Emergent BioSolutions Inc.
Form 10-K
March 06, 2009

**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, 2008**

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** | **14-1902018** |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (IRS Employer Identification No.) |
| **2273 Research Boulevard, Suite 400** | |
| **Rockville, Maryland** | **20850** |
| (Address of Principal Executive Offices) | (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 | Name of Each Exchange on Which Registered |
|---|---|
| **Common stock, $0.001 par value per share** | **New York Stock Exchange** |
| **Series A junior participating preferred stock purchase rights** | **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

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

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 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, 2008 was approximately $131,173,000 based on the price at which the common stock was last sold on that date as reported on the New York Stock Exchange.

As of February 27, 2009, the registrant had 30,171,613 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant s definitive proxy statement for its 2009 annual meeting of stockholders scheduled to be held on May 21, 2009, 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, 2008, 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 2009 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®, s*pi*-VEC , MVAtor and Typhella are our 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, 2008**

**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 exp 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 and procurement contract with the U.S. government, for our recombinant protective antigen anthrax vaccine candidate, or rPA vaccine;
- our plans to expand our manufacturing facilities and capabilities;
- the rate and degree of market acceptance and clinical utility of our products;
- our ongoing and planned development programs, preclinical studies and clinical trials;
- our ability to identify and acquire or in-license products and product candidates that satisfy our selection criteria;
- the potential benefits of our existing collaboration agreements and our ability to enter into selective additional collaboration arrangements;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property portfolio; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this 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 and filed as exhibits hereto, completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

**PART I**

**ITEM 1. BUSINESS**

**Overview**

We are a biopharmaceutical company focused on the development, manufacture and commercialization of vaccines and immune-related therapeutics that assist the body s immune system to prevent or treat disease. We develop vaccines and therapeutics for use against biological agents that are potential weapons of bioterrorism and biowarfare and infectious diseases that have resulted in significant unmet or underserved public health needs. We manufacture and market BioThrax®, also referred to as anthrax vaccine adsorbed, the only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. BioThrax is approved for pre-exposure prevention of anthrax infection by all routes of exposure, including inhalation. We also seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements and collaborations with third parties.

In addition to our licensed BioThrax product, we have product candidates in advanced stages of development and earlier stages of development. Our advanced stage product candidates, which are in Phase II through Phase IV clinical development, which include enhancements to BioThrax, include the following:

*rPA vaccine* an injectable vaccine that is composed of a purified recombinant protein with an alum adjuvant;

*Anthrax immune globulin therapeutic* an intravenous therapeutic antibody product for the treatment of symptomatic anthrax infection, which we are developing in part with funding from the National Institute of Allergy and Infectious Diseases, or NIAID, for which we expect to initiate pivotal human and animal studies in 2009;

*Tuberculosis vaccine* a single-dose, injectable vaccine for use in persons who have been previously vaccinated with Bacille Calmett-Guerin, or BCG, the only vaccine currently available against tuberculosis, for which we anticipate commencing a Phase IIb clinical trial in South Africa in the first half of 2009, 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;

*Typhella (typhoid vaccine live oral ZH9)* a single-dose, drinkable vaccine which 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 a Phase II clinical trial in Vietnam, and for which we are conducting an ongoing clinical trial in the U.S.;

*Hepatitis B therapeutic vaccine* a multiple-dose, drinkable therapeutic vaccine for the treatment of chronic carriers of hepatitis B infection, for which we have completed a Phase I clinical trial in the United Kingdom and are conducting a Phase II clinical program; and

*BioThrax enhancements* label expansions to authorize BioThrax as a post-exposure prophylaxis against anthrax infection in combination with antibiotic treatment, to extend expiry dating from three years to four years and to reduce the number of required doses from five to three, which we are developing with funding from the U.S. Department of Health and Human Services, or HHS.

Our product pipeline also includes the following earlier stage product candidates:

*Advanced BioThrax vaccine* an anthrax vaccine product candidate that would incorporate one or more advanced characteristics articulated by the Biomedical Advanced Research and Development Authority, or BARDA, such as a reduced number of doses, room temperature storage, novel adjuvants, an enhanced immune response, longer expiry dating and a novel delivery method, which we are developing in part with funding from NIAID and BARDA;

*Anthrax monoclonal antibody therapeutic* a human monoclonal antibody product candidate being developed as an intravenous treatment for patients who present symptoms of anthrax disease, which we are developing in part with funding from NIAID and BARDA;

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*Recombinant botulinum vaccine* a prophylactic vaccine product candidate to protect against illness caused by botulinum toxin, which we are developing in collaboration with the United Kingdom Health Protection Agency, or HPA; and

*Chlamydia vaccine* a vaccine for administration to adolescents designed to prevent disease caused by clinically relevant strains of *Chlamydia trachomatis.*

We have derived substantially all of our product sales revenues from BioThrax sales to 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. Revenues from product sales of BioThrax were $169.1 million in 2008, $169.8 million in 2007 and $148.0 million in 2006. 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.

