,119	14,842	949	4,234
Net income per share, basic	0.37	0.49	0.03	0.14
Net income per share, diluted	0.35	0.48	0.03	0.13
<b>Fiscal year 2008</b>				
Revenue	\$ 42,720	\$ 43,485	\$ 56,599	\$ 35,750
Income from operations	11,175	2,558	15,338	856
Net income	7,024	1,815	10,386	1,457
Net income per share, basic	0.24	0.06	0.35	0.05
Net income per share, diluted	0.24	0.06	0.34	0.05

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

**ITEM 9A. CONTROLS AND PROCEDURES**

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2009. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2009, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2009. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework*. Based on this assessment, our management concluded that, as of December 31, 2009, our internal control over financial reporting is effective based on those criteria.

Ernst & Young LLP, the independent registered public accounting firm that has audited our consolidated financial statements included herein, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2009, a copy of which is included in this annual report on Form 10-K.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the fiscal quarter ended December 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM  
ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

Board of Directors and Stockholders of Emergent BioSolutions Inc. and Subsidiaries

We have audited Emergent BioSolutions Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Emergent BioSolutions Inc. and Subsidiaries' management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying "Management's Report on Internal Control over Financial Reporting." Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Emergent BioSolutions Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2009 consolidated financial statements of Emergent BioSolutions Inc. and Subsidiaries, and our report dated March 5, 2010, expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

McLean, Virginia  
March 5, 2010

## **ITEM 9B. OTHER INFORMATION**

### **Executive Compensation**

On March 4, 2010, the Compensation Committee awarded cash bonuses to the following executives in the following amounts: Fuad El-Hibri, \$485,900; Daniel J. Abdun-Nabi, \$231,169; R. Don Elsey, \$142,057; Stephen Lockhart, £67,650; and Kyle W. Keese, \$143,312. Also on March 4, 2010, the Compensation Committee approved the following base salaries and target bonus percentages for the following executives, all effective as of January 1, 2010: Fuad El-Hibri, \$625,600 and 65%; Daniel J. Abdun-Nabi, \$444,475 and 50%; R. Don Elsey, \$357,698 and 45%; Stephen Lockhart, £173,352 and 40%; and Kyle W. Keese, \$325,000 and 40%.

### **Manufacturing**

In November 2009, we amended our Product Supply Agreement with Talecris Biotherapeutics, Inc. to delay commencement of commercial manufacturing for our anthrax immune globulin therapeutic product candidate from January 1, 2010 to March 1, 2010 in order to accommodate negotiations for a long-term resolution regarding commercial production of this product candidate. We recently modified this amendment to further extend the commencement date to April 1, 2010, and are currently continuing to negotiate with Talecris.

## **PART III**

### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

#### **Directors and Executive Officers**

Information regarding our directors may be found under the caption "Election of Directors" in the Proxy Statement for our 2010 Annual Meeting of Stockholders. Information regarding our executive officers may be found under the caption "Executive Officers of the Registrant" in the Proxy Statement for our 2010 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

#### **Compliance with Section 16(a) of the Exchange Act**

Information regarding compliance with Section 16(a) of the Exchange Act by our directors, officers and beneficial owners of more than 10% of our common stock may be found under the caption "Stock Ownership Information—Section 16 (a) Beneficial Ownership Reporting Compliance" in the Proxy Statement for our 2010 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

#### **Code of Ethics**

We have adopted a code of business conduct and ethics that applies to our directors, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), as well as our other employees. A copy of our code of business conduct and ethics is available on our website at [www.emergentbiosolutions.com](http://www.emergentbiosolutions.com). We intend to post on our website all disclosures that are required by applicable law, the rules of the Securities and Exchange Commission or the New York Stock Exchange concerning any amendment to, or waiver of our code of business conduct and ethics.

#### **Director Nominees**

Information regarding procedures for recommending nominees to the board of directors may be found under the caption "Corporate Governance—Director Nomination Process" in the Proxy Statement for our 2010 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

## **Audit Committee**

We have separately designated a standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Additional information regarding the Audit Committee may be found under the captions “Corporate Governance—Board Committees—Audit Committee” and “Corporate Governance—Audit Committee Report” in the Proxy Statement for our 2010 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

## **Audit Committee Financial Expert**

Our board of directors has determined that Zsolt Harsanyi, Ph.D. is an “audit committee financial expert” as defined by Item 407(d)(5) of Regulation S-K of the Exchange Act and is “independent” under the rules of the New York Stock Exchange.

## **ITEM 11. EXECUTIVE COMPENSATION**

Information with respect to this item may be found under the caption “Information About Executive and Director Compensation” in the Proxy Statement for our 2010 Annual Meeting of Stockholders. Such information is incorporated herein by reference. The Compensation Committee Report contained in the Proxy Statement for our 2010 Annual Meeting of Stockholders shall be deemed furnished in this annual report on Form 10-K and shall not be deemed “soliciting material” or “filed” with the Securities and Exchange Commission or otherwise subject to the liabilities of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that we specifically request that such information be treated as soliciting material or specifically incorporate such information by reference into a document filed under the Securities Act or the Exchange Act.

## **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Information with respect to this item may be found under the captions “Stock Ownership Information” and “Information About Executive and Director Compensation—Securities Authorized for Issuance Under Equity Compensation Plans” in the Proxy Statement for our 2010 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

## **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

Information with respect to this item may be found under the captions “Corporate Governance—Transactions with Related Persons” and “Corporate Governance—Board Determination of Independence” in the Proxy Statement for our 2010 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

## **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Information with respect to this item may be found under the captions “Corporate Governance—Registered Public Accounting Firm's Fees” and “Corporate Governance—Pre-Approval Policy and Procedures” in the Proxy Statement for our 2010 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

## **PART IV**

### **ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

#### **Financial Statements**

The following financial statements and supplementary data are filed as a part of this annual report on Form 10-K.

Report of Independent Registered Public Accounting Firm  
Consolidated Balance Sheets at December 31, 2009 and 2008  
Consolidated Statements of Operations for the years ended December 31, 2009, 2008 and 2007  
Consolidated Statements of Cash Flows for the years ended December 31, 2009, 2008 and 2007  
Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2009, 2008 and 2007  
Notes to Consolidated Financial Statements

#### **Financial Statement Schedules**

All financial statement schedules are omitted because they are not applicable or the required information is included in the financial statements or notes thereto.

#### **Exhibits**

Those exhibits required to be filed by Item 601 of Regulation S-K are listed in the Exhibit Index immediately preceding the exhibits hereto and such listing is incorporated herein by reference.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### EMERGENT BIOSOLUTIONS INC.

By: /s/Fuad El-Hibri

Fuad El-Hibri  
Chief Executive Officer and  
Chairman of the Board of Directors  
Date: March 5, 2010

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/Fuad El-Hibri</u> Fuad El-Hibri	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 5, 2010
<u>/s/R. Don Elsey</u> R. Don Elsey	Senior Vice President Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 5, 2010
<u>/s/Daniel Abdun-Nabi</u> Daniel Abdun-Nabi	Director	March 5, 2010
<u>/s/Zsolt Harsanyi, Ph.D.</u> Zsolt Harsanyi, Ph.D.	Director	March 5, 2010
<u>/s/Jerome M. Hauer</u> Jerome M. Hauer	Director	March 5, 2010
<u>/s/Ronald B. Richard</u> Ronald B. Richard	Director	March 5, 2010
<u>/s/Louis W. Sullivan, M.D.</u> Louis W. Sullivan, M.D.	Director	March 5, 2010
<u>/s/Dr. Sue Bailey</u> Dr. Sue Bailey	Director	March 5, 2010

## Exhibit Index

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-139190 filed on December 8, 2006)
3.2	Amended and Restated By-laws of the Registrant, as amended (Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2007 (File No. 001-33137))
4.1	Specimen Certificate Evidencing Shares of Common Stock (Incorporated by reference to Exhibit 4.1 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on October 20, 2006)
4.2	Registration Rights Agreement, dated September 22, 2006, among the Registrant and the entities listed on Schedule 1 thereto (Incorporated by reference to Exhibit 4.3 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
4.3	Rights Agreement, dated November 14, 2006, between the Registrant and American Stock Transfer & Trust Company (Incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-8 (File No. 333-139190) filed on December 8, 2006)
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 (Incorporated by reference to Exhibit 9.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.1*	Employee Stock Option Plan, as amended and restated (Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.2*	Form of Director Stock Option Agreement (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.3*	Amended and Restated 2006 Stock Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009 (File No. 001-33137))
10.4*	Form of Incentive Stock Option Agreement under 2006 Stock Incentive Plan (Incorporated by reference to Exhibit 10.4 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on October 30, 2006)
10.5*	Form of Nonstatutory Stock Option Agreement under 2006 Stock Incentive Plan (Incorporated by reference to Exhibit 10.5 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on October 30, 2006)
10.6#	Form of Restricted Stock Unit Agreement under Amended and Restated 2006 Stock Incentive Plan
10.7#	Annual Bonus Plan for Executive Officers
10.8*	Director Compensation Program (Incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2007 (File No. 001-33137))
10.9† *	Severance Plan and Termination Protection Program (Incorporated by reference to Exhibit 10.6 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on October 20, 2006)
10.10*	Election of Fuad El-Hibri to Participate in the Severance Plan and Termination Protection Program (Incorporated by reference to Exhibit 10.35 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
10.11	Form of Indemnity Agreement (Incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.12†	Contract No. HHSO100200700037C, dated September 25, 2007, between Emergent BioDefense Operations Lansing Inc., and the Department of Health and Human Services (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 (File No. 001-33137))
10.13†	Contract No. HHSO100200800091C between the Department of Health and Human Services and Emergent BioDefense Operations Lansing Inc. dated September 30, 2008 (Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (File No. 001-33137))
10.14†	Filling Services Agreement, dated March 18, 2002, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Hollister-Stier Laboratories LLC, as amended (Incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.15	Amendment No. 5 to the Filling Services Agreement, effective May 14, 2007 between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Hollister-Stier Laboratories LLC (Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137))
10.16†	Exclusive Commercial License of Technology by and among Oxford-Emergent Tuberculosis Consortium Limited, Emergent Product Development UK Limited, Emergent BioSolutions Inc. and Isis Innovation Limited dated July 18, 2008 (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (File No. 001-33137))
10.17†	



Product Supply Agreement, dated June 12, 2006, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics, Inc. (Incorporated by reference to Exhibit 10.34 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on October 20, 2006)

<b>Exhibit Number</b>	<b>Description</b>
10.18#††	Amendment No. 1 to Product Supply Agreement, effective December 19, 2006, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics Inc.
10.19#	Amendment No. 2 to Product Supply Agreement, effective June 25, 2007, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics Inc.
10.20#††	Amendment No. 3 to Product Supply Agreement, effective August 29, 2007, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics Inc.
10.21#	Amendment No. 4 to Product Supply Agreement, effective November 17, 2009, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics Inc.
10.22#††	First Addendum to Product Supply Agreement, effective September 1, 2009, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics Inc.
10.23†	Agreement, dated June 16, 2005, between the Free State of Bavaria and Emergent Product Development UK, formerly ViVacs GmbH (Incorporated by reference to Exhibit 10.43 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on October 20, 2006)
10.24†	License Agreement between U.S. Army Medical Research Institute of Infectious Diseases and the Registrant dated October 7, 2003 (Incorporated by reference to Exhibit 10.21 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 001-33137), filed on March 6, 2009)
10.25	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 (Incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.26#	Consulting Services Agreement, effective April 1, 2009, between the Registrant and The Hauer Group
10.27	Services Agreement, dated August 1, 2006, between East West Resources Corporation and the Registrant (Incorporated by reference to Exhibit 10.36 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
10.28	Amended and Restated Marketing Agreement entered into on February 10, 2009 between Emergent BioDefense Operations Lansing Inc. and Intergen N.V. (Incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 001-33137), filed on March 6, 2009)
10.29	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 (Incorporated by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.30	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 (Incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.31	Lease Agreement, dated May 10, 2007, among Slough Estates (Winnerish) Limited, Emergent Product Development UK Limited and the Registrant (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137))
10.32	Lease Agreement, dated June 27, 2006, between Brandywine Research LLC and the Registrant (Incorporated by reference to Exhibit 10.24 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
10.33	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 (Incorporated by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.34	Promissory Note, dated October 14, 2004, from Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., to Mercantile Potomac Bank (Incorporated by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.35	Loan Agreement, dated October 15, 2004, between Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., and the Department of Business and Economic Development (Incorporated by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.36	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 (Incorporated by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.37	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 (Incorporated by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.38	

- 10.39 Loan Agreement, dated April 25, 2006, among the Registrant, Emergent Frederick LLC and HSBC Realty Credit Corporation (USA) (Incorporated by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
- 10.39 Promissory Note, dated April 25, 2006, from Emergent Frederick LLC to HSBC Realty Credit Corporation (USA) (Incorporated by reference to Exhibit 10.39 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
- 10.40# Loan Agreement, dated December 30, 2009, among the Registrant, Emergent BioDefense Operations Lansing Inc., and HSBC Realty Credit Corporation (USA)
- 10.41# Promissory Note, dated December 30, 2009, from Emergent BioDefense Operations Lansing Inc. to HSBC Realty Credit Corporation (USA)

<b>Exhibit Number</b>	<b>Description</b>
10.42	Loan Agreement, dated June 8, 2007, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Fifth Third Bank (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137))
10.43	Amendment to Loan Agreement between Emergent BioDefense Operations Lansing, Inc. and Fifth Third Bank dated August 15, 2008 (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (File No. 001-33137))
10.44	Revolving Credit Note made by Emergent BioDefense Operations Lansing, Inc. in favor of Fifth Third Bank dated August 15, 2008 (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (File No. 001-33137))
10.45*	Employment Agreement dated September 21, 2007, between Emergent Product Development UK Ltd and Dr. Stephen Lockhart (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated December 10, 2009 (File No. 001-33137))
21.1#	Subsidiaries of the Registrant
23.1#	Consent of Independent Registered Public Accounting Firm
31.1#	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)
31.2#	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)
32.1 #	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2 #	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
#	Filed herewith
†	Confidential treatment granted by the Securities and Exchange Commission as to certain portions. Confidential materials omitted and filed separately with the Securities and Exchange Commission.
††	Confidential treatment requested by the Securities and Exchange Commission as to certain portions. Confidential materials omitted and filed separately with the Securities and Exchange Commission.
*	Management contract or compensatory plan or arrangement filed herewith in response to Item 15(a) of Form 10-K.



EMERGENT BIOSOLUTIONS INC.

Restricted Stock Unit Agreement

**Amended and Restated 2006 Stock Incentive Plan**

This Restricted Stock Unit Agreement is made as of the Agreement Date between Emergent BioSolutions Inc. (the “Company”), a Delaware corporation, and the Participant.

**I. Agreement Date**

Date: \_\_\_\_\_

**II. Participant Information**

Participant: \_\_\_\_\_

Participant Address: \_\_\_\_\_

**III. Grant Information**

Grant Date: \_\_\_\_\_

Number: \_\_\_\_\_ restricted stock units

**IV. Vesting Table**

Vesting Date	Percentage of RSUs that Vest
anniversary of Grant Date	
anniversary of Grant Date	
anniversary of Grant Date	
anniversary of Grant Date	

This Agreement includes this cover page and the following Exhibit, which is expressly incorporated by reference in its entirety herein:

Exhibit A – General Terms and Conditions

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Agreement Date.

EMERGENT BIOSOLUTIONS INC.

PARTICIPANT

\_\_\_\_\_  
Name:  
Title:

\_\_\_\_\_  
Name:

EMERGENT BIOSOLUTIONS INC.

Restricted Stock Unit Agreement

**Exhibit A – General Terms and Conditions**

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Grant of RSUs. In consideration of services rendered to the Company by the Participant, the Company has granted to the Participant, subject to the terms and conditions set forth in this Agreement and in the Company's Amended and Restated 2006 Stock Incentive Plan (the "Plan"), an award of Restricted Stock Units (the "RSUs"), representing the number of RSUs set forth on the cover page of this Agreement. The RSUs entitle the Participant to receive, upon and subject to the vesting of the RSUs (as described in Section 2 below), one share of common stock, \$0.001 par value per share, of the Company (the "Common Stock") for each RSU that vests. The shares of Common Stock that are issuable upon vesting of the RSUs are referred to in this Agreement as the "Shares".

2. Vesting of RSUs and Issuance of Shares.

(a) General. Subject to the other provisions of this Section 2, the RSUs shall vest in accordance with the vesting table set forth on the cover page of this Agreement (the "Vesting Table"). Any fractional RSU resulting from the application of the percentages in the Vesting Table shall be rounded to the nearest whole number of RSUs. Subject to Section 4, as soon as administratively practicable after each vesting date shown in the Vesting Table (the "Vesting Dates"), the Company will issue to the Participant, in certificated or uncertificated form, such number of Shares as is equal to the number of RSUs that vested on such Vesting Date. In no event shall the Shares be issued to the Participant later than 90 days after the Vesting Date.

(b) Employment Termination. Except as set forth in Section 2(c) below, upon the termination of the Participant's employment with the Company for any reason, all unvested RSUs shall be automatically forfeited as of such employment termination. For purposes of this Agreement, employment with the Company shall include employment with a parent or subsidiary of the Company, or any successor to the Company.

(c) Change in Control Event. Upon a Change in Control Event (as defined in the Plan), the RSUs shall be treated in the manner provided in Section 10(b)(iii)(B) of the Plan.

3. Dividends. At the time of the issuance of Shares to the Participant pursuant to Section 2, the Company shall also pay to the Participant an amount of cash equal to the aggregate amount of all dividends paid by the Company, between the Grant Date and the issuance of such Shares, with respect to the number of Shares so issued to the Participant.

4. Withholding Taxes. The Participant must satisfy all applicable federal, state, and local and other income and employment tax withholding obligations associated with the grant, vesting and settlement of the RSUs before the Company will issue any Shares hereunder following a Vesting Date. The withholding obligation may be satisfied by any method permitted under the Plan.

5. Restrictions on Transfer. Neither the RSUs, nor any interest therein (including the right to receive dividend payments in accordance with Section 3), may be transferred by the Participant except to the extent specifically permitted in Section 11(a) of the Plan.

6. Provisions of the Plan. This Agreement is subject to the provisions of the Plan. The Participant acknowledges receipt of the Plan, along with the Prospectus relating to the Plan.

7. Section 409A. This Agreement is intended to comply with Section 409A of the Internal Revenue Code of 1986, as amended, and the guidance issued thereunder ("Section 409A") and shall be interpreted and construed consistently therewith. In no event shall either the Participant or the Company have the right to accelerate or defer delivery of the Shares to a date or event other than as set forth in this Agreement except to the extent specifically permitted or required by Section 409A. In the event that the Participant is a "specified employee" within the meaning of Section 409A and the Shares are to be delivered pursuant to this Agreement in connection with the termination of the Participant's employment, the delivery of the Shares and any dividends payable under Section 3 in connection with such delivery shall be delayed until the date that is six months and one day following the date of the Participant's termination of employment. Solely for purposes of determining when the Shares (and any dividends payable under Section 3) may be delivered in connection with the Participant's termination of employment, such termination of employment must constitute a "separation from service" within the meaning of Section 409A.