We also seek to advance development of our product candidates through external funding arrangements. Revenues from contracts and grants were $9.4 million in 2008, $13.1 million in 2007 and $4.7 million in 2006. 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 immune-related therapeutics. We are focused on four key strategic priorities to achieve this goal and drive our long-term growth. These priorities are:

*Expand biodefense franchise.* Our biodefense business provides several advantages. 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 our biodefense product candidates 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, expanding the market for BioThrax to other customers domestically and internationally and pursuing label expansion improvements for BioThrax. Other product candidates in our biodefense franchise, such as our anthrax immune globulin 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 delivery platform technologies optimizes our research and development investment. Our *spi*-VEC technology is based on our live attenuated typhoid vaccine and employs recombinant technology to insert the gene encoding vaccine antigens or therapeutic proteins into the live attenuated Salmonella bacteria. Our 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 *spi*-VEC and MVA platforms, and may consider opportunistic acquisitions of additional platform technologies.

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*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 new 50,000 square foot manufacturing facility on our Lansing campus. In the event that we obtain an award for the development and procurement of our rPA vaccine candidate, we currently expect to use the new facility for the manufacture of our rPA vaccine product candidate. We designed the plant to be campaignable, or capable of manufacturing multiple fermentation based products, 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 rPA vaccine. 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 mergers and 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 that are based on platform technologies and are either in Phase III clinical trials or well positioned for entry into Phase III clinical trials in the near term as well as in-license one or more novel antigens for development using our platform technologies. Additionally, we may announce, from time to time, the acquisition or license of 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 therapeutics, has grown dramatically as a result of the increased awareness of the threat of global terror activity in the wake of the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. The U.S. government is the principal source of worldwide biodefense spending. Most U.S. government spending on biodefense programs is in the form of development funding from NIAID, BARDA and the DoD, 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, and 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. governments 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 there have been 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 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 disease caused by a specific pathogen. Following vaccination against specific disease, the immune system s memory of antigens induced by the vaccine allows for an immune response to be generated against a future response to a pathogen in order to provide protection against disease. A therapeutic vaccine is slightly different in that it acts to strengthen or modify the immune response in patients already infected with bacterial and viral pathogens in order to clear the pathogens from the infected host. Without treatment, such patients can be subject to recurring bouts of the disease.

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 protective antibodies, known as IgG. These 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 effect. However, unlike immune globulins, monoclonal antibodies are specific to a single antigen and are generally produced in cell culture rather than collected from humans. Monoclonal antibodies are also 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 advanced and earlier stage product candidates. We use multiple technologies to develop our product candidates, including conventional and recombinant technologies. For each development program, we select and apply the technology that we believe is best suited to address the particular disease based on our evaluation of factors such as safety, efficacy, manufacturing requirements, regulatory pathway and cost. We currently hold all commercial rights to BioThrax and all of our product candidates, other than our recombinant botulinum vaccine, for which HPA has the non-exclusive right to make, use and sell to meet public health requirements in the United Kingdom.

| **Product or Product Candidate** | **Prophylactic or Therapeutic** | **Stage of Development** |
|---|---|---|
| BioThrax ® (Anthrax Vaccine Adsorbed) | Pre-exposure prophylactic | FDA approved |
| | Post-exposure prophylactic* | Post-approval label expansion; animal efficacy and human safety and immunogenicity studies ongoing; BLA supplement planned |
| rPA vaccine* | Pre and post-exposure prophylactic | Phase II |
| Advanced BioThrax vaccine* | Pre and post-exposure prophylactic | Preclinical and Phase I |
| Anthrax immune globulin* | Therapeutic | Pivotal animal studies and pivotal human trial planned for 2009 |
| Anthrax monoclonal antibody* | Therapeutic | Preclinical |

| | | |
|---|---|---|
| Typhella (typhoid vaccine live oral ZH9) | Prophylactic | Phase II |
| Tuberculosis vaccine | Prophylactic | Phase II |
| Hepatitis B therapeutic vaccine | Therapeutic | Phase II |
| Recombinant botulinum vaccine* | Prophylactic | Preclinical |
| 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 vaccine candidates can be considered definitive until all clinical trials needed to support a submission for marketing approval are completed and a license granted. 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 vaccine candidates will be successful. A failure of one or more of our clinical trials can occur at any stage of testing.

**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 of the spores. Once inside the body, anthrax spores germinate into bacteria that then multiply. Anthrax bacteria secrete three proteins: protective antigen, lethal factor and edema factor, which individually are non-toxic but can become highly toxic if allowed to interact on the surface of human or animal cells.

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

Inhalational anthrax is the most lethal form of anthrax. We believe that aerosolized anthrax spores are the most likely method to be used in a potential anthrax bioterrorism attack. Inhalational anthrax has been reported to occur from one to 43 days after exposure to aerosolized spores. Initial symptoms of inhalational anthrax are non-specific and may include sore throat, mild fever, cough, 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 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 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 countermeasures.

The only FDA-approved product for pre-exposure prophylaxis against anthrax infection is BioThrax. The only FDA-approved products for post-exposure prophylaxis against anthrax infection 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. Nor are antibiotics effective 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 bacteria following the end of antibiotic treatment and lead to infection. 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 recommends 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 infection 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, as discussed below, we are actively 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.

*Anthrax Vaccines*

*BioThrax.* BioThrax is the only FDA-approved vaccine for the prevention of anthrax infection. It is approved by the FDA as a pre-exposure prophylaxis for use in adults who are at high risk of exposure to anthrax spores. BioThrax is manufactured from a 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, or alum, 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 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, Guillian Barre syndrome, lupus, multiple sclerosis, lymphoma and death, have not been causally linked to the administration of BioThrax. In December 2008, the FDA approved our supplemental biologics license application, or BLA, to provide for intramuscular injection of BioThrax instead of subcutaneous injection and to reduce the number of required doses of BioThrax for pre-exposure prophylaxis from six to five, with an annual booster dose thereafter. We are actively pursuing additional label expansions and improvements for BioThrax, including the following:

- *Reduced dosing schedule.* The FDA s approval of our supplemental BLA in December 2008 for a five-dose regimen, with an annual booster thereafter, was based on an analysis of interim data from an ongoing clinical trial being conducted by the CDC to evaluate whether as few as three doses of BioThrax, administered over six months, with booster doses up to three years apart, will confer an adequate immune response. If the final data from the CDC dose-reduction trial support a further reduction of doses, we plan to file an additional BLA supplement with the FDA for approval of a three-dose regimen, with booster doses thereafter up to three years apart.
- *Extended expiry dating.* The current FDA-approved expiry dating for BioThrax is three years. In December 2006, based on data generated from our ongoing stability studies, we submitted a supplemental BLA to extend the expiry dating of BioThrax from three years to four years, which, if granted, would allow BioThrax to be stockpiled for a longer period of time. This application is still pending and we continue to discuss with the FDA the requirements for approval of this supplement. We anticipate that this application will be approved in 2009.
- *Expanded label indication to include post-exposure prophylaxis.* We plan to seek approval of BioThrax for post-exposure prophylaxis against anthrax infection, to be administered along with antibiotics. In October 2007, we completed a human clinical trial of BioThrax for the post-exposure indication using the anticipated dosing schedule of three doses of BioThrax given two weeks apart. The purpose of this trial was to collect data that, in combination with data from our non-clinical studies, will be used to design our pivotal human clinical trial for this indication. We are currently conducting non-clinical studies for the post-exposure indication pursuant to the FDA animal rule. In these studies, we are evaluating the effect of a humanized dose of BioThrax in combination with antibiotics compared to antibiotics alone in rabbits exposed by inhalation to anthrax spores. We may also conduct one or more pivotal studies in non-human primates.

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 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 infection. 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.

*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 alum adjuvant and is designed to induce antibodies that neutralize anthrax toxins in a manner similar to BioThrax. The vaccine candidate is based on development work at U.S. Army Medical Research Institute of Infectious Disease, or USAMRIID. Our rPA vaccine candidate has been the subject of two research and development grants totaling approximately $100 million from NIAID. The vaccine candidate has completed one Phase II clinical trial, but this trial did not achieve statistically significant results due to product stability issues. We believe that the stability issues have since been resolved, and we do not believe that future trials will be adversely affected by stability concerns. BARDA has issued a request for proposal for a recombinant protective antigen anthrax vaccine for the SNS, which would provide for development funding and the procurement of up to 25 million doses of rPA vaccine. We have submitted a proposal responding to this request, have been advised that our proposal is in the competitive range, and continue to negotiate the terms of a definitive contract award with BARDA. BARDA has informed us that it anticipates awarding an rPA contract to at least one bidder by the end of the first half of 2009. We anticipate this contract may be as large as $400 million to $600 million.

*Advanced BioThrax Vaccine.* We are developing an anthrax vaccine product candidate based on BioThrax combined with an adjuvant, known as CpG 7909, which we license from Pfizer, Inc. We anticipate that this candidate would incorporate advanced characteristics, including one or more of the following: reduced number of doses, room temperature storage, enhanced immune response, longer expiry dating or a novel delivery method. We have obtained additional U.S. government funding to supplement the further development of this vaccine candidate. The DoD s Defense Advanced Research Projects Agency, or DARPA, previously funded a double-blind Phase I clinical trial of BioThrax combined with CpG 7909 pursuant to a collaboration with us and Coley Pharmaceuticals, which owned CpG 7909 before its sale to Pfizer. 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. In this trial, BioThrax combined with CpG 7909 elicited an enhanced immune response.