8. Miscellaneous.

(a) No Rights to Employment. The Participant acknowledges and agrees that the grant of the RSUs and their vesting pursuant to Section 2 do not constitute an express or implied promise of continued employment for the vesting period, or for any period.

(b) Entire Agreement. This Agreement and the Plan constitute the entire agreement between the parties, and supersede all prior agreements and understandings, relating to the subject matter of this Agreement; provided that any separate employment or severance plan or agreement between the Company and the Participant that includes terms relating to the acceleration of vesting of equity awards shall not be superseded by this Agreement.

(c) Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflict of law principles.

(d) Interpretation. The interpretation and construction of any terms or conditions of the Plan or this Agreement by the Compensation Committee shall be final and conclusive.





**ANNUAL BONUS PLAN FOR EXECUTIVE OFFICERS  
EMERGENT BIOSOLUTIONS INC.  
ADOPTED FEBRUARY 25, 2010**

Annual bonuses to be awarded to the chief executive officer (“CEO”), president and chief operating officer (“President”) and other executive officers of Emergent BioSolutions Inc. (“Company”) shall be made in accordance with the terms and conditions of the Company’s Annual Bonus Plan for Executive Officers (“Plan”). The Plan is not the exclusive vehicle for awarding bonuses to executive officers. The Committee may also make discretionary bonuses outside of the framework of the Plan. The Plan is not contained in a formal written document; however, a summary of the material terms of the Plan is set forth below.

Each participant’s annual bonus under the Plan will be determined by multiplying the participant’s annual base salary by (a) a target bonus percentage for such participant, (b) a corporate factor ranging from 0 to 1.5, based on the Company’s achievement of corporate goals determined by the Committee, and (c) an individual factor ranging from 0 to 1.5, based on an evaluation of each participant’s performance of day-to-day responsibilities, behavioral competencies, and participation in the achievement of the corporate goals and achievement of individual goals determined by the Committee. The Plan will apply to bonuses that are earned in 2010 and are payable in 2011, and for each year thereafter.

The Company’s corporate goals will be set at the beginning of each year by the Committee, based on recommendations by the Company’s management. At the end of the year, the Committee will determine the corporate factor based on a quantitative and qualitative review of performance. Each participant’s individual goals will be set at the beginning of each year. A year-end evaluation of each participant may weight individual goals, and the applicable individual factor will be determined based on a quantitative and qualitative review of performance. The Committee’s chair will recommend the CEO’s individual goals and individual factor to the Committee, the CEO will recommend the President’s individual goals and individual factor to the Committee, and the CEO and President will recommend the individual goals and individual factor of each other Plan participant to the Committee. All individual goals and individual factors will be set by the Committee.



**CONFIDENTIAL MATERIALS OMITTED AND FILED SEPERATLY WITH THE SECURITIES AND EXCHANGE COMMISSION.  
 ASTERISK DENOTE OMISSIONS.**

*Talecris*  
 BIOTHERAPEUTICS

**AMENDMENT NO. 1 to the  
 PRODUCT SUPPLY AGREEMENT**

This Amendment No. 1 (the "Amendment"), effective as of December 19, 2006 (the "Effective Date"), is entered into by and between Talecris Biotherapeutics, Inc., headquartered at 79 T.W. Alexander Drive, 4101 Research Commons, P.O. Box 110526, Research Triangle Park, North Carolina 27709 ("Talecris") and Emergent Product Development Gaithersburg Inc. ("Emergent" collectively, with Talecris, the "Parties," and each individually, a "Party"). All terms not defined herein shall have the meaning set forth in the Master Agreement (as defined below).

WHEREAS, the Parties entered into that certain Product Supply Agreement, effective as of June 12, 2006 (the "Master Agreement");

WHEREAS the Parties desire to amend and restate the Master Agreement as set forth herein to modify the requirements for stability testing of the AIG Product and the payment schedule for the testing; and;

WHEREAS, except as specifically modified herein, the Master Agreement, as amended by this Amendment, shall remain in full force and effect.

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

1. Amendment of Article 7.02, Fees Associated With Certain Pre-Commercial Activities, Subpart B Stability Testing, Article 7.02, Subpart B of the Master Agreement is hereby deleted in its entirety and replaced with:

"Emergent shall pay Talecris following Talecris' performance of stability testing, (approved stability protocol attached) and related activities in accordance with Exhibit L, attached hereto and incorporated by reference into the Master Agreement.

2. Applicable Law. This Amendment, and the amended Agreement, shall be governed by the laws of the State of Delaware without regard to any conflicts of law principles.

IN WITNESS WHEREOF, the Parties have executed this Amendment as set forth below.

**TALECRIS BIOTHERAPEUTICS, INC.  
 DEVELOPMENT  
 GAITHERSBURG INC.**

**EMERGENT PRODUCT**

By: /s/ Mary J Kuhn

By: /s/ M J Langford

Name: Mary J. Kuhn

Name: Michael J. Langford

Title: SVP Operations

Title: President

## Exhibit L

### Payment schedule for Amended Stability Protocol

**Purpose:** Emergent has requested a greater amount of stability testing than is stated in the original contract. The original contract required 15 test points to be done on three product lots. The price was \$[\*\*] dollars to perform the 45-test point study. The stability protocol now requested requires 24 test points to be done on 3 AIG product lots. This increases the total number of test points to 72 test points which is an increase of 27 test points. The approved protocol is follows.

#### Calculations:

Talecris Cost to perform the requested protocol (3 lots)	\$ [**]
# of Test Points per lot	24
# of Test Points for 3 lots	72
Cost per test Point	\$ [**]
# of test points of original Stability schedule per lot	15
# of test points for 3 lots	45
Original agreement for Stability Protocol	\$ [**]
Additional test points required	27
Cost to perform additional test points	\$ [**]
Total revised Charge to Emergent for study	\$ [**]

**Invoice Timing:** The study is requested for 5 years. Talecris will invoice Emergent for 20% of the total price each year when the annual report is issued.



**Talecris**  
BIOTHERAPEUTICS

**AMENDMENT NO. 2 to the**

**Product Supply Agreement**

This Amendment No. 2 (the "Amendment"), effective as of June 25, 2007 (the "Effective Date"), is entered into by and between Talecris Biotherapeutics, Inc., headquartered at 79 T.W. Alexander Drive, 4101 Research Commons, P.O. Box 110526, Research Triangle Park, North Carolina 27709 ("Talecris") and Emergent Product Development Gaithersburg Inc. with an address of 300 Professional Drive, Gaithersburg, MD 20879 ("Emergent" collectively, with Talecris, the "Parties," and each individually, a "Party"). All terms not defined herein shall have the meaning set forth in the Master Agreement (as defined below).

WHEREAS, the Parties entered into that certain Product Supply Agreement, effective as of June 12, 2006 (the "Master Agreement");

WHEREAS the Parties desire to amend and restate the Master Agreement as set forth herein; and;

WHEREAS, except as specifically modified herein, the Master Agreement, as amended by this Amendment, shall remain in full force and effect.

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

1. Amendment of Section 7.06, Method of Invoicing for Orders. Section 7.06 of the Master Agreement is hereby amended by adding the following sentence;

"Provided however, Talecris may, at its discretion, invoice Emergent for an Order based solely on; (a) Talecris' determination that Product release testing has been met, and (b) the required samples were provided to Emergent by Talecris, within three (3) days of packaging of product by Talecris, and (c) Emergent has not provided identity test results to Talecris, within thirty-five (35) days of packaging of the product."

2. Amendment of Section 7.07, Remittance of Payments. Section 7.07 of the Master Agreement is hereby amended by deleting section 7.07 entirely and replacing with the following:

a. Timing. 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. Notwithstanding the foregoing, if Emergent has not made arrangements for and obtained the delivery of (i) Finished Product within thirty (30) days of receipt of an invoice into either (a) the custody of Emergent's carrier, or (b) onsite storage at Talecris Facilities subject to any applicable Fees mutually agreed to by the Parties, or (ii) product which meets the Product Specifications (subject to Section 7.06), payment shall be due and payable by Emergent promptly.

b. Method of Payment. 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."

3. Applicable Law. This Amendment, and the amended Agreement, shall be governed by the laws of the State of New York, without regard to any conflicts of law principles.

IN WITNESS WHEREOF, the Parties have executed this Amendment as set forth below.

TALECRIS BIOTHERAPEUTICS, INC.  
DEVELOPMENT GAITHERSBURG INC

EMERGENT PRODUCT

By: /s/ Mary J. Kuhn

By: /s/ M J Langford

Name: Mary J. Kuhn

Title: SVP Operations

Name: Michael Langford

Title: President





**CONFIDENTIAL MATERIALS OMITTED AND FILED SEPERATLY WITH THE SECURITIES AND EXCHANGE COMMISSION.  
ASTERISK DENOTE OMISSIONS.**

***Talecris***  
BIOTHERAPEUTICS

**AMENDMENT NO. 3 to the  
PRODUCT SUPPLY AGREEMENT**

This Amendment No. 3 (the "Amendment"), is entered into by and between Talecris Biotherapeutics, Inc., headquartered at 79 T.W. Alexander Drive, 4101 Research Commons, P.O. Box 110526, Research Triangle Park, North Carolina 27709 ("Talecris") and Emergent Product Development Gaithersburg Inc. with an address of 300 Professional Drive, Gaithersburg, MD 20879 ("Emergent" collectively, with Talecris, the "Parties," and each individually, a "Party"). All terms not defined herein shall have the meaning set forth in the Master Agreement (as defined below).

WHEREAS, the Parties entered into that certain Product Supply Agreement, effective as of June 12, 2006 (the "Original Agreement");

WHEREAS, the Parties entered into certain Amendments to the Original Agreement (Amendment No. 1 effective as of December 19, 2006 and Amendment No. 2 effective as of June 25, 2007) (the Original Agreement, as amended by Amendment Nos. 1 and 2, the "Agreement");

WHEREAS the Parties desire to amend the Agreement for the purpose of amending Exhibit L; and

WHEREAS, except as specifically modified herein, the Agreement, as amended by this Amendment, shall remain in full force and effect.

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

1. Effective Date. The effective date of this Amendment No. 3 shall be August 29, 2007 (the "Effective Date").
2. Amendment of Exhibit L of the Agreement (Term). As of the Effective Date, Exhibit L1 attached to Amendment No. 3 will be added to Exhibit L of the Agreement.
3. Applicable Law. This Amendment No. 3, and the amended Agreement, shall be governed by the laws of the State of New York, without regard to any conflicts of law principles.
4. Counterparts. This Amendment No. 3 may be executed in any number of counterparts, each of which shall be an original, but all of which, when taken together, shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed this Amendment No. 3 as of the Effective Date.

**TALECRIS BIOTHERAPEUTICS, INC.**

**EMERGENT PRODUCT DEVELOPMENT  
GAITHERSBURG INC**

By: /s/ Mary J. Kuhn

By: /s/ M J Langford

Name: Mary J. Kuhn

Name: Michael Langford

Title: SVP Operations

Title: President

## Exhibit L1

Payment Schedule for Amended Stability Program to include Stability testing specifically for the Fraction II + III Paste and the Sterile Filling Bulk

Purpose: Emergent has requested a greater amount of stability testing than is stated in the original contract. The original contract provided no provisions for the stability studies listed below.

The stability protocol is attached.

Pricing: Total of \$[\*\*] to implement and complete the attached stability protocol.

Invoicing: The total payment of \$[\*\*] should be made in three equal payments when the respective reports are issued. Each payment will be for \$[\*\*].

- A. 90 day final report on sterile filling bulk stability
- B. 12 month interim report on II + III Paste stability
- C. 24 month final report on II + III Paste stability

Payment of each invoice will be due 30 days after invoicing.

*Talecris*  
BIOTHERAPEUTICS

Amendment No. 4 to  
**Product Supply Agreement**

This Amendment No. 4 (“*Amendment*”), effective as of November 17, 2009 (“*Effective Date*”), is entered into by and between **Talecris Biotherapeutics, Inc.** (“*Talecris*”), with a business address of 79 T.W. Alexander Drive, 4101 Research Commons, P.O. Box 110526, Research Triangle Park, North Carolina 27709, and **Emergent Product Development Gaithersburg Inc.** (“*Emergent*”), with a business address of 300 Professional Drive, Gaithersburg, Maryland 20879. For the purposes of this Amendment, Emergent and Talecris shall each be deemed a “*Party*” and together the “*Parties*”.

WHEREAS, the Parties entered into that certain Product Supply Agreement, dated June 12, 2006 (as subsequently amended by the Parties, the “*Original Agreement*”); and

WHEREAS, the “Commercial Term” of the Original Agreement (as defined therein) is scheduled to begin on January 1, 2010 (pursuant to Section 10.01(b) thereof); and

WHEREAS, the parties wish to amend the Original Agreement to delay the commencement of the Commercial Term in order to allow the Parties to evaluate and discuss potential paths forward in light of the approaching Commercial Term;

NOW THEREFORE, for good and valuable consideration, including the promises set forth herein, the parties agree as follows:

- 1) Recitals; Capitalized Terms; Controlling Effect. The foregoing recitals are deemed to be true and accurate in all respects and are hereby incorporated into this Amendment by reference. Capitalized terms used herein shall have the same meanings ascribed to them in the Original Agreement unless otherwise expressly defined herein. In the event of any conflict between the terms of the Original Agreement and the terms of this Amendment, the terms of this Amendment shall govern and control. The Original Agreement and this Amendment are collectively referred to hereinafter as the “**Agreement**”.
- 2) Amendment to Original Agreement.
  - a) Pre-Commercial Term: Section 10.1(a) (Pre-Commercial Term) of the Original Agreement is hereby amended as follows: Delete all instances of “January 1, 2010” and replace them with “March 1, 2010”.
  - b) Commercial Term: Section 10.1(b) (Commercial Term) of the Original Agreement is hereby amended as follows: Delete “January 1, 2010” and replace it with “March 1, 2010”.
- 3) Incorporation of Prior Agreements. The Agreement contains the entire understanding of the Parties hereto with respect to the subject matter hereof, and no prior or other written or oral agreement or undertaking pertaining to any such matter shall be effective for any purpose.
- 4) Governing Law. This Amendment, 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 conflict of law principles.

5) Interpretation; Full Force And Effect; Counterparts. The Amendment shall be construed reasonably to carry out its intent without presumption against or in favor of either Party. The Original Agreement shall remain in full force and effect in accordance with its original terms and provisions, except as expressly modified by the terms of this Amendment. This Amendment may be executed by the Parties hereto in one or more counterparts, all of which shall be valid and binding on the party or parties executing them and all counterparts shall constitute one and the same document for all purposes. Each Party represents and warrants that this Amendment has been duly authorized, executed and delivered by or on behalf of such Party.

IN WITNESS WHEREOF, Emergent and Talecris have entered into this Amendment as of the Effective Date.

**Emergent Product Development  
Gaithersburg Inc.**

By: /s/Kyle Keese  
Name: Kyle Keese  
Title: SVP Mfg Ops  
Date: 12/3/09

**Talecris Biotherapeutics, Inc.**

By: /s/ Mary J. Kuhn  
Name: Mary J Kuhn  
Title: EVP Operations  
Date: 11/23/09

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<p><b>CONFIDENTIAL MATERIALS OMITTED AND FILED SEPERATLY WITH THE SECURITIES AND EXCHANGE COMMISSION.</b>  <b>ASTERISK DENOTE OMISSIONS.</b></p>
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*Talecris*  
 BIOTHERAPEUTICS

**First Addendum to  
 Product Supply Agreement**

This First Addendum (this "**Addendum**") to that certain Product Supply Agreement dated June 12, 2006, as previously amended on December 19, 2006, June 25, 2007, and August 29, 2007, and as hereinafter amended from time to time (the "**Agreement**"), is entered into as of August 15, 2009, and effective as of September 1, 2009 (the "**Addendum Effective Date**"), by and between Talecris Biotherapeutics, Inc., ("**Talecris**") headquartered at 79 T.W. Alexander Drive, 4101 Research Commons, P.O. Box 110526, Research Triangle Park, North Carolina 27709 and Emergent Product Development Gaithersburg Inc. ("**Emergent**"), a Delaware corporation having offices at 300 Professional Drive, Gaithersburg, MD 20879. For the purposes of this Addendum, Emergent and Talecris shall each be deemed a "**Party**" and together the "**Parties**." All terms not defined herein shall have the meaning set forth in the Agreement.

WHEREAS, the Parties entered into the Agreement in order to, among other things, allow for Talecris to receive, process, and manufacture human plasma, plasma intermediates, final container products (such as Finished Product) and other materials (collectively, the "**Materials**") on behalf of Emergent or its agents; and

WHEREAS, the Parties have determined that, in addition to the rights and obligations set forth in the Agreement, Talecris has in the past and will continue to store, warehouse, and hold Materials on behalf of Emergent or its agents as more fully described herein.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1) Business Terms.

- a. Services. Upon the terms and conditions set forth below or as otherwise required by the Agreement or the applicable Material Storage Schedule, Emergent hereby engages Talecris to store Materials as specified in a Material Storage Schedule executed hereunder (the "**Services**"). Talecris reserves the right, upon reasonable advance notice to Emergent, to refuse to accept or accumulate Materials on behalf of Emergent that are in addition to those Materials specified in any executed Material Storage Schedule; provided, however, that the foregoing right of refusal shall not apply to any Materials set forth in any mutually-agreed rolling forecast of Materials to be manufactured by Talecris.
- b. Standards and Conditions.
  - i. General. Unless otherwise specified in the applicable Material Storage Schedule or required by applicable law, cGMP (if applicable) or good practices for the industry, Talecris shall use Commercially Reasonable Efforts in the performance of Services.
  - ii. Storage Conditions. Unless otherwise agreed in writing, Talecris will store, otherwise handle and maintain the Materials using the same degree of care, under the same conditions, and in the same facilities as Talecris does for its own products and materials of a similar nature. Talecris shall perform the Services in accordance with its then-current standard operating procedures, plans, protocols, and business judgment. Talecris reserves the right to transfer Materials to other Talecris-owned or controlled locations or facilities as reasonably necessary to ensure the continued proper storage and handling of such Materials; provided, however, that Talecris shall not make any transfer to any location or facility not owned or controlled by Talecris without providing Emergent with at least thirty (30) days' written notice and allowing Emergent a reasonable opportunity to inspect or otherwise obtain relevant information regarding the suitability of such alternate facility. Talecris shall be solely responsible for any breaches of this Addendum or the Agreement by a third party storage agent or transporter, except in the event that such third party is engaged under emergency circumstances in an attempt to prevent or limit loss of, or damage to, the Materials pursuant to section 1(b)(iv) below.
  - iii. Location. Talecris will store Materials at any of its facilities in Clayton, NC and/or Benson, NC (the "**Facilities**"), unless otherwise agreed between the Parties. Regardless of location, Talecris shall monitor and record temperature as required



by applicable laws and regulations, and in any event, shall do so in the same manner it addresses such data concerning its own products and materials in the same Facilities.