The results of a clinical trial are statistically significant if they are unlikely to have occurred by chance. We determined the statistical significance of the 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 efficacy and are neither required nor sufficient to enable a product candidate to proceed to Phase II clinical development. Phase I clinical trials are required to establish the safety of a product candidate, not its immunogenicity, before Phase II clinical trials may begin.

The immunogenicity parameters for 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.

*Anthrax Therapies*

*Anthrax Immune Globulin Therapeutic.* We are developing a human anthrax immune globulin therapeutic product as a treatment for patients who present with symptoms of anthrax disease. We expect that, if approved, this product would be prescribed as a single-dose 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 anthrax immune globulin therapeutic product candidate at its FDA-approved facilities. We have manufactured two full-scale lots of this product candidate under current good manufacturing practices, or cGMP, using a validated and approved process at Talecris. We plan to rely on the FDA s animal rule to support approval of our anthrax immune globulin therapeutic product candidate.

We currently are conducting efficacy studies of this product candidate in infected rabbits, and we plan to commence further non-clinical efficacy studies in 2009. In March 2007, we filed an IND for a Phase I clinical trial to evaluate the safety and pharmacokinetics of our anthrax immune globulin therapeutic candidate in healthy human volunteers. We expect to commence this clinical trial in 2009. NIAID has provided us grant and contract funding of up to $13.4 million 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 believe that favorable data from the non-clinical efficacy studies and safety and pharmacokinetic data from the human clinical trial would be sufficient to support an application to the FDA for marketing approval of this product candidate.

*Anthrax Monoclonal Antibody Therapeutic.* In addition to our anthrax immune globulin therapeutic product candidate, which is a polyclonal antibody therapeutic, we are developing a monoclonal antibody therapeutic. This human monoclonal antibody product candidate is being developed as an intravenous treatment for patients who present with symptoms of anthrax disease and is being funded in part under a contract from NIAID and BARDA to support efficacy testing in non-clinical studies and the establishment of cGMP manufacturing process. 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 product candidate is deemed to be licensable.

**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 World Health Organization, or 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, that contains deletions in two genes of the *Salmonella typhi* bacterium designed to attenuate virulence and replication. 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 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 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 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, which is suggestive of systemic protective immunity, and 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, which is suggestive of mucosal protective immunity. In the aggregate, 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 vaccine 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. Preliminary data analysis suggests the vaccine was well tolerated and capable of producing an immune response. The clinical study report is being prepared.

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, the remainder of our planned clinical development program for this vaccine 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 study.

*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 the Phase III trial. The Wellcome Trust has provided funding for 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 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 study.

*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.

**Tuberculosis**

*Disease overview.* Tuberculosis, or TB, is an infection with *Myobacterium tuberculosis,* which manifests primarily as an illness of the respiratory system and is spread by coughing, sneezing and associated respiratory actions. According to the 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 *Myobacterium tuberculosis* worldwide in 2005, one third of the world s population. 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 pulmonary 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 2 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, an even more deadly form of 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 *Myobacterium tuberculosis* complicates treating the infection, indicating that a vaccine may be the most appropriate countermeasure for controlling TB.

*Tuberculosis Vaccine.* Our tuberculosis vaccine candidate uses the attenuated Modified Vaccinia virus Ankara, or MVA, as a vaccine delivery platform to present antigen 85A to the immune system. Antigen 85A is a major antigen from *Myobacterium 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 previously vaccinated with BCG. The vector, or carrier, MVA is a weakened strain of the smallpox vaccine and a highly attenuated strain of Vaccinia virus 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 has been designed to increase the immune response and 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-naïve, 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 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, two 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 selction and non-interference study intended to involve approximately 471 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 EPI vaccines administered simultaneously to infants previously vaccinated with BCG is underway. In South Africa, an open label, non-randomized placebo-controlled Phase II trial with approximately 168 subjects is ongoing to evaluate the safety and immunogenicity of MVA85A in healthy children and infants who received prior BCG vaccination.

A Phase IIb trial in infants is anticipated to start in South Africa in the first half of 2009. This trial is planned to include 2,784 infants in a double-blind, randomized placebo-controlled evaluation of MVA85A/AERAS-485 for safety, immunogenicity and prevention of TB in BCG-vaccinated, HIV-negative infants. The trial is planned to be conducted at a single site in South Africa and infants will be followed both for the development of tuberculosis and for serious adverse events.

**Hepatitis B**

*Disease overview.* Hepatitis B is a highly infectious virus transmitted from person to person by contact with blood and bodily fluids. Most hepatitis B infections in adults result in acute hepatitis, with the immune system eventually clearing the infection. However, in approximately 8% to 10% of infected adults and a much larger proportion of infected children, the immune system fails to clear the virus, resulting in immune tolerance of the virus and chronic infection. In addition, pregnant women suffering from hepatitis B can pass the infection on to their babies during childbirth. Babies born infected rarely clear the infection, with over 90% becoming chronically infected. According to the WHO, as many as 40% of people with chronic hepatitis B infection develop serious liver disease, including cirrhosis and liver cancer.

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

Prophylactic vaccines based on recombinant protein subunit preparations are effective in preventing hepatitis B infection. Childhood vaccination with these vaccines is common in industrialized countries and in some of the developing world. Childhood immunization programs have reduced the number of chronic carriers of hepatitis B infection by up to 90% in parts of the world where hepatitis B is most common. In the United States, infection rates for acute hepatitis B have decreased by approximately 77% over the past 20 years. However, these existing vaccines have not proven to be effective in treating people with chronic hepatitis B infection. As a result, there remains a significant number of people who are chronically infected with hepatitis B and require treatment to prevent the development of liver disease and to reduce the risk of transmitting the infection to others.

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

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

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

We have completed a preclinical program of pharmacology and toxicity studies of our hepatitis B therapeutic vaccine candidate. In mice that were administered our vaccine candidate, the hepatitis B core antigen was produced and immune responses were elicited against the antigen. In

separate toxicology studies also conducted in mice, our vaccine candidate was non-toxic.

In February 2004, we completed an open-label, dose escalating Phase I clinical trial of our vaccine candidate in the United Kingdom in 30 healthy adult volunteers to evaluate the safety and immunogenicity of two dose levels of our vaccine candidate. The vaccine candidate demonstrated immunogenicity and was well tolerated by trial participants, with no serious adverse events reported.

In the fourth quarter of 2006, we initiated a Phase II clinical trial of our vaccine candidate in trial participants chronically infected with the hepatitis B virus in the United Kingdom, which we subsequently expanded to Serbia to increase the rate of participant recruitment. In the second quarter of 2008, we ceased enrolling patients in this trial as a result of recruiting difficulties related to the standard of care in the developed world because we administer our product candidate as a monotherapy. As a result, we will not obtain statistically meaningful data from this trial. We are currently seeking to identify alternative trial sites in endemic areas of the world where we anticipate recruitment rates will be higher.

**Botulinum**

*Disease overview.* Botulism is a frequently fatal disease caused by botulinum toxins produced by the bacterium *Clostridium botulinum.* *Clostridium botulinum* is widely distributed in soil and aquatic environments throughout the world. Botulinum bacteria produce seven distinct serotypes, each of which elicits a distinct antibody response. Naturally occurring outbreaks of botulism in humans have been reported from exposure to four of the seven serotypes: A, B, E and F. Botulism normally occurs when an individual consumes contaminated food containing botulinum toxin. Once consumed, the toxin rapidly attacks nerve cells, resulting in paralysis of peripheral muscles, including the muscles involved in respiration. Botulism can also be contracted if botulinum bacteria contaminate wounds or colonize the intestine of infants, which is referred to as infant botulism. Botulinum toxins are among the most potent and dangerous of biological weapons. Exposure to very small quantities of botulinum toxin can cause the rapid onset of life threatening paralytic disease syndrome. It has been estimated that a single gram of toxin evenly dispersed and inhaled could kill more than one million people.

*Prevalence, market opportunity and current treatment.* As with anthrax countermeasures, we believe that the U.S. government and foreign, state and local governments will be the principal potential customers for botulinum countermeasures, including both vaccines and therapeutics. Because purified botulinum toxin is stable and extremely potent when administered in very small quantities, it has the potential to be used as a biological weapon, either through deliberate contamination of the food supply or drinking water or as an aerosol.

Currently, there is no FDA-approved botulinum vaccine on the market, although the DoD has provided development funding to a competitor of ours for the development of a recombinant botulinum vaccine that addresses two of the seven serotypes of botulinum neurotoxin. These two botulinum serotypes, A and B, are responsible for approximately 85% of all cases of botulism. Because of the rapid onset of symptoms following exposure to the botulinum toxin, prophylactic vaccines, which take several weeks to mount an effective protective immune response, are not useful as post-exposure treatments for botulism. In addition, antibiotics are not effective post-exposure treatments since they work by killing the botulinum bacteria that produce the toxin, but do not act directly against the botulinum toxin itself. Currently, the only FDA-approved treatment for botulism is a human botulinum immune globulin product for the treatment of infant botulism caused by type A or type B *Clostridium botulinum.* The supply of this product is limited. The product was derived from plasma taken from individuals who had been vaccinated with an experimental pentavalent botulinum toxoid vaccine that is no longer in production. In addition, the CDC manages a supply of experimental botulinum immune globulin derived from equine plasma. However, the experimental equine immune globulin is subject to at least two shortcomings. First, because the human body recognizes the equine immune globulin as a foreign substance, its efficacy may be limited. Second, the antibody immune response against the equine immune globulin can lead to potential severe side effects, including anaphylactic shock, if the equine immune globulin is administered more than once. To screen for sensitivity to the equine immune globulin, patients are given small challenge doses of the equine immune globulin before receiving a full dose. HHS has awarded a development and supply contract to a competitor of ours for development and supply of a botulinum immune globulin derived from equine plasma that addresses all seven serotypes of botulinum neurotoxin.