- iv. Emergency Situations. In the event of an emergency or other urgent situation that Talecris, in its best judgment, believes may lead to damage or risk to the Materials, Talecris reserves the right to transfer some or all Materials to an alternative location or storage facility. To the extent reasonably possible and prudent, Talecris will transfer the Materials in the same manner and with the same frequency that Talecris transfers its own products and materials of a similar nature that are being stored at the same Facility and in proximity to the Materials. In the event that Talecris utilizes the facilities of any third party in connection with such transfer or eventual storage, Talecris shall use commercially reasonable efforts to require such third party to be bound to Talecris by obligations with respect to the storage and handling of Materials that are substantially similar to those contained in this Addendum. Talecris shall notify Emergent promptly of any transfer made pursuant to this subsection, and use its best commercial efforts to notify Emergent in advance. In the event that Emergent requires or prohibits moving, modifying or storing the Materials in a manner against the recommendations or instructions of Talecris, Emergent shall, except for the gross negligence or intentional misconduct of Talecris or its agents, be solely responsible for any harm or damage to the Materials incurred thereafter with respect to the Materials stored or moved against the recommendations or instructions of Talecris. In the event that Emergent determines, in its sole discretion, to re-transfer or otherwise assume control of or responsibility for such transferred Materials, Talecris shall reasonably cooperate with and assist Emergent in completing such activities.
- v. Performance. With respect to certain Materials which may be specified above, the Parties agree as follows:
1. Final Product: Storage of Final Product by Talecris will not be deemed "Services" under this Addendum until such Final Product is released by Talecris to Emergent pursuant to the terms of the Agreement and Talecris issues the corresponding invoice to Emergent for the product Processing Fee.
  2. Plasma and Paste: Storage of plasma and paste by Talecris will not be deemed "Services" until after Talecris has held such Materials for three (3) months.
- vi. Removal of Materials. Talecris may, upon six (6) months' prior written notice to Emergent, require removal of Materials from the Facility; provided, however, that Talecris shall not require such removal as a result of any agreement to store a third party's products or materials of a similar nature at the Facility. Notwithstanding the foregoing, in the event that Emergent reasonably determines that it cannot locate a suitable storage facility for the Materials or otherwise arrange for alternate storage within such six-month period, Talecris shall use commercially reasonable efforts to cooperate with Emergent and will extend the storage period at the Facility until such time as Emergent secures alternate storage for the Materials. In no event shall the foregoing storage period extend beyond twelve (12) months from the original removal notice date. Emergent may, upon ten (10) business days' prior written notice, require delivery (in accordance with the terms of the Agreement) of all or any part of the Materials from the Facility; provided, however, that the Parties acknowledge and agree that Talecris shall be allowed additional time to prepare Materials for delivery if reasonably necessary and upon notice to Emergent of the reasons for any such delay. Upon request by either Party to deliver Materials to Emergent, Talecris shall cooperate with Emergent with respect to removal of Materials and, at Emergent's expense, follow Emergent's reasonable written instructions for such removal. Talecris reserves the right to withhold such cooperation until all amounts due and payable by Emergent to Talecris (except to the extent disputed in good faith) in connection with this Addendum are paid to Talecris.
- c. Delivery Conditions. Delivery of Materials will be made to Emergent or such other Persons approved by Emergent in writing at such time(s) as reasonably determined by Emergent.
- d. Compensation / Payment Terms
- i. Subject to the terms of any Material Storage Schedule, Emergent agrees to pay, and Talecris agrees to accept payment, for all Services properly rendered during the term of this Addendum. Payment and prices shall be as set forth on the applicable Material Storage Schedule. Talecris shall be solely responsible for its expenses related to this Addendum unless otherwise expressly agreed by Emergent in writing. Such expenses are not to exceed \$175 per pallet per month without the express written preapproval of Emergent, which will not be unreasonably withheld. Notwithstanding the foregoing, Emergent shall be responsible for any reasonable expenses necessarily incurred by Talecris in connection with preservation, relocation or transfer of Materials as described in Paragraph 1) b) iv) above.
  - ii. Emergent shall pay all undisputed amounts to Talecris net-thirty (30) days from the date of an invoice showing in reasonable detail the basis for such invoice, and the amount currently due, as set forth herein. All invoices shall be submitted in writing to Emergent as follows:

Manner and Location for Payments: U.S. first-class mail to primary business address

Accounting Codes (Must be noted on all invoices for payment to be processed):



G/L No.:

Cost Center:

Project Code (if applicable):

Address for Invoices to Emergent:

Emergent BioSolutions Inc.  
2273 Research Blvd., Suite 400  
Rockville, MD 20850  
Attn: Accounts Payable

- e. Risk of Loss / Insurance. Risk of loss for Materials stored by Talecris pursuant to this Addendum shall be governed by the terms of the Agreement. Notwithstanding the foregoing, the parties acknowledge and agree that except to the extent caused by Talecris' gross negligence, intentional misconduct or material breach of this Addendum, upon the release of Finished Product to Emergent, all risk of loss for such Finished Product shall be borne by Emergent, even if such Finished Product is stored by Talecris pursuant to this Addendum.
- f. Warranty & Disclaimer. TALECRIS IS NOT A COMMERCIAL STORAGE FACILITY OR STORAGE SERVICES PROVIDER. ACCORDINGLY, WITH RESPECT TO THE SERVICES COVERED BY THIS ADDENDUM, TALECRIS MAKES NO WARRANTY OF MERCHANTABILITY, SATISFACTORY QUALITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE.
- g. Limitation of Liability; Damages. Talecris shall have no liability hereunder to the extent arising from negligent acts or omissions. Except to the extent caused by Talecris' gross negligence, intentional misconduct or material breach of this Addendum, Talecris' aggregate liability for any losses, injury or damages to persons, Materials, or properties arising out of or in connection with this Addendum or for any other claims, losses, costs or damages whatsoever arising out of or resulting from or in any way related to the Services or this Addendum from any causes or causes, arising under any theory of law, shall be limited to the total amount of compensation actually received by Talecris from Emergent under this Addendum during the preceding eighteen (18) months. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY IN CONTRACT OR IN TORT FOR INCIDENTAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS ARISING HEREUNDER, EXCEPT TO THE EXTENT OF GROSS NEGLIGENCE OR WILLFUL MISCONDUCT ON THE PART OF SUCH PARTY, ITS EMPLOYEES, AGENTS, REPRESENTATIVES, OR SUBCONTRACTORS. The liability of each of Talecris and Purchaser to the other for any damages arising under this Agreement shall not exceed five million U.S. Dollars (\$5,000,000).
- h. Insurance. Emergent, at its own expense, shall submit to Talecris prior to commencement of the Services under this Addendum, certificates of insurance evidencing that such insurance was obtained. Deductible amounts under the foregoing policies shall be paid by Emergent. Without limiting the insurance requirements under the Agreement, Emergent shall maintain at least \$2,000,000 in transit insurance and \$15,000,000 in property insurance, covering Materials (including finished products) stored at Talecris' facility, pursuant to this Addendum. For the duration of this contract and for three years thereafter, Emergent and Talecris shall maintain General Liability and Products Liability insurance or self-insurance with minimum limits of \$5,000,000 per occurrence. Certificates of insurance providing evidence of such coverage shall be provided to each respective Party when the contract is signed. Talecris shall reasonably cooperate with Emergent for the scheduling and completion of any reasonable or necessary insurance-related loss-control inspections of the Facility, which inspections shall not occur more frequently than once per year during the Term of this Addendum. The findings of any such inspections shall be used solely to establish Emergent's insurance rates and terms, and shall not be understood or used to obligate Talecris to modify its conduct or policies, or otherwise to take or refrain from taking any specific action.
- i. Nonexclusive. Notwithstanding the terms of the Agreement (including Section 2.04 (Exclusivity)), and notwithstanding the terms of the Exclusivity Agreement referenced in such Section, the parties agree that except with respect to removal of Materials as specified in Paragraph 1) b) vi) above and storage commitments described in Paragraph 1) a), the Services governed by this Addendum shall be nonexclusive with respect to each Party. Nothing shall prohibit Talecris from providing similar or identical services to other entities, and nothing shall prohibit Emergent from obtaining similar or identical services from other entities.
- 2) Confidentiality. This Addendum, and the rights and obligations arising hereunder, shall be deemed confidential information subject to Article 13 (Confidentiality) of the Agreement.

- 3) Applicable Law. This Addendum and any 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.
- 4) Effect. Except as expressly set forth herein, this Addendum shall not limit or otherwise affect any term or provision of the Agreement, and all other terms and conditions of the Agreement shall survive and shall remain in full force and effect. This Addendum is hereby incorporated into and made a part of the Agreement. Specifically, but without limitation, the following sections of the Agreement shall, except as modified herein, apply to this Addendum: 15.11 (Force Majeure), 15.13 (Limitation of Damages).
- 5) Term and Termination.
- a. Term. Unless earlier terminated as set forth below, this Addendum shall be in effect from the Addendum Effective Date until the termination or expiration of the Agreement, or until terminated in accordance with the terms of this Section.
- b. Termination.
- i. This Addendum may be terminated by mutual written agreement by the Parties.
- ii. Either Party may terminate this Addendum for a material breach hereof by the other Party by providing thirty (30) days written notice to the other Party, unless such breach is cured within such thirty (30) day period.
- iii. Except for removal of Materials as provided in Paragraph 1) b) vi), either Party may terminate this Addendum without cause by providing ninety (90) days written notice to the other Party.
- iv. Termination of this Addendum shall not affect the binding nature or effectiveness of the Agreement. Breach of this Addendum by either Party shall not be deemed a breach of the Agreement.
- 6) Counterparts. This Addendum may be executed via facsimile signature and in any number of counterparts with the same effect as if all of the Parties had signed the same document. All fully executed counterparts shall be construed together and shall constitute one and the same Agreement.

IN WITNESS WHEREOF, the Parties have executed this Addendum as of the Addendum Effective Date,

**TALECRIS BIOTHERAPEUTICS, INC.**

By: /s/ Craig Farquharson  
Name: Craig Farquharson  
Title: Senior Director Global Supply Chain

**EMERGENT PRODUCT DEVELOPMENT  
GAITHERSBURG INC.**

By: /s/ Kyle Keese  
Name: Kyle Keese  
Title: SVP Manufacturing OPS

**SCHEDULE A-1**

**MATERIAL STORAGE SCHEDULE #1**

This Schedule 1-A is made as part of the "FIRST ADDENDUM TO PRODUCT SUPPLY AGREEMENT" (the "**Addendum**"), by and between Talecris Biotherapeutics, Inc., ("**Talecris**") and Emergent Product Development Gaithersburg Inc. ("**Emergent**"), and made subject to the terms and conditions of the Product Supply Agreement referenced therein (the "Agreement").

Pricing: Talecris shall perform the Services at the prices set forth herein, with respect to the Materials specified in this Material Storage Schedule. Talecris reserves the right to increase such prices after the first anniversary of this Material Storage Schedule by a percent not to exceed the greater of (a) five percent (5%) or (b) CP-M. "CPI-M" shall mean a percentage equal to the unadjusted percentage change for the previous twelve-month period (ending four months prior to the date of Talecris' price increase) published in the Consumer Price Index for Medical Care, by the U.S. Department of Labor, Bureau of Labor Statistics.

**Terms for Material Storage Services Already Provided through August 2009:**

<b>Material</b>	<b>AIG Lot #</b>	<b>Cost per Pallet per Month</b>	<b>Number of Pallets</b>	<b>Storage Start-Date</b>	<b>Total Charges</b>
Final Container	[**]	\$ [**]	2	March 2007	\$ [**]
Final Container	[**]	\$ [**]	2	June 2008	\$ [**]
Final Container	[**]	\$ [**]	2	June 2009	\$ [**]

IN WITNESS WHEREOF, the Parties have executed this Schedule as of the date of the last signature below:

**TALECRIS BIOTHERAPEUTICS, INC.**

By: /s/ Craig Farquharson  
 Name: Craig Farquharson  
 Title: Senior Director Global Supply Chain  
 Date: August 27, 2009

**EMERGENT PRODUCT DEVELOPMENT  
 GAITHERSBURG INC.**

By: /s/ Kyle Keese  
 Name: Kyle Keese  
 Title: SVP Manufacturing OPS  
 Date: 1 Sep 09



## CONSULTING SERVICES AGREEMENT

This Consulting Services Agreement (“Agreement”) is made effective the 1<sup>st</sup> day of April 2009 (the “Effective Date”), by and between **Emergent BioSolutions Inc.** (“Emergent”), a Delaware corporation, with offices at 2273 Research Boulevard, Suite 400, Rockville, Maryland 20850, and **The Hauer Group** (“Consultant”), located at 7850 Southdown Road, Alexandria, VA 22308, Emergent and Consultant are sometimes hereinafter referred to in the singular as “Party” and collectively as the “Parties”.

WHEREAS, Emergent and its Affiliates (as hereinafter defined) are engaged in the development, production, and commercialization of biopharmaceutical products;

WHEREAS, Consultant is engaged in providing consulting services as described in this Agreement; and

WHEREAS, Emergent and, as applicable, its Affiliates (as hereinafter defined) desires to engage Consultant to provide certain services from time to time as mutually agreed by the Parties, and Consultant desires to be so engaged.

NOW, THEREFORE, in consideration of the mutual covenants herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be bound, agree as follows:

1. **Services.** Consultant agrees to provide certain services from time to time as requested by Emergent or any of Emergent’s Affiliates as specified in Exhibit A attached hereto (the “Services”). In the event that Consultant is requested or required to perform work for the Services beyond that which is specifically set forth in Exhibit A, any such additional services and an appropriate adjustment to the amounts owed shall be negotiated in good faith and the Parties shall amend this Agreement to reflect such additional services and any additional or modified terms in respect thereof prior to the provision of such new services.

2. **Payment for Services.** Emergent shall compensate Consultant for Services in accordance with the payment terms set forth in Exhibit A, and all invoices for payment shall be submitted to Emergent as detailed therein. Notwithstanding the foregoing, for any invoice to be processed and paid, such invoice must refer to the applicable Emergent Accounting Code designated in Exhibit A. If Consultant bills on an hourly basis, all invoices must be accompanied by a timesheet detailing the hours worked and signed by both Consultant and Emergent. Payment of Consultant’s invoices shall be in full compensation for the Services performed by Consultant unless expressly agreed otherwise in writing by the Parties. Invoices shall be payable within thirty (30) days of receipt by Emergent. Representatives of Consultant performing Services hereunder will not receive employee benefits from Emergent, including but not limited to paid vacation, sick leave or any insurance benefits, even if such representatives are physically situated at Emergent’s offices.

3. **Expenses.** Emergent shall pay for or reimburse Consultant for out-of-pocket expenses reasonably incurred in the performance of Services hereunder; provided, however, that expenses shall only be paid for or reimbursed if in compliance with Emergent’s Travel Policy (as previously provided to Consultant or as updated by Emergent from time-to-time and disclosed to Consultant), or otherwise expressly authorized in Exhibit A or as agreed in writing by the Parties. Consultant shall submit monthly invoices detailing expenses incurred during the immediately preceding month by appropriate category and shall provide supporting documentation as is acceptable to Emergent in its reasonable discretion. It is agreed that expenses shall not be marked up. This Agreement relates to the provision of Services only. In the event Consultant deems it necessary to purchase equipment, goods, software or other tangible or intangible property for which it will seek reimbursement from Emergent, no such purchase shall be made and Emergent shall not be responsible for reimbursement to Consultant unless Consultant has received Emergent’s express, prior written authorization.

4. **Confidentiality of Information.** Consultant acknowledges that this Agreement creates a confidential relationship between Consultant and Emergent. Consultant and Emergent acknowledge that, in order to perform the Services, it will be necessary for Emergent to allow Consultant to have access to certain commercially valuable, proprietary, and confidential information of Emergent and its Affiliates. Consultant agrees to keep confidential and not, without the prior written consent of Emergent, to publish, disclose to any third party or use (except for purposes of performance under this Agreement) any confidential information, in either written, electronic or oral form whether or not marked as “confidential” or “proprietary,” and without limitation, any and all information relating to the business, prospective business, technical processes, finances, price lists, customer lists, information relating to the licensing or approval of any of the products, business plans, business prospects, employee information, information regarding facilities, operations and financial condition and results, inventions, improvements, trade secrets, know-how, processes, formulas, methods, assays, data, instrumentation, sales and marketing information, standard operating procedures, clinical trials, clinical trial data, clinical specimens, study protocols, investigators’ brochures and instructions or other



scientific or technical information, and any documentation and materials specifically developed or prepared for or by Consultant in performance of Services under this Agreement (collectively, the "Confidential Information"). The obligations of this paragraph do not pertain to information which is generally known or hereafter becomes generally known to the public through no fault of Consultant or is disclosed by Consultant with the written approval of Emergent. Consultant shall return all such Confidential Information to Emergent upon completion of the Services hereunder or upon Emergent's request.

If Confidential Information is sought by any source, including any governmental organization, Consultant must immediately notify Emergent of such request and refuse to divulge any such information at least until a representative of Emergent is permitted to address the situation and either consents to the disclosure or has the opportunity to engage legal means to protect the disclosure of such information.

5. **Authorized Contacts.** With respect to the performance of Services, Consultant shall report to the Authorized Contact(s) identified in Exhibit A (or such other person that may hold the same position at a later date) or such other person(s) as such Authorized Contact(s) may designate from time to time in writing.

6. **Deliverables and Reports.** Consultant shall make weekly reports and such other reports as Emergent or its Affiliates may from time to time request.

7. **Ownership of Work.** All right, title, and interest in and to all data, information, documents, materials and inventions relating to or arising out of the Services shall belong to and be the property of Emergent. Consultant agrees, without further payment by Emergent, to make any assignments and execute all documents necessary to effect Emergent's title thereto in all countries of the world. Furthermore, all documents and materials prepared by Consultant in the performance of its duties hereunder will constitute works-made-for-hire and shall belong to and be the exclusive property of Emergent and shall be surrendered by Consultant to Emergent upon request. Consultant hereby assigns to Emergent all rights that Consultant may have to data, information, documents, materials and inventions referred to in this paragraph. The above assignments and surrender shall be made once payment in full has been made by Emergent to Consultant as detailed in Exhibit A.

#### 8. **Term and Termination.**

This Agreement shall become effective as of the Effective Date set forth above and shall continue in effect for one (1) year thereafter or until the Agreement otherwise terminates under this Section 8 (the "Term"); provided, however, that in the event that any requested Services are then outstanding, the Term shall be automatically extended until such Services are completed or are terminated by either Party.