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*Recombinant Botulinum Vaccine.* We are developing a recombinant protein subunit trivalent botulinum vaccine for protection against botulinum serotypes A, B and E in collaboration with HPA. We hold an exclusive license from HPA for use of recombinant technology in the development of our vaccine candidate. HPA is also providing us with process development expertise and access to its facilities. We are designing this vaccine candidate to be administered by intramuscular injection with an alum adjuvant in a three-dose regimen. Our recombinant vaccine candidate is based on fragments of the botulinum A, B and E toxins that we have selected as antigens because we believe them to be non-toxic and immunogenic.

We are producing these recombinant antigens in an *E. coli* expression system. We believe that our technology will allow us to develop stable monovalent and multivalent vaccine products capable of producing neutralizing antibody to all three toxin types. We have established a small scale production process for botulinum serotypes A, B, and E vaccines and have conducted preclinical proof-of-concept studies of these vaccine candidates. In these studies, the individual vaccines elicited antibodies and provided protection against challenge with the corresponding botulinum toxin. Additionally, a trivalent vaccine composed of the A, B and E individual vaccines was seen to elicit neutralizing antibody against all three toxin types. We anticipate that the manufacture of our recombinant vaccine in a cGMP facility will not require the high level of containment that is required for the production of conventional, non-recombinant botulinum toxoid vaccines that involve cultivation of the disease-causing organism.

Additionally, we have rights to develop a human botulinum immune globulin therapeutic product as intravenous therapeutic for symptomatic botulinum exposure. We believe that botulinum immune globulin has the potential to provide immediate protection from the effects of botulinum toxin.

We plan to rely on the FDA animal rule in connection with the development of our recombinant botulinum vaccine candidate. We have been awarded U.S. government grant funding from NIAID to support the further development of our recombinant botulinum vaccine candidate. We will continue to assess, and may alter, our future development plans for this product based on the U.S. government s interest in providing development funding for, and procuring, botulinum countermeasures.

**Chlamydia**

*Disease overview.* Chlamydia is the most prevalent sexually transmitted bacterial disease in the world. It is caused by infection with the bacterium *Chlamydia trachomatis. Chlamydia trachomatis* can cause urogenital disorders such as uritheritis, cervicitis, pelvic inflammatory disease, ectopic pregnancy and infertility among females and is the leading cause of non-gonococcal uritheritis and epidemiditis in males. *Chlamydia trachomatis* also causes the ocular disease trachoma, which is a form of vesicular conjunctivitis. Trachoma is the leading cause of preventable blindness worldwide.

*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 effective antibiotic treatments have been effective at containing *Chlamydia trachomatis* in the United States and Europe. Although *Chlamydia trachomatis* infection can be treated with antibiotics, control measures based on antimicrobial treatment alone are difficult due to the incidence of infection, the percentage of asymptomatic infections and deficiencies in diagnosis.

*Chlamydia Vaccine.* We are developing a recombinant protein subunit Chlamydia vaccine for clinically relevant strains of *Chlamydia trachomatis,* including strains that cause ocular disease. We are designing our vaccine candidate to be administered by injection with a novel adjuvant in a three-dose regimen. We are currently evaluating in-license opportunities for the adjuvant. We have cloned our vaccine candidate and produced it in *E. coli.* In preclinical studies, our vaccine candidate protected against both upper reproductive tract disease and lower reproductive tract infection induced by *Chlamydia trachomatis.*

**Manufacturing**

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 new 50,000 square foot manufacturing facility on our Lansing campus. We have incurred costs of approximately $75 million through December 2008 for the building and associated capital equipment, as well as for validation and qualification activities required for regulatory approval and initiation of manufacturing. Although we have made progress on qualification and validation activities required for the commercial manufacture of BioThrax, we currently believe that we may use the facility for the manufacture of our rPA vaccine candidate in the event that we are awarded a development and procurement contract for our rPA vaccine candidate from HHS. We designed the plant 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 vaccine candidate. In the event we do not get an award for the development and procurement of our rPA vaccine candidate, we intend to use the facility for the manufacture of BioThrax and potentially additional products.