This Agreement shall terminate upon the expiration of the Term or the first to occur of the following events:

- (i) On the date Emergent provides Consultant with written notice (setting out with particularity) that this Agreement is being terminated for "cause." For purposes of this Agreement, Consultant shall be deemed terminated for cause if Emergent terminates Consultant after:
  - (a) shall have committed any act or acts of embezzlement, theft or fraud against Emergent;
  - (b) shall have been convicted of a felony or any crime involving moral turpitude, whether or not related to the Services;
  - (c) shall have committed any act or acts of negligence or willful misconduct; or
  - (d) shall have committed a breach of the representations, warranties or covenants contained in Sections 4, 7, 9, 11 or 16 herein.
- (ii) On the date either Party terminates the Agreement for convenience on not less than ten (10) days' prior written notice.

Upon termination of this Agreement, Emergent shall have no further liability other than for payment in accordance with the terms of this Agreement for Services provided prior to the termination date. If this Agreement is terminated by Emergent under Section 8(b)(i)(d), in addition to any other rights or remedies available at law or in equity, Consultant will surrender any claim for payment under the Agreement and will refund any payments received under this Agreement.

The provisions of Sections 2, 3, 4, 7, 8, 11 (with respect to 11(d), only for twelve months following termination or expiration), 13, 14, 15, 16 and 18 shall survive the expiration or termination of this Agreement for any reason.

**9. Representations and Warranties. Consultant represents and warrants that:**

(a) the Services performed hereunder will be performed in a competent, diligent and workmanlike manner consistent with the expected industry standards of professional conduct;

(b) Consultant and any of Consultant's personnel performing Services will perform the Services for Emergent hereunder and have been advised of the restrictions and obligations set forth in this Agreement, including without limitation, the requirements of confidentiality (Section 4), compliance with laws (Section 11) and non-solicitation (Section 16); and

(c) Consultant has full power to enter into and fully perform this Agreement and has the full and unrestricted right to disclose to Emergent any information Consultant makes available to Emergent under this Agreement.

**10. Relationship of Parties.** With respect to the subject matter of this Agreement, the Parties are and remain independent contractors. This Agreement shall not be deemed to create an employer/employee relationship, joint venture, partnership, association, or agency between the Parties. Consultant is not authorized to incur or create any obligation express or implied on behalf of Emergent or to bind Emergent in any manner whatsoever.

**11. Compliance with Laws.** In performing the Services, Consultant shall comply with all applicable existing and future laws, rules and regulations. Consultant covenants and agrees to perform its duties and responsibilities under this Agreement in accordance with the highest standards of ethical business conduct and will not engage in any acts or activities that are illegal or that may adversely affect or reflect upon the business, integrity or goodwill of Emergent. Without limiting the generality of the foregoing, Consultant represents, warrants and agrees that:

(a) Consultant will comply with all applicable existing and future treaties, laws, regulations, including but not limited to those governing employment practices (including those governing employee recruiting and hiring), anti-bribery, anti-corruption and anti-gratuities laws or other similar laws.

(b) Consultant will comply with all Emergent stated policies and procedures applicable to consultants operating at Emergent's offices, including without limitation, those governing safety, health, harassment, and discrimination.

(c) Consultant will prohibit its staff from involvement with the payment or giving of anything of value, either directly or indirectly, to an official of any government, political party or official thereof, any candidate for foreign political office, or any official of an international organization, for the purpose of influencing an act or decision in its official capacity, or inducing that official to use his/her influence with any government, to assist Emergent in obtaining or retaining business for or with, or directing business to, any person, or for obtaining an improper advantage. Consultant agrees to comply with the provisions of this Section 11(c) and take no action that it believes might cause Emergent to be in violation of international, federal, state or local laws or regulations, or Emergent's policies and procedures, as well as any action by Consultant that might be construed as a violation of international, federal, state or local law, or Emergent's policies and procedures.

(d) At such times as may be requested by Emergent, Consultant will certify to Emergent in writing that: (1) Consultant understands the requirements of applicable anti-corruption or anti-bribery laws that apply to the Consultant and the Agreement; (2) Consultant believes it has complied with all applicable laws, regulations, and Emergent's policies and procedures; (3) Consultant has, specifically, not made, offered to give or agreed to give anything of value, directly or indirectly, whether in cash or in kind to or for the benefit of any government official or "foreign official," political party or official thereof, or candidate for political office, or official of an international organization, for the purpose of carrying out this Agreement; (4) Consultant does not know or have any reason to believe that any employee, agent, representative or other person retained by Consultant has violated any of the foregoing undertakings; and (5) Consultant will immediately advise Emergent if Consultant should learn or have reason to believe that there has been a violation of any of the foregoing undertakings.

(e) Emergent BioSolutions Inc. ("EBSI"), is a publicly traded company on the New York Stock Exchange. Consultant acknowledges the laws and regulations prohibiting "insider trading," including the purchase or sale of securities of a company while in the possession of material information that has not been generally disclosed in the marketplace. Consultant represents that it may have access to certain material nonpublic information of EBSI, Emergent, and/or their Affiliates and will not engage in insider trading or disclose such information to any third parties.

**12. Definition of Affiliate.** "Affiliate" shall mean any direct or indirect, current or future subsidiary of a Party, or any other entity which is controlled by a Party or which controls a Party. The term "control" as used herein shall mean possession, directly or indirectly of at least fifty percent (50%) of the voting equity of another entity (or other comparable interest for an entity other than a corporation), or the power to direct or cause the direction of the management or policies of an entity whether through ownership of securities, by contract or otherwise.

13. **Export Control Technology.** The Parties acknowledge that any products, software, and technical information provided under this Agreement may be subject to the United States, United Kingdom and other export laws and regulations and any use or transfer of such products, software and technical information may require authorization under those regulations. The parties agree that they will not use, distribute, transfer, view or transmit such products, software or technical information (even if incorporated in other products) except in compliance with the applicable export regulations. The parties also agree to sign written assurances and other export related documents as may be required for compliance with applicable export regulations.

14. **Indemnification and Limitation of Liability.** Consultant shall hold harmless and indemnify Emergent, its employees, agents and representatives, from and against any and all suits, demands, losses, damages, judgments, claims, costs, (including reasonable attorneys' fees and costs) or other liability (including, without limitation personal injury or death) (collectively "Liability"), to the extent that such Liability arises from or is related to the performance of Services under this Agreement or the negligence, act or omission of Consultant or any of her agents or representatives.

15. **Dispute Resolution.** All disputes or claims arising under this Agreement that cannot be resolved by the Parties shall be submitted to non-binding mediation for a period of thirty days, which may be extended by written agreement of the Parties. If such dispute is not resolved amicably through mediation or otherwise within the specified period, either Party may pursue remedies available to it at law or in equity, subject to the terms of this Agreement.

16. **Non-Solicitation.** Consultant agrees that, during the term of this Agreement, and for a period of twelve (12) consecutive months after termination of such Agreement, Consultant will not knowingly (i) directly induce or attempt to induce or otherwise counsel, advise, solicit or encourage any employee to leave the employ of Emergent or accept employment with Consultant or any other person or entity, (ii) directly induce or attempt to induce or otherwise counsel, advise, solicit or encourage any person who at the time of such inducement, counseling, advice, solicitation or encouragement had left the employ of Emergent within the previous six (6) months to accept employment with any person or entity besides Emergent or (iii) solicit, interfere with, or endeavor to cause any customer, client, or business partner of Emergent to cease or reduce its relationship with Emergent or induce or attempt to induce any such customer, client, or business partner to breach any agreement that such customer, client, or business partner may have with Emergent.

17. **Force Majeure.** Neither Party shall be liable for delay or failure in the performance of any of its obligations under this Agreement if and to the extent such delay or failure is due to circumstances beyond the reasonable control of such Party, including but not limited to fires, floods, explosions, accidents, acts of God, war, riot, strike, lockout or other concerted acts of workers, acts of government and shortages of materials. The Party claiming force majeure shall use its commercially reasonable efforts to eliminate or prevent the cause so as to continue performing its obligations under this Agreement. During such time that the event of force majeure causes such a delay or failure of performance, this Agreement and the Parties' obligations and responsibilities under it shall be deemed suspended until the event of force majeure ceases.

18. **Miscellaneous Provisions.**

(a) **Governing Law and Jurisdiction.** This Agreement and its interpretation shall be governed by the laws of the State of Delaware without reference to its conflict of law or choice of law provisions.

(b) **Non-Waiver.** No delay by or omission of any Party in exercising any right, power, privilege, or remedy shall impair such right, power, privilege, or remedy or be construed as a waiver thereof.

(c) **Remedies.** The rights and remedies provided in this Agreement are cumulative and are not exclusive of other rights or remedies provided by law.

(d) **Taxes.** Consultant shall be fully responsible for payment of all income taxes, social security taxes, and for any other taxes or payment which may be due and owing by Consultant as the result of fees or amounts paid to it by Emergent under this Agreement, and Consultant shall indemnify and hold harmless Emergent from and against any such tax or payment.

(e) **Notices.** Any notice hereunder shall be given by first class mail, express mail, or facsimile (followed by confirmation), addressed to the Parties at the addresses given in the preamble of this Agreement, or to such other address as a Party may later designate in writing to the other Party. Notice given by Consultant to Emergent shall be directed to the President of EBSI; provided, however that Notice of any legal action, claim or other legal matter given by Consultant to Emergent shall be directed to the Legal Department of EBSI.

(f) **Use of Name.** Neither Party shall use the name, tradename or trademark of the other Party in a press release, advertising, publicity or promotional activity without the prior written consent of the other Party.

(g) **Severability.** In the event that any section or any part of a section of this Agreement should be declared void, invalid, or unenforceable by any court of law, for any reason, such a determination shall not render void,

invalid, or unenforceable any other section or any part of any other section of this Agreement and the remainder of this Agreement shall remain in full force and effect.

(h) Headings. Headings and titles of parts and sections are for convenience only and have no interpretative significance.

(i) Successors. This Agreement and the covenants hereof are binding on the Parties and their respective heirs, executors, representatives, trustees, permitted assigns, and successors in interest.

(j) Assignability. This Agreement may not be assigned by Consultant without the prior, express written consent of Emergent. This Agreement may not be assigned by Emergent without the prior, express written consent of Consultant; provided, however, that this Agreement may, without Consultant's written consent, be assigned and transferred to any Affiliate of Emergent upon such assignee assuming Emergent's obligations hereunder, in which event Consultant agrees to continue to perform the duties and obligations according to the terms hereof to or for such assignee or transferee of this Agreement.

(k) Counterparts. This Agreement may be signed in two identical copies, each of which shall be deemed to be an original copy, and a facsimile copy shall constitute a legally binding, enforceable document.

(l) Integration. This Agreement, along with the corresponding Exhibit, constitutes the entire agreement of the Parties, supersedes all prior discussions, negotiations and understandings verbal and written, if any, and may only be amended or modified by a written agreement signed by both Parties. In the event of a conflict between the terms of this Agreement and the terms of any Exhibit or attachment hereto, proposal, quotation or any Consultant documentation, the terms of this Agreement shall prevail.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date set forth in the preamble.

**Emergent BioSolutions Inc.**

**The Hauer Group**

By: /s/Daniel J. Abdun-Nabi

By: /s/Jerome M. Hauer

By: Daniel J. Abdun-Nabi

By: Jerome M. Hauer

Title: President & Chief Operating Officer

Title: Chief Executive Officer

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## EXHIBIT A

### Scope of Work and Compensation

The Services shall include, without limitation, the following:

**Contract Objective:**

To assist Emergent BioSolutions in enhancing its corporate image and visibility, and expanding opportunities for BioThrax and its pipeline product candidates.

**Summary of expected activities:**

Strategic Support of Corporate Objectives

- Consultation to CEO, President and Senior Management on corporate strategic issues
- General consultation and directed project support to including but not limited to:
  - Relationship management with targeted media outlets and reporters;
  - Introductions to relevant government officials;
  - Introductions to potential commercial partners.
- Other projects as may be directed by the CEO, President or Senior Management

Domestic and International Marketing

- Target audiences:
  - o KOLs, decision makers or senior officials in health or emergency planning departments or agencies of foreign governments
  - o Senior leadership and decision makers in first responder communities in major cities in the US, including individuals such as the Chief of Police, Fire Chiefs, Head of HAZMAT units, Head of Counter-Terrorism Units, Head of EMS/Paramedics Units (both independent and those attached to fire departments) and other groups who may believe themselves to be at high risk for exposure to anthrax
  - o Senior leadership and decision makers in health departments in major cities in the US to help support decision makers in the first responder communities when making a medical decision surrounding the use of BioThrax
- Specific activities targeted at these markets including the following:
  - o Contacting individuals within the target audiences, prioritizing and arranging initial meetings/teleconferences with senior leadership and decision makers within the first responder and health department communities
  - o As needed and appropriate, attend meetings with Emergent executives when meeting with these key officials
  - o Provide input and information on senior leadership and decision makers prior to meetings to ensure meeting materials and messaging are appropriate and tailored for the audience
  - o 2 to 4 meetings will be arranged per month with target audiences.

Place of Services: All Services shall be performed on-site at Emergent's offices (as specified in the preamble to this Agreement), unless otherwise directed by Emergent. Consultant agrees that he may be required to travel domestically and internationally to satisfy the scope of work and identified objectives.

Authorized Contact(s): Daniel J. Abdun-Nabi  
 President  
 Emergent BioSolutions Inc.  
 2773 Research Blvd., Suite 400  
 Rockville, MD 20850  
 Phone: (301) 795-1830  
 AbdunNabiD@ebsi.com

Compensation: In exchange for the services provided above, Emergent shall compensate Consultant at the rate of \$15,000.00 per month.

Agreement Start Date: April 1, 2009

Travel: The Parties agree that Consultant may book his own air travel for reservations in business class longer than 2.5 hours of flight time. All other travel will be pursuant to Emergent's Travel Policy (as provided to Consultant and updated by Emergent from time-to-time in writing) and all necessary lodging, rental car and other travel reservations shall be made by an Emergent Administrative Assistant and MAY NOT be made directly by Consultant. Emergent will not reimburse for expenses that fail to comply with this process. If airline, lodging, rental car or other travel reservations are to be made in connection with Services provided under this Agreement, it is Consultant's responsibility to contact the Emergent Authorized Contact to request that such arrangements be made.

Emergent Accounting Code: \_\_\_\_\_ (Must be noted on all invoices in order for payment to be processed.)

## LOAN AGREEMENT

THIS LOAN AGREEMENT (this “**Agreement**”) is dated as of December 30, 2009, by and among **EMERGENT BIODEFENSE OPERATIONS LANSING INC.**, formerly known as BioPort Corporation, a Michigan corporation, which maintains its chief executive office at 3500 N. Martin Luther King, Jr. Blvd., Building One, Third Floor, Lansing, Michigan 48906 (the “**Borrower**”), and **EMERGENT BIOSOLUTIONS INC.**, a Delaware corporation (the “**Guarantor**”) and **HSBC REALTY CREDIT CORPORATION (USA)**, a Delaware corporation (the “**Bank**”).

WHEREAS, Borrower previously executed and delivered to Bank that certain Promissory Note dated as of June 29, 2007, in the original principal amount of \$30,000,000.00 (the “**Original Note**”). The Original Note was issued pursuant to a Loan Agreement dated as of June 29, 2007, among Borrower, Guarantor and Bank (the “**Original Loan Agreement**”) and was secured by among other things that certain Guaranty dated as of June 29, 2007 from Guarantor in favor of Bank (the “**Original Guaranty**”).

WHEREAS, Bank and Borrower have agreed to restructure the debt evidenced by the Original Note pursuant to that certain Promissory Note (Term Loan) dated as of the date hereof from Borrower payable to the order of Bank (the “**Note**”, which term shall include any and all amendments, restatements and modifications thereto) evidencing that certain loan in the original principal amount of \$22,750,000.00 (hereinafter referred to as the “**Loan**”).

WHEREAS, the Loan will be of benefit to the Guarantor and the Guarantor desires to induce the Bank to make the Loan by guaranteeing the payment of the Loan pursuant to that certain Guaranty dated as of the date hereof (the “**Guaranty**”, as also defined below);

WHEREAS, the Bank is willing to make the Loan to the Borrower upon the terms and subject to the conditions hereinafter set forth;

WHEREAS, in connection with the execution and delivery of the Note, the Guaranty, this Loan Agreement and the other documents related to the Loan, the Original Note, the Original Guaranty and the Original Loan Agreement and any other documents previously delivered to the Bank in connection with the Original Note shall be hereby terminated and replaced with the Note, the Guaranty, this Loan Agreement and the other documents related to the Loan dated as of the date hereof.

NOW, THEREFORE, in consideration of the foregoing and of the agreements, covenants and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows;

### SECTION 1. DEFINITIONS

As used herein, the following terms, when initial capital letters are used, shall have the respective meanings set forth below. In addition, all terms defined in the applicable Uniform Commercial Code shall have the meanings given therein unless otherwise defined herein.

1.01 Defined Terms. As used in this Agreement, the following terms shall have the following meanings, unless the context otherwise requires:

“**Affiliate**” shall mean (a) any entity in which the Borrower legally or beneficially owns or holds, directly or indirectly, any capital stock, membership interest or other equity interest; (b) any person or entity that is a partner in or member of the Borrower or a partnership or limited liability company in which the Borrower is a partner, (c) any person that is a director, officer, member, stockholder (legally or beneficially) or other affiliate of any of the foregoing or of the Borrower; and (d) any person or entity that directly or indirectly controls, is under the control of, or is under common control with, the Borrower, including, without limitation, any person or entity that directly or indirectly has the right or power to direct the management or policies of the Borrower and any person or entity whose management or policies the Borrower directly or indirectly has the right or power to direct.

“**Collateral**” shall mean the real property and personal property of the Borrower upon which the Borrower has granted a lien to the Bank pursuant to the Security Agreement and the Mortgage.

“**Developed Campus**” shall mean the portion of the Property located in Ingham County, Michigan.

“**Environmental Laws**” shall mean all federal, state and local laws, whether now or hereafter enacted, and as amended from time to time, relating to pollution or protection of the environment and the handling of Hazardous Materials; including, without limitation, laws relating to emissions, discharges, releases or threatened releases of Hazardous Materials into the environment (including, without limitation, ambient air, surface water, ground water or land), or otherwise relating to the manufacture, generation, production, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials, and any and all regulations, codes, plans, orders, decrees, judgments, injunctions, notices or demand letters issued, entered, promulgated or approved thereunder.

“**ERISA**” shall mean the Employee Retirement Income Security Act of 1974, as amended from time to time, and any successor legislation, and all regulations, codes, orders, decrees, judgments, injunctions, notices or demand letters issued, entered, promulgated or approved thereunder.

“**Event of Default**” shall mean any of the events specified in Section 6 hereof, provided that any requirement for the giving of notice, the lapse of time, or both has been satisfied.

“**Fifth Third Loan**” shall mean that certain financing arrangement with Fifth Third Bank related to (i) that certain revolving credit loan in the amount of \$15,000,000.00 evidenced by that certain Amended and Restated Loan Agreement dated June 11, 2007 by and between the Borrower and Fifth Third Bank, a Michigan banking corporation and that certain Amended and Restated Security Agreement dated June 11, 2007 by and between the Borrower and Fifth Third Bank, (ii) that certain term loan in the amount of \$2,400,000 evidenced by that certain term note dated August 10, 2004 by and between the Borrower and Fifth Third Bank, and (iii) various other notes, security agreements, loan agreements and credit documents related to such revolving loan and term loan (collectively, the “**Fifth Third Loan Documents**”), which are secured, respectively, by a lien on the proceeds of Government Contracts (as defined in the Fifth Third Loan Documents) and a lien on certain computer software known as the “The Enterprise Resource Planning System”

“**GAAP**” shall mean generally accepted accounting principles as in effect from time to time.

“**Guaranty**” shall mean the Guaranty, of even date herewith, made and executed by the Guarantor for the benefit of the Bank, as amended, supplemented, restated or modified from time to time.

“**Hazardous Materials**” shall mean any (i) hazardous, regulated and/or toxic chemicals, materials, substances or wastes occurring in the air, water, soil or ground water or noise in, on, over or under the Property or the improvements thereon, as defined by the Comprehensive Environmental Response, Compensation, and Liability Act (Superfund or CERCLA), and the Superfund Amendments and the Reauthorization Act of 1986 (SARA), 42 U.S.C. § 9601 et seq., the Emergency Planning and Community Right-to-Know Act, 42 U.S.C. § 11001 et seq., the Resource Conservation and Recovery Act (the Solid Waste Disposal Act or RCRA), 42 U.S.C. § 6901 et seq., the Federal Water Pollution Control Act, (CWA), 33 U.S.C. § 1251 et seq., the Clean Air Act (CAA), 42 U.S.C. § 7401 et seq., the Hazardous Materials Transportation Act, 49 U.S.C. § 1801 et seq., the Federal Water Pollution Control Act, 33 U.S.C. § 1251 et seq., the Safe Drinking Water Act, 42 U.S.C. § 300 et seq. and the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C.A. §136 et seq., the Uranium Mill Tailings Radiation Control Act, 42 U.S.C. § 7901 et seq., the Occupational Safety and Health Act, 29 U.S.C. § 655 et seq., the National Environmental Policy Act, 42 U.S.C. § 4321 et seq., and the Noise Control Act, 42 U.S.C. § 4901 et seq., or comparable state statutes, as each such statute may be amended from time to time, and/or as defined in regulations promulgated thereunder; (ii) oil, petroleum products, and their by-products; (iii) any substance, the presence of which is prohibited or controlled by any other applicable federal or state or local laws, regulations, statutes or ordinances now in force or hereafter enacted relating to waste disposal or environmental protection with respect to hazardous, toxic or other substances generated, produced, leaked, released, spilled or disposed of at or from the Property; (iv) any other substance which by law requires special handling in its collection, storage, treatment or disposal including, but not limited to, asbestos or asbestos-containing material in any form that could be friable, polychlorinated biphenyls (PCBs), was formaldehyde foam insulation and lead-based paints, but not including small quantities of such materials present on the Property in retail containers, (v) Microbial Matter or infectious substances; (vi) underground or above-ground storage tanks, whether empty or containing any substance, the presence of which on the Property is prohibited by any federal, state or local authority; (vii) any substance that requires special handling; and (viii) any other material or substance now or in the future defined as a “hazardous substance,” “hazardous material,” hazardous waste,” “toxic substance,” “toxic pollutant,” “contaminant,” or “pollutant” within the meaning of any Environmental Laws. “Microbial Matter” shall mean the presence of fungi or bacterial matter (which is not normally found in the environment) which reproduces through the release of spores or the splitting of cells, including, but not limited to, mold, mildew and viruses, whether or not such Microbial Matter is living. Notwithstanding the foregoing, ordinary and necessary quantities of any materials or substances used by Borrower in the normal course of its research or manufacturing operations in compliance with Environmental Laws shall not be “Hazardous Materials” and shall not be or cause a breach of this Agreement.

“**Intercreditor Agreement**” shall mean that certain Intercreditor Agreement between Fifth Third Bank and the Bank, consented to by the Borrower and the Guarantor, dated as of August 25, 2006.

“**Lien**” shall mean any mortgage, pledge, assignment, security interest, encumbrance, hypothecation, lien, encroachment, reservation, right of way, easement, covenant, condition, restriction or charge of any kind (including any conditional sale or other title retention agreement, any financing lease having substantially the same economic effect as any of the foregoing, and the filing or authorization of, any financing statement under the Uniform Commercial Code or comparable law of any jurisdiction).

“**Loan**” means the loan of even date herewith from the Bank to the Borrower evidenced by the Note.

“**Loan Documents**” shall mean the Note, this Agreement, the Guaranty, the Mortgage, the Security Agreement and any other agreement or document referred to herein or now or hereafter delivered and executed by the Borrower and/or the Guarantor and/or the Bank in connection with the Loan contemplated hereby, together with any and all revisions, amendments, restatements and modifications to, replacements of and substitutions for, any of the foregoing.

“**Mortgage**” shall mean, collectively, the Mortgage dated as of August 25, 2006, as amended by the First Amendment to Mortgage dated as of June 29, 2007, and as further amended by the Second Amendment to Mortgage dated of even date herewith,

made and executed by the Borrower for the benefit of the Bank, as further amended, supplemented, restated or modified from time to time, to secure the Note, which Mortgage creates a first lien on the Property.

“**Note**” shall mean that certain Promissory Note (Term Note) of even date herewith in the principal amount of \$22,750,000.00, executed by the Borrower, payable to Lender and consented to by the Guarantor to evidence the Loan, as amended, supplemented, restated, replaced or modified from time to time.

“**Permitted Liens**” shall mean with respect to the Borrower and the Collateral: (a) Liens, if any, for taxes, front foot benefit charges, assessments and other charges enumerated in Section 1.03(a) of the Mortgage, not yet due or payable; (b) applicable building and zoning laws and regulations; (c) any mechanic’s, artisan’s, materialman’s, landlord’s, carrier’s or other like Lien arising in the ordinary course of business with respect to obligations which are not due; (d) any and all municipal and public utility easements of record; (e) any Lien arising out of a judgment, order or award with respect to which the Borrower shall in good faith be prosecuting diligently an appeal or proceeding for review and with respect to which there shall be in effect a subsisting stay of execution pending such appeal or proceeding for review, provided appropriate reserves therefor are established by the Borrower in accordance with GAAP and provided such Lien is subordinate to any security interest of the Bank in the property encumbered by such Lien; (f) any deposit of funds made in the ordinary course of business to secure obligations of the Borrower under worker’s compensation laws, unemployment insurance laws or similar legislation, to secure public or statutory obligations of the Borrower, to secure surety, appeal or customs bonds in proceedings to which the Borrower is a party, or to secure the Borrower’s performance in connection with bids, tenders, contracts (other than contracts for the payment of money), leases or subleases made by the Borrower in the ordinary course of business; (g) any Lien set forth in the Title Insurance Policy Nos. TRO-06-100063 and TRO-06-100064 issued by Lawyers Title Insurance Corporation, as updated; (h) any lease, sublease or agreement for occupancy or use of any part of the Property, so long as those leases, subleases or agreements are subordinate to the Mortgage and have been approved by the Bank; (i) a Lien in favor of the Bank; (j) such other matters affecting title to the Property as are approved by the Bank in writing; (k) subject to the terms of the Intercreditor Agreement, Liens arising out of or related to the Fifth Third Loan, including any extension, amendment or renewal of such Liens; (l) the liens listed on Schedule 1.1 attached hereto; (m) any liens related to licenses and use agreements in favor of such vendors or licensors related to intellectual property used by Borrower; and (n) any restrictions and encumbrances imposed on Borrower pursuant to intellectual property out-licensed by Borrower to third parties in the ordinary course of Borrower’s business.

“**Property**” shall mean that certain real property, improvements, fixtures and other real property interests owned by the Borrower and located in Clinton County and Ingham County, Michigan, as more particularly described in the Mortgage.

“**Security Agreement**” shall mean the Security Agreement of even date herewith from the Borrower to the Bank granting to the Bank a Lien on the personal property of the Borrower (excepting the collateral for the Fifth Third Loan as permitted pursuant to the Intercreditor Agreement), as amended, supplemented, restated or modified from time to time.

“**Subsidiary**” shall mean any corporation, partnership or limited liability company, at least a majority of the outstanding equity interests or voting stock of which, now or in the future, is owned or controlled by the Borrower, directly or indirectly, or through one or more intermediaries.

“**UCC Collateral**” shall mean all of the personal property of the Borrower upon which the Borrower has granted the Bank a lien pursuant to the Security Agreement.

1.02 Accounting Terms. As used in this Agreement and any of the other Loan Documents, as well as in any certificate, report or other document made or delivered pursuant to or in connection with this Agreement, accounting terms not defined herein and accounting terms only partly defined herein shall have the respective meanings given to them under GAAP.

1.03 Use of Defined Terms. All terms defined in this Agreement shall have the defined meanings when used in any of the other Loan Documents or in any certificate, report or other document made or delivered pursuant to or in connection with this Agreement, unless the context shall require otherwise.

## SECTION 2. LOAN AND REPAYMENT

2.01 Loan. Subject to the terms and conditions set forth herein and in the Note, the Bank agrees to lend to the Borrower, in a single advance to be made on or about the date hereof, the sum of Twenty-Two Million Seven Hundred Fifty Thousand and No/100 Dollars (\$22,750,000.00).

2.02 Repayment of Loan. The Borrower shall repay the Loan, together with interest accrued thereon, in accordance with the terms of the Note.

2.03 Fee. As of the date hereof, the Borrower has paid to the Bank an aggregate commitment fee in the amount of \$45,500.00 (the “**Commitment Fee**”) for the Loan.

## SECTION 3. CONDITIONS PRECEDENT

The Bank shall have no obligation to make any advance under the Loan Documents unless and until:

3.01 Delivery of Documents. The Borrower shall have delivered to the Bank the following:



(i) certificates of good standing for the Borrower certified by the Secretary of State, or other appropriate governmental authority, of the state of incorporation of the Borrower and of the Borrower's principal place of business;

(ii) a certificate of the Borrower, certifying as to attached copies of its certificate of incorporation and bylaws and the resolutions of its Board of Directors authorizing the execution, delivery and performance of the Loan Documents to which the Borrower is a party, the borrowings by the Borrower hereunder, and the granting of the Liens contemplated by the Loan Documents, and certifying as to the incumbency, authority and signatures of the officers of the Borrower authorized to sign the Loan Documents on behalf of the Borrower;

(iii) a certificate of good standing for the Guarantor certified by the Secretary of State, or other appropriate governmental authority, of the state of incorporation of the Guarantor and of the Guarantor's principal place of business;

(iv) a certificate of the Guarantor, certifying as to attached copies of its certificate of incorporation and bylaws and the resolutions of its Board of Directors authorizing the execution, delivery and performance of the Loan Documents to which the Guarantor is a party, and certifying as to the incumbency, authority and signatures of the officers of the Guarantor authorized to sign the Loan Documents on behalf of the Guarantor;

(v) the original Agreement executed by the Borrower and the Guarantor;

(vi) the original Note executed by the Borrower and consented to by the Guarantor;

(vii) the original Guaranty executed by the Guarantor;

(viii) the original Mortgage executed by the Borrower;

(ix) the original Security Agreement executed by the Borrower;

(x) a written opinion of counsel to the Borrower and the Guarantor dated as of the date of this Agreement and addressed to the Bank, which opinion must be, in form and content, satisfactory to the Bank;

(xi) such financing statements or other documents which the Bank may reasonably request in connection with the Collateral; evidence satisfactory to the Bank that all filings under the Uniform Commercial Code or with any federal or state agency or department that the Bank or its counsel deems necessary or desirable in connection with the creation and perfection of the security interests granted under the Loan Documents have been effected; and such other evidence as the Bank may require that confirms that, as a result of such filings, the Bank's security interest in the Collateral is consistent with the representation contained in this Agreement relating thereto;

(xii) the insurance policies evidencing the insurance coverages required by the Loan Documents, together with proof of payment of the premiums for such insurance;

(xiii) the Commitment Fee due to the Bank, plus all other fees and expenses payable to the Bank and third parties in connection with its due diligence, preparation and negotiation of the Loan Documents, filing of various security documents, including legal and administrative fees;

(xiv) with respect to all other advances, fees payable to the Bank, including reasonable legal fees, commitment fees, administration fees, etc.;

(xv) such executed agreements, notices or other documents in form and substance satisfactory to the Bank in connection with the Bank's control of any rights in any deposit accounts, electronic chattel paper, investment property or letter of credit; and

(xvi) such other loan documents, agreements, consents, approvals, certificates, resolutions, instruments, opinions and other documents and materials as listed on any closing checklist or as the Bank may reasonably request.

3.02 **Compliance.** The Borrower and the Guarantor shall have complied and shall then be in compliance in all material respects with all material terms, covenants and conditions of this Agreement.

3.03 **No Default.** There shall exist no Event of Default (as hereinafter defined) and no event which, upon notice or lapse of time or both, would constitute an Event of Default.

3.04 **Representations True.** The representations and warranties contained in this Agreement shall be true and correct in all material respects.

3.05 **No Material Adverse Change.** There shall be no materially adverse change in the total financial condition of the Borrower or the Guarantor, taken as a whole, from the financial condition of the Borrower or the Guarantor, as the case may be, as set forth in the financial statements furnished to the Bank pursuant to this Agreement or from the financial condition of the Borrower or any

Guarantor previously disclosed to the Bank in any other manner.

3.06 Appraisal. The Bank shall have received, at the Borrower's expense, an appraisal for the Property showing that the amount of the Loan is no more than 65% of the fair market value of the Property, and being otherwise satisfactory in form and substance to the Bank.

3.07 Environmental. The Bank shall have received, at the Borrower's expense, environmental reports with respect to the Property which are satisfactory in form and substance to the Bank.

#### SECTION 4. REPRESENTATIONS AND WARRANTIES

To induce the Bank to enter into this Agreement, the Borrower, as to itself, and the Guarantor, as to itself, represent, warrant and agree as of the date hereof and continuing so long as any obligation of the Borrower and/or the Guarantor exists to the Bank under the Loan Documents as follows:

4.01 Corporate Status: Subsidiaries. The Borrower is a corporation, duly organized and validly existing in the jurisdiction in which it is organized, has the power and authority to own its properties and to carry on its business as currently conducted, and is duly qualified to do business and is in good standing in each jurisdiction in which the transaction of its business makes such qualification necessary. The Borrower has no subsidiaries other than those previously disclosed to the Bank in writing.

4.02 Mergers and Consolidations. Except as previously disclosed to the Bank in writing, no entity has merged into the Borrower or been consolidated with the Borrower, and the business of the Borrower has not ever been conducted as a partnership or proprietorship in the past.

4.03 Purchase of Assets. Except as disclosed in Schedule 4.03 attached hereto or as previously disclosed to Bank in writing, no entity has sold substantially all of its assets to the Borrower or sold assets to the Borrower outside the ordinary course of such seller's business or in a transaction subject to the bulk transfer laws at any time in the past.

4.04 Borrower's and Guarantor's Authority and Capacity. The Borrower and the Guarantor have the full legal right, authority and capacity to execute, deliver and perform the Loan Documents to which they are a party and to incur the obligations provided for therein. The execution, delivery and performance of the Loan Documents and the obligations provided for therein have been duly and validly authorized by all necessary corporate actions on the part of the Borrower and the Guarantor (all of which actions are in full force and effect), and do not and will not require any consent or approval of the stockholders of the Borrower which has not been obtained.

4.05 Binding Agreement of Borrower and the Guarantor. The Loan Documents are the valid and legally binding obligations and agreements of the Borrower and of the Guarantor, enforceable in accordance with their respective terms.

4.06 No Conflicting Law and Agreements. Except as disclosed in Schedule 4.06 attached hereto, the execution, delivery and performance by the Borrower and the Guarantor of the Loan Documents to which it is a party will not violate any provision of law, any order of any court or government instrumentality or agency, any indenture, any loan or credit agreement or any other material agreement, commitment, lease, contract, mortgage, note or other instrument binding on the Borrower or Guarantor or affecting the Property, or be in conflict with, result in a breach of, in any material respect, or constitute (with due notice, lapse of time, or both) a default (as defined therein) under any such indenture, agreement, commitment, lease, contract, mortgage, note or other instrument, or result in the creation or imposition of any Lien (other than a Permitted Lien) of any nature whatsoever upon any of the Collateral, or result in or require the acceleration of any indebtedness of the Borrower or Guarantor.

4.07 Compliance with Laws. The Borrower and the Guarantor are in compliance in all material respects with any federal, state and local laws, rules and regulations including, but not limited to Environmental Laws and the Fair Labor Standards Act. The Borrower and the Guarantor maintain all of the necessary material permits, licenses and certifications necessary for the operation of their businesses. All of the foregoing are in full force and effect and not in known conflict with the rights of others. The Borrower is not in breach of or default (as defined therein) under the provisions of any of the foregoing, nor is there any event, fact, condition or circumstance which, with notice or passage of time or both, would constitute or result in a conflict, breach, default or event of default (as defined therein) under, any of the foregoing which, if not remedied within any applicable grace or cure period could reasonably be expected to have a material adverse effect on the Borrower.

4.08 Taxes. The Borrower and the Guarantor have filed or caused to be filed all Federal, state and local income, excise, property and other tax returns which are required to be filed. All such returns are true and correct in all material respects and the Borrower and the Guarantor have paid or caused to be paid all taxes, assessments, interest and penalties as shown on such returns or on any assessment received by them, to the extent that such taxes have become due, including, but not limited to, all F.I.C.A. payments and withholding taxes. Except as disclosed in Schedule 4.08 attached hereto, the amounts reserved as a liability for income and other taxes payable in the most recent financial statements of the Borrower and the Guarantor provided to the Bank pursuant to this Agreement are sufficient for the payment of all unpaid Federal, state, county and local income, excise, property and other taxes, whether or not disputed, of the Borrower and the Guarantor accrued for or applicable to the period and on the dates of such financial statements and all years and periods prior thereto and for which the Borrower, any existing Subsidiary or the Guarantor may be liable in its or their own right or as a transferee of the assets of, or as successor to, any other person or entity.

4.09 Financial Condition. The financial statements of the Borrower and the Guarantor and other related information previously submitted to the Bank are true, complete and correct in all material respects, fairly represent the financial condition of the Borrower and the Guarantor and the results of their respective operations and transactions as of the dates and for the periods of such statements and have been prepared in accordance with GAAP applied on a consistent basis throughout the period involved. There are no liabilities, direct or indirect, fixed or contingent, matured or unmatured, known to the Borrower or the Guarantor which are not required to be reflected therein pursuant to GAAP. There has been no material adverse change in the business, operations, prospects, assets, properties or condition (financial or otherwise) of the Borrower or the Guarantor, taken as a whole since the date of said financial statements.