We also own two buildings in Frederick, Maryland that are available to support our future manufacturing requirements. We have incurred costs of approximately $4 million through December 2008 related to initial engineering design and preliminary utility build out of one of these buildings. Moving forward with our plans for this building will be contingent on progress of our existing development programs or the acquisition of new product candidates. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project. However, we may elect to lease or sell one or both of these facilities to third parties.

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

Hollister-Stier Laboratories LLC performs the contract filling operation for BioThrax 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 has agreed to perform plasma fractionation and purification and contract filling of our anthrax immune globulin therapeutic candidate for preclinical, clinical and commercial use 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 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 royalties on net sales on a country-by-country basis for commercial product manufactured by Talecris under the contract. Our contract with Talecris expires December 31, 2014. We have the option to extend the term for an additional five-year period upon notice to Talecris at least 12 months prior to the expiration of the initial term. After three years following initiation of commercial manufacturing, either party may terminate the contract upon two years advance notice. We have the right to terminate the contract, under specified circumstances, if we discontinue our production of anthrax immune globulin source plasma or the development of our anthrax immune globulin therapeutic candidate. Talecris is in the process of being acquired by CSL. We do not anticipate that this acquisition will have an adverse impact on our relationship with Talecris.

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 candidate for future trials. We are in the process of identifying a new contract manufacturer for our monoclonal anthrax antibody 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.

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

**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, and a joint venture in Malaysia, 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 Crucell, Cangene, Human Genome Sciences, Dor BioPharma, Dynport Vaccine Company LLC, Elusys, Bavarian Nordic 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 commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop.

Any product candidate that we successfully develop and commercialize is likely to compete with currently marketed products, such as vaccines and therapeutics, including antibiotics, and with other product candidates that are in development for the same indications. 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 this vaccine 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, 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 and has submitted a response to the same BARDA request for proposal for the procurement and development of an rPA vaccine to which we have responded. PharmAthene has announced that their proposal has been deemed to be technically acceptable and within the competitive range. Panacea is also developing an rPA vaccine.

*Anthrax immune globulin and monoclonal 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.

*Botulinum.* In April 2005, the DoD provided additional funding to DynPort Vaccine Company LLC for the continued development of a recombinant bivalent botulinum vaccine for protection against botulinum serotypes A and B. This vaccine is called bivalent because it addresses two of the seven serotypes of botulinum neurotoxin. In June 2006, HHS awarded a five-year development and supply contract with a base value of $362 million to Cangene for a heptavalent botulinum immune globulin derived from equine plasma. The contract provides for the supply of 200,000 doses of a botulinum immune globulin for the SNS.

*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 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 candidate.

*Hepatitis B therapeutic vaccine.* Currently available therapies for this patient population consist mainly of antiviral drugs and immunotherapies, such as interferons. There are multiple follow on antiviral immunotherapies as well as therapeutic vaccines being developed by potential competitors.

*Chlamydia vaccine.* There is no vaccine currently on the market for chlamydia. Although we are not aware of any competing chlamydia vaccine candidate in clinical development, competitors may have chlamydia vaccine 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 27, 2009, we owned or licensed exclusively a total of 34 U.S. patents and 43 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, from OETC relating to our tuberculosis vaccine product candidate and from HPA relating to our recombinant botulinum vaccine 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 candidates that are in clinical development.

*Typhella (typhoid vaccine).* We hold three U.S. patents relating to Typhella. These patents have claims to the composition of matter of the vaccine 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 93 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 33 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.

*Hepatitis B therapeutic vaccine.* Our hepatitis B therapeutic vaccine candidate uses our proprietary *spi*-VEC oral delivery system technology to deliver hepatitis B core antigen to the human immune system. *spi*-VEC is based on our live attenuated typhoid vaccine candidate and employs recombinant technology to insert the gene for hepatitis B core antigen into the live attenuated *Salmonella* bacteria. As a result, the patents relating to Typhella also protect our hepatitis B therapeutic vaccine candidate. In addition, we hold one U.S. patent with claims to the use of attenuated *Salmonella* organisms for the delivery of hepatitis B vaccine antigens, which expire in 2019.We also have two pending U.S. patent applications relating to our hepatitis B therapeutic vaccine candidate, which if issued also would expire in 2019. We have 18 foreign counterparts to our issued U.S. patent under the European Patent Convention that expire in 2019, and four foreign patent applications relating to our hepatitis B therapeutic vaccine candidate that, if issued, would expire in 2019.

*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 and hepatitis B therapeutic vaccine candidates. We also own 48 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 17 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 typh*i 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 consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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, OETC, and HPA, which are described below. We also have a license agreement with the Bavarian State Ministry of the Environment, Public Health and Consumer Protection, or StMUGV, relating to 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 candidate in May 2008, we have become a licensee under an October 2003 agreement with USAMRIID pursuant to which we have exclusive worldwide rights to develop, manufacture and commercialize product candidates falling within the scope of a valid claim of the licensed patent technology, for human use as a vaccine for the prevention or treatment of anthrax infection. The licensed patent technology includes two U.S. patents that cover the strain of *B. anthrasis* used to prepare our rPA vaccine 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 an annual license fee, payments upon the achievement of certain development and regulatory milestones, and royalties on sales of licensed products 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. 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.