4.10 Title To Properties. The Borrower has good, valid, insurable (in the case of real property) and marketable title to all of its properties and assets including the Collateral (whether real or personal, tangible or intangible) reflected on the financial statements referred to in this Agreement, except for such properties and assets as have been disposed of since the date of such financial statements as no longer used or useful in the conduct of its business or as have been disposed of in the ordinary course of business, and all such properties and assets are free and clear of all Liens except for Permitted Liens. Except as noted in Title Insurance Policies Nos. TRO-06-100063 and TRO-06-100064 issued by Lawyers Title Insurance Corporation in favor of Bank, as updated, none of the real property included in such properties of the Borrower is subject to any covenant or other restriction preventing or limiting the right of the record owner to convey or use it, all such real property has adequate rights of ingress and egress, and the Developed Campus has direct and unobstructed access to electric, gas, water, sewer and telephone lines, all of which are adequate for the uses to which such property is currently devoted.

4.11 Litigation. Except as disclosed in Schedule 4.11 attached hereto, there are no actions, claims, suits or proceedings pending, or, to the knowledge of the Borrower or the Guarantor, threatened or reasonably anticipated against or affecting the Borrower or the Guarantor at law or in equity including, without limitation, under ERISA or any Environmental Laws or before or by any governmental instrumentality or agency (domestic or foreign), commission, board, bureau, arbitrator or arbitration panel, and there is no probable judgment, liability or award which may reasonably be expected to result in any material adverse change in the business, operations, prospects, properties or assets or condition, financial or otherwise, of the Borrower or the Guarantor. The Borrower is not in default with respect to any judgment, order, writ, injunction, decree, rule, award or regulation of any court, governmental instrumentality or agency, commission, board, bureau, or arbitrator or arbitration panel.

4.12 No Other Defaults. Except as disclosed in Schedule 4.12 attached hereto, neither the Borrower nor the Guarantor is in default under any contract, agreement, commitment or other instrument which default would have a material adverse effect on the business, properties or condition, financial or otherwise, of the Borrower or the Guarantor, or in the performance of any covenants or conditions respecting any of their indebtedness. No holder of any indebtedness of the Borrower or Guarantor has given notice of any asserted default thereunder. No liquidation or dissolution of the Borrower or the Guarantor and no receivership, insolvency, bankruptcy, reorganization or other similar proceeding relative to the Borrower or the Guarantor or their properties is pending or, to the knowledge of the Borrower or the Guarantor, is threatened against them or any of them.

4.13 ERISA. (a) The pension, profit sharing, savings, stock bonus and other deferred compensation plans established and maintained by the Borrower, the Guarantor and any Commonly Controlled Entity (as defined below) which are subject to the requirements of ERISA, if any, were stated in their inception or have, since ERISA became effective with respect to such plans, been amended and restated in a manner designed to qualify under the applicable requirements of ERISA and the Internal Revenue Service Code of 1986, as amended (the “Code”); and subsequent to such statement, or restatement, those plans and their related trusts have received favorable determinations from the Internal Revenue Service holding that such plans and trusts so qualify; (b) to the knowledge of the Borrower and the Guarantor, there is no current matter which would materially adversely affect the qualified tax-exempt status of any pension, profit-sharing, savings, stock bonus or other deferred compensation plan and their related trusts of either of the Borrower or any Commonly Controlled Entity under the Code; (c) neither the Borrower, the Guarantor, nor any Commonly Controlled Entity has incurred in connection with any such plan any “accumulated funding deficiency” (as defined in Section 302 of ERISA or Section 412(a) of the Code) whether or not waived; (d) there has been no “prohibited transaction” (within the meaning of Section 4975 of the Code or Section 406 of ERISA) involving any such plan of the Borrower, the Guarantor, or any Commonly Controlled Entity; (e) no “reportable event,” as defined by Title IV of ERISA, has occurred with respect to any plan subject to the minimum funding requirements of Section 412 of the Code maintained for employees of the Borrower or any Commonly Controlled Entity; (f) no “multi-employer plan” (as defined in ERISA) to which either the Borrower, the Guarantor or any Commonly Controlled Entity has an obligation to contribute, has “terminated,” as that term is defined in ERISA; (g) neither the Borrower, the Guarantor, nor any Commonly Controlled Entity has withdrawn, in a “complete withdrawal” (as defined in ERISA), from any “multi-employer plan” to which either the Borrower or such Commonly Controlled Entity had an obligation to contribute; (h) neither the Borrower, the Guarantor nor any Commonly Controlled Entity has withdrawn, in a “partial withdrawal” (as defined in ERISA), from any “multi-employer plan” to which either the Borrower, the Guarantor or such Commonly Controlled Entity had an obligation to contribute; and (i) no “multi-employer plan” to which either the Borrower, the Guarantor or any Commonly Controlled Entity had an obligation to contribute is in “reorganization” (as defined in ERISA and the Code) nor has notice been received from the administrator of any “multi-employer plan” to which either the Borrower, the Guarantor, or any Commonly Controlled Entity has an obligation to contribute that any such plan will be placed in “reorganization.” For purposes of this Section, the term “Commonly Controlled Entity” means any corporation which is a member of a controlled group of corporations (as defined for purposes of Section 414(6) of the Code) of which the Borrower is a member and any trade or business (whether or not incorporated) which is under “common control” (as defined for purposes of Section 414(c) of the Code) with the Borrower.

4.14 Other Security Interests. The Borrower is the owner of the Collateral, free from any Lien except a Permitted Lien.

4.15 Franchises, Patents, Etc. Borrower owns or licenses all franchises, licenses, trademarks, trade names, copyrights or patents necessary to the conduct of the present business of the Borrower. The Borrower has no actual knowledge of and has not received any notice to the effect that any product it manufactures or sells, or any service it renders, or any process, method, know-how, trade secret, part or material it employs in the manufacture of any product it makes or sells or any service it renders, or the marketing or use by it or another of any such product or service, may infringe any trademark, trade name, copyright, patent, trade secret or legally protectable right of any other person or entity.

4.16 Approvals. No approval, consent or other action by any governmental instrumentality or agency or any other person or entity, which approval, consent, or other action has not been obtained or taken or which does not remain in effect as of the date hereof, is or will be necessary to permit the valid execution, delivery and performance by the Borrower and the Guarantor of the Loan Documents.

4.17 Tradenames. Except as disclosed in Schedule 4.17 attached hereto, the Borrower utilizes no tradenames in the conduct of its business and has not changed its name.

4.18 Labor Relations. There are no strikes, work stoppages, material grievance proceedings or other material controversies pending or, to the best of the Borrower's knowledge, threatened between the Borrower and any employees engaged in the business of the Borrower or any union or other collective bargaining unit representing such employees. The Borrower has complied and is in material compliance with all laws relating to the employment of labor, including, without limitation, provisions relating to wages, hours, collective bargaining, occupational safety and health, equal employment opportunities and the withholding of income taxes and social security contributions, the non-compliance with which might materially adversely affect its business, operations, prospects, assets, properties or condition (financial or otherwise).

## SECTION 5. COVENANTS

The Borrower and the Guarantor covenant and agree that, so long as any of the Loan Documents shall remain in effect, unless the Bank shall otherwise consent in writing, they will:

5.01 Payment of Loan. Comply with the terms and conditions for repayment of the Loan in accordance with the terms of the Note and Guaranty.

5.02 Financial Statements. Furnish to the Bank:

(a) as soon as available but in no event more than one hundred twenty (120) days after the last day of each fiscal year of the Borrower and the Guarantor, consolidated financial statements of the Borrower and the Guarantor containing a balance sheet, a statement of income and expenses and a statement of changes in financial condition as of the close of such period, prepared in accordance with GAAP applied on a basis consistent with prior periods, showing the financial condition of the Borrower and the Guarantor at the close of such year in form reasonably satisfactory to the Bank and prepared and audited by Ernst & Young, or another independent certified public accountant reasonably satisfactory to the Bank and on an annual basis forward looking management prepared projections for the Borrower and the Guarantor;

(b) as soon as available but in no event more than forty five (45) days after the last day of each quarter of each fiscal year of the Borrower and the Guarantor, consolidated financial statements of the Borrower and the Guarantor containing a balance sheet, a statement of income and expenses and a statement of changes in financial condition as of the close of such period, prepared in accordance with GAAP applied on a basis consistent with prior periods, showing the financial condition of the Borrower and the Guarantor at the close of such period, in form reasonably satisfactory to the Bank;

(c) in the event that a portion of the Property has been leased to third party, unaffiliated tenants, as soon as available but in no event more than forty five (45) days after the last day of each quarter of each fiscal year, a detailed budget and report of operating expenses for the Property;

(d) in the event that a portion of the Property has been leased to third party, unaffiliated tenants, as soon as available but in no event more than forty five (45) days after the last day of each fiscal year, projections for the Property for the following fiscal year;

(e) promptly, and from time to time, such other information regarding the operation, business, affairs and financial condition of the Borrower and the Guarantor as the Bank may reasonably request, including, but not limited to interim financial statements including an income statement, balance sheet, aging of accounts receivable and/or accounts payable; and

(f) within forty five (45) days after the last day of each of the quarters of each fiscal year of the Borrower, a certificate of the chief financial officer of the Borrower certifying that to the best of his knowledge no Event of Default has occurred and is continuing or, if an Event of Default has occurred and is continuing, a statement as to the nature thereof and the action which is proposed to be taken with respect thereto.

The financial statements of the Borrower and the Guarantor delivered to the Bank pursuant to this Section shall each be certified by the president or chief financial officer of the Borrower or the Guarantor, as the case may be, as to the authenticity, accuracy of integrity of the representation contained therein and as having been prepared in accordance with GAAP applied on a basis

consistent with prior periods. Any such financial information provided to the Bank shall be maintained by the Bank as confidential proprietary records. The Bank hereby acknowledges that the Borrower may not have its own separate financial statements and shall be permitted to supply financial statements consolidated with Guarantor's and other subsidiaries of the Guarantor's financial statements.

5.03 Maintaining Records: Access to Properties and Inspections. Maintain financial records in accordance with GAAP consistently applied and permit any authorized representative designated by the Bank to visit and inspect any of the properties of the Borrower or the Guarantor (including, without limitation, their books of account, records, correspondence and other papers and to make extracts therefrom) and to discuss their affairs, finances and accounts with their respective officers and their respective independent certified public accountants or other parties preparing statements for or on behalf of the Borrower or the Guarantor, subject to advance notice and subject to safety limitations and legal limits of general applicability.

5.04 Place of Business, Location of Records; Notices. Maintain their executive offices and their records at their current locations. The Bank shall be entitled to rely upon the foregoing unless it receives fourteen (14) days advance written notice of a change in such executive offices or in such office where such records are kept.

5.05 Maintenance of Business. (a) Maintain the corporate existence of the Borrower and the Guarantor in good standing and in existence in the State of its original formation; and (b) maintain and keep in full force and effect all material necessary licenses and permits for the proper conduct of the Borrower's and the Guarantor's business and shall immediately cure any failure to maintain necessary permits and licenses as soon as it has knowledge of such failure.

5.06 Insurance. The Borrower shall maintain and pay for insurance covering such risks and in such amounts and with such insurance companies as shall be satisfactory to the Bank, and deliver the policies or certificates of all such insurance to the Bank with satisfactory lender's loss payable endorsements naming the Bank as loss payee; and maintain, with financially sound and reputable insurers, insurance with respect to their properties and business against such casualties and contingencies of such types (including personal injury and property damage liability insurance, automobile liability insurance, product liability insurance, biomedical insurance, worker's compensation insurance, business interruption insurance, employee dishonesty insurance, and directors' and officers' liability insurance) and in such amounts as is customary in the case of persons or entities in the same or similar business. Each policy or insurance required hereunder shall require the insurer to give not less than thirty (30) days prior written notice to the Bank in the event of cancellation of such policy for any reason whatsoever, and shall provide that the interest of the Bank thereunder shall not be impaired or invalidated by any act or neglect of the Borrower or the owner of any of the insured property or by the occupation of the premises wherein such property is located for purposes more hazardous than are permitted by such policy. If the Borrower fails to provide and pay for such insurance, the Bank may, at the Borrower's expense, procure the same, but shall not be required to do so. The Borrower agrees to deliver to the Bank, promptly as rendered, true copies of any reports made to any insurance company.

5.07 Execution of Documents. At the reasonable request of the Bank, execute and deliver such financing statements, documents and instruments including, but not limited to, written acknowledgments from any third party holding all or any portion of the Collateral that it does so for the Bank's benefit and any control agreements with respect to any investment property, letter-of-credit rights, deposit accounts or electronic chattel paper, and perform all other acts as the Bank deems necessary or desirable, and pay, upon demand, all reasonable costs and expenses (including reasonable attorneys' fees and disbursements) incurred by the Bank in connection therewith.

5.08 Obligations and Taxes. Pay all indebtedness and obligations promptly and in accordance with their terms, and pay and discharge promptly all taxes, assessments and governmental charges or levies imposed upon them or in respect of their property and the Collateral, including, but not limited to, all F.I.C.A. payments and withholding taxes, before the same shall become in default, as well as all claims for labor, materials, and supplies or otherwise which, if unpaid, might become a Lien upon such properties or any part thereof, provided, however, that the Borrower and the Guarantor are not required hereby to pay and discharge or to cause to be paid and discharged any such indebtedness, obligation, tax, assessment, charge, levy or claim so long as the validity thereof shall be contested in good faith by appropriate proceedings and the Borrower and the Guarantor shall set aside on their books reserves which are in conformity with generally accepted accounting principles and which the Bank deems adequate with respect to any such tax, assessment, charge, levy or claim so contested.

5.09 Litigation Notice. Give the Bank prompt notice of any action, suit or proceeding at law or in equity or by or before any governmental instrumentality or agency (domestic or foreign), commission, board, bureau, arbitrator or arbitration panel which, if adversely determined, could materially impair or affect the right of the Borrower to carry on its business substantially as now conducted or could materially affect its respective business, operations, prospects, properties, assets (including the Collateral) or condition, financial or otherwise, in each case if in excess of \$1,000,000.00.

5.10 Notification Relating to Hazardous Materials. Immediately advise the Bank in writing of (a) any and all enforcement, cleanup, remediation or removal, pursuant to any governmental or regulatory actions instituted, completed or threatened pursuant to any applicable federal, state, or local laws, ordinances or regulations relating to any Hazardous Material and/ or violation of Environmental Laws affecting the Property or the business operations of the Borrower, and (b) all claims made or threatened by any third party against the Borrower relating to damages, contribution, cost recovery compensation, loss or injury resulting from any violations of Environmental Laws. The Borrower shall immediately notify the Bank of any remedial action related to a release of Hazardous Materials in violation of Environmental Laws taken by the Borrower with respect to the Property or the business operations of the Borrower. Borrower hereby discloses to Bank that an underground storage tank ("UST") was installed on the Property prior to

or during the Property's ownership by the State of Michigan (the "State"), which owned the Property prior to the Borrower. The UST was subsequently removed by the State prior to the ownership of the Property by Borrower. The State conducted environmental testing on the Property, and acknowledged responsibility for any issues associated with the UST.

5.11 Access Onto Property and to the UCC Collateral. Allow the appropriate agents and contractors of the Bank to enter upon the Property and to have reasonable access to the UCC Collateral for the purposes of conducting environmental investigations and audits (including taking physical samples) and such other action deemed necessary by the Bank to insure compliance by the Borrower with all Environmental Laws, subject to advance notice and subject to safety limitations and legal limits of general applicability. The Borrower acknowledges that no adequate remedy at law exists for a violation of this covenant and agrees that the Bank is entitled to specific performance of its rights under this covenant, subject to advance notice and subject to safety limitations and legal limits of general applicability. The right of access granted herein shall continue until this Agreement is terminated

5.12 Notice of Default: Material Adverse Change. Promptly notify the Bank of any condition or event that constitutes, or with the running of time, the giving of notice, or both, would constitute, an Event of Default, and promptly inform the Bank of any material adverse change in the financial condition of the Borrower or of the Guarantor, as set forth in Section 6.11 below.

5.13 Borrower's Claims. Promptly notify the Bank in writing of any action or omission of the Bank which the Borrower claims caused or may cause injury, loss or damage to the Borrower. Failure of the Borrower to so notify the Bank of such claim of which it has knowledge within one hundred eighty (180) days after the Borrower determines that it has such claim shall constitute a waiver of such claim.

5.14 Defense of Collateral. Defend the Collateral, and the Bank's security interest therein, against all claims and demands of all persons at any time claiming the same or any interest therein (except to the extent Bank agrees to waive such failure to defend as Bank has determined such failure would not have a material adverse effect on Bank) and pay, upon demand, all reasonable costs and expenses (including reasonable attorneys' fees and disbursements) incurred by the Bank in connection therewith.

5.15 Use of Proceeds. Use the proceeds of the Loan for any commercial purpose not violative of or inconsistent with any provision of this Agreement or the Loan Documents.

5.16 Compliance with Laws. Comply, in all material respects, with all federal, state and local laws, rules and regulations including, but not limited to Environmental Laws and the Fair Labor Standards Act applicable to its business, whether now in effect or hereafter enacted, and upon request of the Bank, the Borrower will provide the Bank with such evidence of compliance as the Bank may reasonably request.

5.17 Hazardous Materials. With respect to all property owned, subleased, operated or occupied by the Borrower, maintain and cause all operators, tenants, subtenants, licensees and occupants of all such property to maintain such property free of all Hazardous Materials, other than those Hazardous Materials used in material compliance with all Environmental Laws and prevent all such property from being used for the manufacture, generation, production, processing, distribution, use, treatment, storage, disposal, transport or handling of any Hazardous Materials other than in material compliance with all Environmental Laws; and deliver to the Bank copies of all reports prepared by Borrower or its Affiliates, excepting clinical trial reports, or provided to Borrower or its Affiliates by any governmental authority, any environmental auditor or engineer, or any other person, relating to or in connection with the Borrower's compliance with or violation of any Environmental Laws, unless the Borrower cannot obtain such reports or copies thereof.

5.18 Deposit Relationship. The Guarantor shall maintain its primary deposit relationship with the Bank and shall establish a deposit account and cash management facility with the Bank.

5.19 Liens. Not create or permit to exist any Lien on the Property or the UCC Collateral except Permitted Liens.

5.20 Disposition of Property. The Borrower shall not sell, lease or otherwise dispose of any assets with a value in excess of \$250,000 except for the sale of inventory in the ordinary course of business and the disposition, in the ordinary course of business, of machinery, technology, intellectual property and equipment that has become obsolete, damaged, unsuitable or unnecessary for its business.

5.21 Loan. The Borrower shall not make loans or advances to any person except for (a) loans and advances to Affiliates and Subsidiaries, and (b) loans and advances to other persons not exceeding \$250,000 at any time.

5.22 Guarantees. The Borrower shall not guarantee, endorse, assume or otherwise incur or allow to exist any contingent liability in respect of any obligation of any other person, except 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 with a maximum aggregate liability for the Borrower of \$500,000.00.

5.23 Merger, Name Changes, etc. Not enter into any merger, consolidation, reorganization or recapitalization, or purchase or otherwise acquire all or substantially all of the assets, obligations, capital stock or other equity interest in any other person, if an uncured Event of Default has occurred or such transaction would result in an Event of Default. The Borrower shall provide prior written notice to the Bank of any anticipated name change and will execute any additional Loan Documents necessary to confirm and re-affirm the obligations of the Loan Documents in connection with any such name change.

5.24 Affiliate Transactions. Not engage in any transaction with an Affiliate on terms that are less favorable than could be obtained in a commercially reasonable transaction with a person who is not an Affiliate.

5.25 Indebtedness. The Borrower shall not incur or permit to exist any indebtedness for borrowed money other than (a) indebtedness to the Bank, (b) the Fifth Third Loan, and any refinancing thereof, (c) purchase money indebtedness, and (d) other indebtedness that does not exceed \$500,000 in the aggregate at any time outstanding. The Guarantor shall not incur any indebtedness for borrowed money if such transaction would result in the occurrence of an Event of Default.

## SECTION 6. EVENTS OF DEFAULT

The occurrence of any one or more of the following events shall constitute an Event of Default hereunder (subject to any applicable notice and cure periods contained in the Loan Documents):

6.01 Payments. Default shall be made in the payment of the principal of, or any installment of principal of, or interest on, the Note within ten (10) days of when due, whether at the due date thereof, at a date fixed for prepayment thereof, upon acceleration thereof or otherwise.

6.02 Representations. Any representation or warranty made in or in connection with any of the Loan Documents shall prove to have been false or misleading in any material respect when made or deemed to have been made.

6.03 Covenants. Default shall be made in the due observance or performance of any covenant, condition or agreement on the part of the Borrower or the Guarantor pursuant to the terms of any of the Loan Documents and such default shall continue unremedied for thirty (30) business days after notice to the Borrower and the Guarantor thereof.

6.04 (a) Voluntary Bankruptcy, Etc. The Borrower or the Guarantor: (i) voluntarily is adjudicated as bankrupt or insolvent, (ii) seeks or consents to the appointment of a receiver or trustee for itself or for all or any part of its property, (iii) files a petition seeking relief under the bankruptcy or similar laws of the United States or any state or any other competent jurisdiction, (iv) makes a general assignment for the benefit of creditors, or (v) admits in writing its inability to pay its debts as they mature.

(b) Involuntary Bankruptcy, Etc. A court of competent jurisdiction enters an order, judgment or decree appointing, without the consent of the Borrower or the Guarantor, a receiver or trustee for the Borrower or the Guarantor or for all or any part of their property, or a petition is filed against the Borrower or the Guarantor seeking relief under the bankruptcy or other similar laws of the United States or any state or other competent jurisdiction, and such petition, order, judgment or decree shall remain in force undischarged or unstayed for a period of 60 calendar days.

### 6.05 Intentionally Deleted.

6.06 Cross Default. The occurrence of (a) an uncured event of default (as defined therein) under any of the Loan Documents, (b) any uncured event of default under (i) any promissory note payable to the Bank under which the Borrower, the Guarantor, Emergent Commercial Operations Baltimore LLC, a Delaware limited liability company ("Emergent Baltimore"), or Emergent Product Development Gaithersburg Inc., a Delaware corporation ("Emergent Gaithersburg") is an obligor, or (ii) any other agreement between the Borrower, the Guarantor, Emergent Baltimore or Emergent Gaithersburg and the Bank, (c) an uncured event of default (as defined therein) under the Fifth Third Loan, or (d) an uncured event of default (as defined therein) under any other indebtedness or liability for borrowed money of the Borrower in an amount in excess of \$1,000,000.00, if the effect of such default is to accelerate the maturity of such evidence of indebtedness or liability or to permit the holder thereof to cause any indebtedness to become due prior to its stated maturity and the Bank determines, in its discretion, that such default impairs or prevents the Borrower from performing its obligations under the Loan Documents.

6.07 Judgment. Unless, in the opinion of the Bank, adequately covered by insurance, the entry of one or more final judgments, decrees or orders for the payment of money involving more than \$1,000,000.00 in the aggregate against the Borrower or the Guarantor and all applicable periods for appeal have terminated and such judgment or decree is not satisfied within sixty (60) days thereafter.

6.08 Loss, Damage to Collateral. Loss, theft, damage, or destruction of any material portion of the Collateral for which there is either no insurance coverage or for which, in the opinion of the Bank, there is insufficient insurance coverage.

6.09 Validity of Loan Documents. Any Loan Document shall, at any time after its execution and delivery and for any reason, cease to be in full force and effect or shall be declared null and void, or the validity or enforceability thereof shall be contested by the Borrower or the Guarantor, or the Borrower or the Guarantor shall deny it has any further liability or obligation thereunder.

6.10 Payments to Subordinated Creditors. The Borrower makes any payment on account of indebtedness that has been subordinated to the Loan, other than payments specifically permitted by the terms of such subordination or in the ordinary course of business.

6.11 Material Adverse Change. There shall be a materially adverse change in the total financial condition of the Borrower or the Guarantor, taken as a whole.

## SECTION 7.

## RIGHTS AND REMEDIES

7.01 Remedies. If any one or more Events of Default shall occur, then in each and every such case, the Bank may at any time thereafter exercise and/or enforce any of the following rights and remedies:

(a) Acceleration. Declare the Note to be immediately due and payable, together with accrued interest thereon, without presentment, demand, protest or notice of dishonor, all of which the Borrower and the Guarantor hereby waive.

(b) Possession and Collection (i) Take possession or control of, sell or otherwise dispose of all of any part of the Collateral, subject to the terms of Section 4.2 of the Security Agreement; (ii) endorse as the agent of the Borrower any chattel paper, documents, or instruments forming all or any part of the Collateral; (iii) pay, purchase, contest, or compromise any encumbrance, charge, or lien that, in the opinion of the Bank, appears to be prior or superior to its Lien and pay all reasonable expenses incurred in connection therewith; (iv) take any other action which the Bank deems necessary or desirable to protect and realize upon its security interest in the Collateral; and (v) in addition to the foregoing, and not in substitution therefor, exercise any one or more of the rights and remedies exercisable by the Bank under other provisions of this Agreement, under the Note, under any of the other Loan Documents, or provided by applicable law (including, without limitation, the Uniform Commercial Code as in effect in any applicable jurisdiction) and may specifically disclaim any warranties of title or the like. In taking possession of the Collateral the Bank may proceed without legal process, if this can be done without breach of the peace. The Borrower waives any right it may have to require the Bank to pursue any third person for payment of the Loan.

(c) Receiver. Obtain appointment of a receiver for all or any of the Collateral, the Borrower and the Guarantor hereby consenting to the appointment of such a receiver and each agreeing not to oppose any such appointment. Any receiver so appointed shall have such powers as may be conferred by the appointing authority including any or all of the powers, rights and remedies which the Bank is authorized to exercise by the Loan Documents, and shall have the right to incur such obligations and to issue such certificates therefor as the appointing authority shall authorize.

(d) Performance by Bank. Make such payment or perform any of the conditions, covenants, terms, stipulations or agreements contained in this Agreement or any of the other Loan Documents for the account and at the expense of the Borrower.

7.02 Sales on Credit. If the Bank sells any of the Collateral upon credit, the Borrower will be credited only with payments actually made by the purchaser, received by the Bank and applied to the indebtedness of the purchaser. In the event the purchaser fails to pay for the Collateral, the Bank may resell the Collateral and the Borrower shall be credited with the proceeds of the sale.

7.03 Proceeds. Any proceeds of the collection of the Loan or of the sale or other disposition of the Collateral will be applied by the Bank to the payment of fees and costs, and any balance of such proceeds (if any) will be applied by the Bank to the payment of the remaining Loan (whether then due or not), at such time or times and in such order and manner of application as the Bank may from time to time in its sole discretion determine. If the sale or other disposition of the Collateral fails to pay the Loan in full, the Borrower and the Guarantor shall remain jointly and severally liable to the Bank for any deficiency.

7.04 Notices. Any notices required under the Uniform Commercial Code with respect to the sale or other disposition of the Collateral shall be deemed reasonable if mailed by the Bank to the persons entitled thereto at their last known address at least ten (10) days prior to disposition of the Collateral.

**7.05 Waiver of Jury Trial. THE BORROWER, THE GUARANTOR AND THE BANK HEREBY VOLUNTARILY AND KNOWINGLY WAIVE ANY RIGHT THEY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION, PROCEEDING, OR COUNTERCLAIM BROUGHT BY ANY PARTY AGAINST THE OTHER ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREIN. THE BORROWER AND THE GUARANTOR ACKNOWLEDGE THAT THEY HAVE BEEN INFORMED BY THE BANK THAT THE PROVISIONS OF THIS PARAGRAPH CONSTITUTE A MATERIAL INDUCEMENT UPON WHICH THE BANK HAS RELIED, IS RELYING AND WILL RELY IN MAKING THE LOAN. THE BORROWER AND THE GUARANTOR HEREBY CERTIFY THAT NO REPRESENTATIVE OR AGENT OF THE BANK (INCLUDING ITS COUNSEL) HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT THE BANK WOULD NOT, IN THE EVENT OF LITIGATION, ENFORCE THIS WAIVER OF RIGHT TO JURY TRIAL. THE BORROWER AND THE GUARANTOR ACKNOWLEDGE THAT THEY HAVE CONSULTED WITH AN ATTORNEY AND FULLY UNDERSTAND THE LEGAL EFFECT OF THE PROVISIONS OF THIS PARAGRAPH.**

7.06 Cumulative Remedies. Each right, power and remedy of the Bank as provided for in the Loan Documents, or now or hereafter existing at law or in equity or by statute or otherwise shall be cumulative and concurrent and shall be in addition to every other such right, power or remedy, and the exercise or beginning of the exercise by the Bank of any one or more of such rights, powers or remedies shall not preclude the simultaneous or later exercise by the Bank of any or all other such rights, powers or remedies. The Bank may comply with any applicable state or federal law requirements in connection with a disposition of the Collateral and compliance will not be considered to adversely affect the commercial reasonableness of any sale of the Collateral.

7.07 No Waiver. No failure or delay by the Bank in insisting upon the strict performance of any term, condition, or covenant of the Loan Documents or in exercising any right, power or remedy consequent upon an Event of Default shall constitute a waiver of any such term, condition or covenant or of any such breach, or preclude the Bank from exercising any such right, power or remedy at



any later time or times. By accepting payment after the due date of any amount payable under the Loan Documents, the Bank shall not be deemed to waive the right either to require prompt payment when due of all other amounts payable under the Loan Documents, or to declare a default for failure to effect such prompt payment of any such other amount.

## SECTION 8.                      MISCELLANEOUS

8.01 Survival. All covenants, agreements, representations and warranties made in this Agreement and the Loan Documents shall survive the execution and delivery of the Note and shall continue in full force and effect so long as the Note, or any of the other obligations under the Loan Documents, or any renewal or extensions of the Note, is outstanding and unpaid.

8.02 Notices. All notices, demands, instructions and other communications required or permitted to be given to or made upon any party hereto shall be in writing, personally delivered or sent by postage prepaid first class certified mail, return receipt requested, overnight courier or by facsimile machine, and shall be deemed to be given on the day that such writing is delivered or sent by facsimile machine or one (1) business day after such notice is sent by overnight courier or three (3) business days after said notice is sent by certified mail. Unless otherwise specified in a notice sent or delivered in accordance with the foregoing provisions of this paragraph, notices, demands, instructions and other communications in writing shall be given to or made upon the respective parties hereto at their respective addresses indicated for such party below:

**Bank:**                      HSBC Realty Credit Corporation (USA)  
1800 Tysons Boulevard, Suite 50  
McLean, Virginia 22102  
Attention: Jaron R. Campbell, Vice President  
Facsimile Number: (917) 229-0937

With a simultaneous copy to:            McGuireWoods LLP  
1750 Tysons Boulevard, Suite 1800  
McLean, Virginia 22102-3915  
Attention: E. Kristen Moye, Esquire  
Facsimile Number: (703) 712-5238

**Borrower and  
Guarantor:**

Emergent BioSolutions Inc.  
2273 Research Boulevard, Suite 400  
Rockville, Maryland 20850  
Attn: Don Elsey, CFO, Finance Department  
Attn: Denise Esposito, General Counsel, Legal Department  
Facsimile Number: (301) 944-0173

With a simultaneous copy to:            Emergent BioDefense Operations Lansing Inc.  
3500 N. Martin Luther King, Jr. Blvd.  
Building One, Third Floor  
Lansing, MI 48906  
Attn: Finance Department  
Facsimile Number: 517-327-1560

With a simultaneous    Dickinson Wright PLLC  
copy to:    301 E. Liberty Street, Suite 500  
Ann Arbor, MI 48104-2266  
Attn: Colleen M. Shevnock, Esquire  
Facsimile Number: (734) 623-1625

or at such other address as the parties may have furnished to each other in writing, and shall be deemed to be given on delivery or upon mailing.

8.03 Costs and Expenses. The Borrower and the Guarantor shall bear any and all reasonable fees, costs and expenses, of whatever kind and nature, including any taxes of any kind and reasonable attorneys' fees and disbursements, which the Bank may incur: (a) in connection with the closing of the Loan, including, without limitation, the filing of public notices, the preparation of the Loan Documents, the recording of the UCC financing statements, and the making of title examinations, and in connection with any amendment of the Loan Documents; (b) in maintaining, preserving, enforcing or foreclosing any pledge, lien, encumbrance or security interest granted hereunder or in connection herewith, whether through judicial proceedings or otherwise; (c) in conducting audits of the Borrower's business and with respect to the Collateral; and (d) in successfully defending or prosecuting any actions or proceedings arising out of or relating to transactions with any one or more of the Borrower and the Guarantor. All such fees, costs and expenses until paid shall be included in the Loan or deducted from any amount due the Borrower or the Guarantor. The Borrower and the Guarantor agree that the attorneys retained by the Bank shall represent only the interests of the Bank.

8.04 Indemnification of Bank. The Borrower and the Guarantor shall protect and indemnify the Bank from and against any and all demands, suits, losses, assessments, fines, claims, damages, penalties, causes of action, costs or other expenses (including, without limitation, reasonable attorneys' fees and disbursements), imposed upon or incurred by or asserted against the Bank or the directors, officers, agents or employees of the Bank, except those arising out of the willful misconduct or gross negligence of the Bank, by reason of and including but not limited to liability or damage resulting from: (a) any failure on the part of the Borrower to perform or comply with any of the terms of this Agreement; (b) any action brought against the Bank attacking the validity of this Agreement or any other Loan Document; and/or (c) actual or threatened damage to the environment, agency costs of investigation, personal injury or death, or property damage, due to a release or alleged release of Hazardous Materials, on or under the Property or arising from the Borrower's business operations or in the surface or ground water located on or under the Property arising from the Borrower's business operations, or gaseous emissions from the Property or arising from the Borrower's business operations resulting from the use or existence of Hazardous Materials, whether such claim proves to be true or false. The term "property damage" as used in this Section includes, but is not limited to, damage of any real or personal property of the Borrower, the Bank, and of any third parties. Any amounts payable to the Bank under this Section which are not paid within thirty (30) days after written demand therefor by the Bank shall bear interest at the rate of interest in effect under the Note from the date of such demand. In the event any action, suit or proceeding is brought against the Bank or the directors, officers, agents or employees of the Bank by reason of any such occurrence, the Borrower, upon the request of the Bank and at the Borrower's expense, shall resist and defend such action, suit or proceeding or cause the same to be resisted and defended by counsel designated by the Borrower and approved by the Bank. Such obligations under this Section as shall have accrued at the time of any termination of this Agreement shall survive any such termination.

8.05 Reinstatement of Liens. If, at any time after payment in full by the Borrower of the Loan and termination of the Bank's Liens, any payments on the Loan previously made by the Borrower or any other person must be disgorged by the Bank for any reason whatsoever (including, without limitation, the insolvency, bankruptcy, or reorganization of the Borrower or such other person), this Agreement and the Bank's Liens granted hereunder shall be reinstated as to all disgorged payments as though such payments had not been made, and the Borrower shall sign and deliver to the Bank all documents and things necessary to reperfect all terminated Liens.

8.06 Bank Disclosures. Upon the prior written consent of the Borrower (such consent not to be unreasonably withheld or delayed), the Bank may issue press releases concerning, and otherwise publicly announce or publicize, financings provided by the Bank to the Borrower. The Borrower hereby authorizes the Bank to disclose to any parent, subsidiary or affiliate of the Bank, and hereby authorizes all such parents, subsidiaries and affiliates of the Bank, to disclose to the Bank, the financial record of the Borrower.

8.07 Participation. The Bank shall have the right to grant participations in the Loan held by it to others at any time and from time to time, and the Bank may divulge to any such participant or potential participant all information, reports, financial statements and documents obtained in connection with this Agreement, the Note and any of the other Loan Documents or otherwise.

8.08 Change, etc. Neither this Agreement nor any term, condition, representation, warranty, covenant or agreement contained herein may be changed, waived, discharged or terminated orally, but only by an instrument in writing signed by the party against whom such change, waiver, discharge or termination is sought.

8.09 Governing Law. This Agreement, the Note and the other Loan Documents shall be governed and construed in accordance with the laws of the State of Maryland, except to the extent that the law of other jurisdictions governs the creation, perfection and enforcement of Liens on the Property pursuant to the Mortgage and on the UCC Collateral pursuant to the Security Agreement.

8.10 Terms Binding. All of the terms, conditions, stipulations, warranties, representations and covenants of this Agreement shall apply to and be binding upon and shall inure to the benefit of the Borrower, the Guarantor and the Bank and each of their respective heirs, executors, personal representatives, successors and assigns and all persons or entities who become bound as a debtor under this Agreement, but neither the Borrower nor the Guarantor shall have the right to assign this Agreement to any person or entity without the prior written consent of the Bank.

8.11 Invalidity of Certain Provisions. If any term or provision of this Agreement or the application thereof to any person or circumstances shall, to any extent, be invalid or unenforceable, the remainder of such term or provision or the application thereof to persons or circumstances other than those as to which it is held invalid or unenforceable shall not be affected thereby and shall be valid and enforceable to the fullest extent permitted by law.

8.12 Merger Integration and Interpretation. The Loan Documents contain the entire agreement of the parties with respect to the matters covered and the transactions contemplated hereby and thereby, and no other agreement, statement or promise made by any such party, or by any employee, officer, agent or attorney of any such party, which is not contained herein or therein, shall be valid or binding. Neither this Agreement nor any uncertainty or ambiguity herein shall be construed or resolved against the Bank or the Borrower, whether under any rule of construction or otherwise. On the contrary, this Agreement has been reviewed by each of the parties and its counsel and shall be construed and interpreted according to the ordinary meaning of the words used so as to accomplish the purposes and intentions of all parties hereto fairly.

8.13 No Partnership; Control; Third Parties. This Agreement contemplates the extension of credit by the Bank, in its capacity as a lender, to the Borrower, in its capacity as a borrower, and for the payment of interest and repayment of principal by the Borrower to the Bank. The relationship between the Bank and the Borrower is limited to that of creditor/secured party, and debtor. The provisions herein for compliance with financial covenants, delivery of financial statements, and other covenants are intended solely

for the benefit of the Bank to protect its interests as lender in assuring payments of interest and repayment of principal, and nothing contained in this Agreement shall be construed as permitting or obligating the Bank to act as financial or business advisor or consultant to the Borrower, as permitting or obligating the Bank to control the Borrower, or to conduct the Borrower's operations, as creating any fiduciary obligation on the part of the Bank to the Borrower, as creating any joint venture, agency, or other relationship between the parties other than as explicitly and specifically stated in this Agreement. The Borrower acknowledges that it has had the opportunity to obtain the advice of experienced counsel of its own choosing in connection with the negotiation and execution of this Agreement and to obtain the advice of such counsel with respect to all matters contained herein, including, without limitation, the provision herein relative to the waiver of trial by jury. The Borrower further acknowledges that it is experienced with respect to financial and credit matters and has made its own independent decision to apply to the Bank for credit and to execute and deliver this Agreement. The terms and provisions of the Note and the Loan Documents are for the benefit of the Borrower and the Bank, their respective successors, assigns, endorsees and transferees and all persons claiming under or through them and no other person shall have any right or cause of action or account thereof.

8.14 Electronic Transmission of Data. The Bank, the Borrower and the Guarantor agree that certain data related to the Loan (including confidential information, documents, applications and reports) may be transmitted electronically, including transmission over the Internet. This data may be transmitted to, received from or circulated among agents and representatives of the Borrower, the Guarantor and/or the Bank and their affiliates and other persons involved with the subject matter of this Agreement. The Borrower and the Guarantor acknowledge and agree that (a) there are risks associated with the use of electronic transmission and that the Bank does not control the method of transmittal or service providers, (b) the Bank has no obligation or responsibility whatsoever and assumes no duty or obligation for the security, receipt or third party interception of any such transmission, and (c) the Borrower and the Guarantor will release, hold harmless and indemnify the Bank from any claim, damage or loss, including that arising in whole or part from the Bank's strict liability or sole, comparative or contributory negligence, which is related to the electronic transmission of data.

8.15 Gender etc. Whenever used herein, the singular shall include the plural, the plural shall include the singular, and the use of the masculine, feminine or neuter gender shall include all genders.

8.16 Authority to File Financing Statements and Amendments. The Borrower hereby authorizes the Bank to file Uniform Commercial Code Financing Statements describing the Collateral without the Borrower's signature thereon. After notice to the Borrower, the Bank is authorized to file amendments without the Borrower's signature thereon to any financing statements naming the Bank as a secured party in order to add collateral or a debtor. The Borrower is not authorized to file correction statements to financing statements.

8.17 Heading. The section and subsection headings of this Agreement are for convenience only, and shall not limit or otherwise affect any of the terms hereof.

8.18 Counterparts. To facilitate execution, this Agreement may be executed in any number of counterparts as may be required; and it shall not be necessary that the signatures of, or on behalf of, each party, or that the signatures of all persons required to bind any party, appear on each counterpart; but it shall be sufficient that the signature of, or on behalf of, each party, or that the signatures of the persons required to bind any party, appear on one or more counterparts. All counterparts shall collectively constitute a single agreement. It shall not be necessary in making proof of this Agreement to produce or account for more than a number of counterparts containing the respective signatures of, or on behalf of, all of the parties hereto.

8.19 Termination of Prior Agreement. Borrower has previously executed and delivered to Bank that certain Loan Agreement dated June 29, 2007 (the "**Original Loan Agreement**"). In connection with the execution and delivery of this Agreement, the Original Loan Agreement shall be hereby terminated and replaced with this Agreement.

(Signature Page Follows)

IN WITNESS WHEREOF, each of the parties hereto has caused this Agreement to be executed, sealed and attested the day and year first above mentioned.

**BORROWER:**

ATTEST:  
LANSING INC., a Michigan corporation

EMERGENT BIODEFENSE OPERATIONS

/s/Kimberly S. Ridgely  
Name: R. Don Elsey  
Title: Treasurer

By: /s/R. Don Elsey(SEAL)

**GUARANTOR:**

ATTEST:  
a Delaware corporation

EMERGENT BIOSOLUTIONS INC.,

/s/Kimberly S. Ridgely  
Name: R. Don Elsey  
Title: Treasurer

By: /s/R. Don Elsey(SEAL)

**BANK:**

HSBC REALTY CREDIT CORPORATION (USA),  
a Delaware corporation

By: /s/Jaron R. Campbell(SEAL)  
Name: Jaron R. Campbell  
Title: Vice President



**PROMISSORY NOTE**  
**(Term Note)**

\$22,750,000.00 December 30, 2009

FOR VALUE RECEIVED, **EMERGENT BIODEFENSE OPERATIONS LANSING INC.**, formerly known as BioPort Corporation, a Michigan corporation (the “**Borrower**”) promises to pay to the order of **HSBC REALTY CREDIT CORPORATION (USA)**, a Delaware corporation (hereinafter referred to as the “**Bank**”) at its office at 1130 Connecticut Avenue, N.W., 12<sup>th</sup> Floor, Washington, D. C. 20036, or at such other place as the Bank may from time to time direct, the sum of TWENTY-TWO MILLION SEVEN HUNDRED FIFTY THOUSAND AND NO/100 DOLLARS (\$22,750,000.00), with interest computed daily on the unpaid principal balance at the Interest Rate (as such term is hereinafter defined), and payable according to the repayment terms set forth herein (the “**Loan**”). The Loan is made pursuant to a Loan Agreement of even date herewith (the “**Loan Agreement**”) among the Borrower, the Bank and Emergent BioSolutions Inc. (the “**Guarantor**”). The Loan is guaranteed by a Guaranty of even date herewith from the Guarantor to the Bank (the “**Guaranty**”). The Loan is secured by, among other things, those certain Mortgages dated as of August 25, 2006, from the Borrower in favor of the Bank, each as amended by a First Amendment to Mortgage dated June 29, 2007, and each as further amended by a Second Amendment to Mortgage of even date herewith (collectively, the “**Mortgage**”), and a Security Agreement of even date herewith from the Borrower to the Bank (the “**Security Agreement**”). This Note, the Loan Agreement, the Guaranty, the Mortgage, the Security Agreement and any other documents entered into in connection with the Loan are referred to as the “**Loan Documents**”).

Interest Rate and Payment Terms

This Note shall bear interest at a rate per annum (the “**Interest Rate**”) equal to 90-day LIBOR plus three and 25/100 percent (3.25%). “**LIBOR**” shall mean the rate of interest (rounded upwards if necessary to the next 100th of one percent) determined by the Bank to be the prevailing rate per annum at which deposits in United States dollars for the applicable period are offered to the Bank by first class banks in the London Interbank Market in which the Bank regularly participates at any such time (as shown on the Reuters Screen LIBOR01 Page, at approximately 11:00a.m. (London time) on the proposed borrowing date), or, in the discretion of the Bank, the base, reference or other rate then designated by the Bank for general commercial loan reference purposes, it being understood that such rate is a reference rate, not necessarily the lowest, established from time to time, which serves as the basis upon which effective interest rates are calculated for loans making reference thereto. Interest will accrue on any non-banking day at the rate in effect on the immediately preceding banking day.

This Note shall be payable in monthly installments of principal and interest in the amount required to amortize this Note over fifteen (15) years, payable on the 1<sup>st</sup> day of each month beginning January 1, 2010, and in one final balloon payment of all accrued interest and outstanding principal on December 30, 2014 (the “**Maturity Date**”).

The Interest Rate on this Note: (a) will not exceed applicable legal limits, and in the event a payment is made by the Borrower or received by the Bank in excess of the applicable legal limits, such excess payment shall be credited as a payment of principal; and (b) shall be computed on the basis of 360-day year and charged for the actual number of days elapsed in each interest calculation period.

In the event that the Bank shall determine that by reason of circumstances affecting the interbank Eurodollar market, adequate and reasonable means do not exist for determining LIBOR, or Eurodollar deposits in the relevant amount and for the relevant maturity are not available to the Bank in the interbank Eurodollar market, the Bank shall give the Borrower prompt notice of such determination. If such notice is given, and until such notice is withdrawn, the Interest Rate on this Note shall be a rate per annum equal to the Prime Rate plus 2.25%. “**Prime Rate**” means the rate per annum from time to time established by the Bank as the Prime Rate and made available by the Bank at its main office or, in the discretion of the Bank, the base, reference or other rate then designated by the Bank for general commercial loan reference purposes, it being understood that such rate is a reference rate, not necessarily the lowest, established from time to time, which serves as the basis upon which effective interest rates are calculated for loans making reference thereto. If, after the date of this Note, any applicable law, treaty, regulation or directive, or any change therein or in the interpretation or application thereof, shall make it unlawful for the Bank to make or maintain any LIBOR loan, the Interest Rate on this Note shall be a rate per annum equal to the Prime Rate plus 2.25%, for so long as such illegality exists.

Prepayment

Upon five (5) business days’ written notice from the Borrower to the Bank, the Borrower may prepay the outstanding principal balance of this Note, in whole or in part, subject to the following terms and conditions:

(a) any prepayment must include payment of all interest accrued and unpaid on the amount so prepaid as of the date of such prepayment;

(b) partial prepayment shall not postpone the due date of any subsequent payment, nor shall it change the amount of any monthly payment otherwise required to be made under this Note, unless the Bank otherwise agrees in writing and in advance of receipt of such partial prepayment;

(c) Borrower shall pay a breakage fee equal to the aggregate of all costs, fees and penalties incurred by Bank in connection with such prepayment; and

(d) if the Interest Rate at the time of prepayment has been converted to a fixed rate pursuant to an ISDA Master Agreement or other interest rate protection agreement (“**Master Agreement**”), the Borrower shall pay a prepayment fee equal to the aggregate of any breakage fees related to such Master Agreement.

#### Late Charge

In the event the Borrower fails to make a payment of principal and/or interest in fully collected funds within fifteen (15) days after such payment is due, the Borrower shall pay a late charge to the Bank in an amount equal to five percent (5%) of the overdue installment.

#### Default Interest

Upon an Event of Default (as such term is hereinafter defined) and until such Event of Default is cured or this Note is paid in full, this Note shall bear interest at a rate equal to three percent (3%) per annum above the Interest Rate in effect on the date of such Event of Default.

#### Events of Default and Remedies

Subject to any applicable notice and cure periods contained in the Loan Documents, each of the following shall constitute a default (“**Event of Default**”) under this Note:

- (a) A failure to make a payment of any sum within ten (10) days of when due under this Note.
- (b) A failure to perform or observe any of the covenants, conditions or terms of this Note or any other Loan Document.

Upon the occurrence of an Event of Default or failure to pay the balance hereof when otherwise due, and notwithstanding the payment of any late charges: (i) all remaining payments under this Note shall become due and payable together with interest accrued to the date of payment without notice, at the option of the Bank; (ii) the Borrower shall reimburse the Bank for any reasonable expenses, costs and attorneys’ fees which the Bank may incur in connection with the collection of any monies due under this Note or in connection with the enforcement of any right under this Note or under any of the Loan Documents; and (iii) the Bank may exercise any or all of the other rights, powers and remedies provided for in any of the Loan Documents, or now or hereafter existing at law or in equity or by statute or otherwise.

#### Miscellaneous

The Borrower hereby waives demand, presentment for payment, protest, and notice of dishonor, and agrees that at any time and from time to time and with or without consideration, the Bank may, without notice to or further consent of the Borrower and without in any manner releasing, lessening or affecting the obligations of the Borrower: (a) release, surrender, waive, substitute, settle, exchange, compromise, modify, extend or grant indulgences with respect to: (i) this Note; and (ii) all or any part of any collateral or security for this Note; or (b) grant any extension or other postponements of the time of payment hereof.

Each right, power and remedy of the Bank as provided for in this Note, or now or hereafter existing at law or in equity or by statute or otherwise, shall be cumulative and concurrent and shall be in addition to every other right, power or remedy, and the exercise or beginning of the exercise by the Bank of any one or more of such rights, powers or remedies shall not preclude the simultaneous or later exercise by the Bank of any or all of such other rights, powers or remedies.

No failure or delay by the Bank to insist upon the strict performance of any term, condition or covenant of this Note, or to exercise any right, power or remedy upon a breach hereof, shall constitute a waiver of any such term, condition or covenant or of any such breach, nor shall it preclude the Bank from exercising any such right, power or remedy at any later time or times, unless such waiver is in writing signed by an authorized representative of the Bank. If the Bank accepts any payment after its due date, this does not constitute a waiver of the Bank’s right to receive timely payment of all other subsequent amounts or to declare a default for the failure to make any other subsequent payment when due.

Any payment on this Note coming due on a day on which the Bank is not open to conduct full banking business shall be due on the next succeeding business day. Each payment hereunder may be applied to pay interest, principal, late fees or costs as the Bank, in its sole discretion, may determine.

All notices under this Note shall be given as provided in the Loan Agreement.

The Borrower authorizes the Bank to disburse funds represented by this Note to the Borrower and agrees that such disbursement shall be deemed to be full and absolute consideration for the undertaking to make payment hereunder. The Borrower hereby authorizes the Bank to disclose to any subsidiary or affiliate of the Bank, to any fiduciary institution or to any banking institution, credit union or savings and loan association organized under the laws of any State, and hereby authorizes all subsidiaries and affiliates of the Bank, to disclose to the Bank, the financial records of the Borrower.

**THE BORROWER AND THE BANK HEREBY VOLUNTARILY AND KNOWINGLY WAIVE ANY RIGHT THEY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY ACTION, PROCEEDING, OR COUNTERCLAIM BROUGHT BY EITHER PARTY AGAINST THE OTHER ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS NOTE AND THE TRANSACTIONS CONTEMPLATED HEREIN. THE BORROWER ACKNOWLEDGES THAT IT HAS BEEN INFORMED BY THE BANK THAT THE PROVISIONS OF THIS PARAGRAPH CONSTITUTE A MATERIAL INDUCEMENT UPON WHICH THE BANK HAS RELIED, IS RELYING AND WILL RELY IN MAKING THE LOAN. THE BORROWER HEREBY CERTIFIES THAT NO REPRESENTATIVE OR AGENT OF THE BANK (INCLUDING ITS COUNSEL) HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT THE BANK WOULD NOT, IN THE EVENT OF LITIGATION, ENFORCE THIS WAIVER OF RIGHT TO JURY TRIAL. THE BORROWER ACKNOWLEDGES THAT IT HAS CONSULTED WITH AN ATTORNEY AND FULLY UNDERSTANDS THE LEGAL EFFECT OF THE PROVISIONS OF THIS PARAGRAPH.**

This Note shall be governed by and construed under and in accordance with the laws of the State of Maryland (but not including the choice of law rules thereof). The Borrower hereby submits to the non-exclusive jurisdiction of any State of Maryland court or Federal court sitting in the State of Maryland in any action or proceeding arising out of or relating to this Note, and hereby waives any objection it may have to the laying of venue of any such action or proceeding in any of said courts and any claim that it may have that any such action or proceeding has been brought in an inconvenient forum. A final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

Whenever used herein, the word "Borrower" or "Bank" shall be deemed to include, as appropriate, its/his/her respective heirs, personal representatives, successors and assigns. All words used herein shall be deemed to refer to the singular, plural, masculine, feminine or neuter as the identity of the person or entity or the context may require.

Borrower has previously executed and delivered to Bank that certain Promissory Note dated June 29, 2007, in the original principal amount of \$30,000,000.00 (the "Original Note"). In connection with the execution and delivery of this Note, the Original Note shall be hereby terminated and replaced with this Note evidencing a total loan amount of \$22,750,000.00.

(Signature Page Follows)



IN WITNESS WHEREOF, the Borrower has duly executed this Note under seal as of the date and year first hereinabove set forth.

EMERGENT BIODEFENSE OPERATIONS

LANSING INC., formerly known as BioPort Corporation, a Michigan corporation

By: /s/ R. Don Elsey (SEAL)

Name: R. Don Elsey  
Title: Treasurer

**CONSENT OF THE GUARANTOR**

The undersigned Guarantor hereby consents to the terms of this Note and acknowledges it has guaranteed this Note pursuant to the terms of that certain Guaranty executed by the undersigned of even date herewith.

EMERGENT BIOSOLUTIONS INC.,  
a Delaware corporation

By: /s/Jay G. Reilly(SEAL)

Name: Jay G. Reilly

Title: Assistant Secretary



**List of Subsidiaries**

<b>Name of Subsidiary</b>	<b>Jurisdiction of Incorporation or Organization</b>
*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 Manufacturing Operations Meriden LLC	Delaware
Emergent Product Development UK Limited	England
Oxford Emergent Tuberculosis Consortium Limited	England
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 Holding Asia Pte. Ltd.	Singapore
Emergent Commercial Operations Baltimore LLC	Delaware

\*Emergent BioDefense Operations Lansing Inc. has registered to do business as Emergent BioDefense.

**CONSENT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3 No. 333-155311) of Emergent BioSolutions Inc. and Subsidiaries,
- (2) Registration Statement (Form S-8 No. 333-139190) pertaining to the Employee Stock Option Plan, as amended and restated, the 2006 Stock Incentive Plan and individual director options agreements of Emergent BioSolutions Inc. and Subsidiaries, and
- (3) Registration Statement (Form S-8 No. 333-161154) pertaining to the Employee Stock Option Plan, as amended and restated, and the 2006 Stock Incentive Plan of Emergent BioSolutions, Inc.

of our reports dated March 5, 2010, with respect to the consolidated financial statements of Emergent BioSolutions Inc. and Subsidiaries, and the effectiveness of Emergent BioSolutions Inc. and Subsidiaries' internal control over financial reporting, included in this Annual Report (Form 10-K) for the year ended December 31, 2009.

/s/Ernst & Young LLP

McLean, Virginia  
March 5, 2010

## CERTIFICATION

I. Fuad El-Hibri, certify that:

1. I have reviewed this Annual Report on Form 10-K of Emergent BioSolutions Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information, and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 5, 2010

/s/Fuad El-Hibri  
Fuad El-Hibri  
Chief Executive Officer







## CERTIFICATION

I, R. Don Elsey, certify that:

1. I have reviewed this Annual Report on Form 10-K of Emergent BioSolutions Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information, and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 5, 2010

/s/R. Don Elsey  
R. Don Elsey  
Chief Financial Officer





**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Emergent BioSolutions Inc. (the "Company") for the year ended December 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Fuad El-Hibri, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 5, 2010

/s/ Fuad El-Hibri  
Fuad El-Hibri  
Chief Executive Officer



**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Emergent BioSolutions Inc. (the "Company") for the year ended December 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Fuad El-Hibri, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 5, 2010

/s/ R. Don Elsey  
R. Don Elsey  
Chief Financial Officer