*OETC agreement*. In July 2008, we entered into a technology licensing 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 three foreign patents and 25 foreign patent applications which, if issued as patents, would expire in 2025.

Under the OETC license, we were required to pay OETC a signing fee, and are required to make payments upon the achievement of certain development, regulatory and sales milestones and royalties on sales of the licensed product in developed countries. We must also reimburse a portion of the patent costs incurred by the University of Oxford and Isis Innovation Limited in the past and reimburse OETC for future patent costs in certain developed countries. We have also agreed that in order to retain our commercial license rights, if the planned Phase IIb trial of the licensed product in infants is successful, we will meet all costs and expenses of a Phase III clinical trial of the licensed product in infants.

Under the OETC license, we are generally required to do the following: 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 certain price levels and 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 certain level of annual sales of the licensed product in the developed world.

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

The licensed patent portfolio includes three U.S. patents with claims to the composition of matter of recombinant components of *Clostridium botulinum,* and the use of such components in vaccines for the treatment or prevention of *Clostridium botulinum* infection or toxicity. These patents expire in 2016. Additional composition of matter and method of use claims are pending in seven U.S. patent applications, which if issued as patents also would expire in 2016. The licensed portfolio also includes 31 foreign patents and 11 foreign applications, which if issued would expire in 2016.

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

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

In November 2004, we also entered into two separate development agreements with HPA pursuant to which HPA agreed to conduct specified tests, studies and other development activities with respect to our recombinant botulinum vaccine and a botulinum toxoid product in accordance with mutually-agreed development plans. We have paid minimum contractual commitments of $1.0 million under each development agreement to compensate HPA for this development work. HPA also agreed to provide us with clinical supplies of recombinant botulinum vaccine and botulinum toxoid product for clinical trials.

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

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

The license agreement does not have a specified term. In addition, StMUGV may terminate the license agreement upon the insolvency or liquidation of our wholly owned subsidiary, Emergent Product Development GmbH, formerly ViVacs GmbH. 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 and biological products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, recordkeeping, approval, advertising, sale, promotion, import, and export of our 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. Biologics are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, or the PHSA, the regulations promulgated under the FDCA and the PHSA and other federal, state, and local statutes and regulations. Violations of regulatory requirements at any stage may result in various adverse consequences, including delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions, including withdrawal of product approval, labeling restrictions, seizure of products, fines, injunctions and civil and criminal penalties.

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

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

**Preclinical Studies and the IND**

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

**Clinical Trials**

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

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

Clinical trials must be conducted in compliance with good clinical practice, or GCP, requirements. 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 be phased-in over the next two years. Some states have similar clinical trial reporting laws.

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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, 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 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 biologic, 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 a manufacturing inspection, approves the applicable manufacturing process for the drug or biological product and determines that the facility is in compliance with cGMP requirements. If the manufacturing facilities and processes fail to pass the FDA inspection, we will not receive approval to market these products.

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

**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 programs, one of which is Fast Track designation, are designed to facilitate the development and review of new drugs and biologics 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 or biologic 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. Products in Fast Track drug development programs also may receive priority review or accelerated approval and sponsors may be able to submit portions of an application before the complete application is submitted. 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.

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**Ongoing Regulation**

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

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

The FDA s rules for advertising and promotion require in particular that we not promote our products for unapproved uses and that our promotion be fairly balanced and adequately substantiated. We must also submit appropriate new and supplemental applications and obtain FDA approval for certain planned changes to the approved product, product labeling or manufacturing process.

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

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

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

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**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 biologic, 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 and 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 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 Institutional Review Board approval or to an IND, depending on factors such as whether donors are to be vaccinated according to the vaccine s approved schedule. The FDA also regulates the process of testing, storage and processing of source plasma, which is used to manufacture immune globulin candidates for use in clinical trials and, after approval by the FDA, for commercial distribution.

**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 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 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. 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.

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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 for 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.

**Foreign Regulation**

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

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

Unlike the United States, the European Union member states do not have separate rules or review procedures for biologics and vaccines. Regulators apply broadly consistent principles and standards when reviewing applications, although they accept that the nature of the efficacy data supporting a vaccine application is likely to differ from the data that would support applications for the majority of therapeutic products. However, there are special procedures for some types of vaccine products. For example, influenza vaccines are subject to accelerated review and approval each year following the release by the 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**

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

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

The European Union operates an equivalent system to encourage the development and marketing of medicinal products for rare diseases. Applications for orphan designations are submitted to the 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.

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 Community when the application is made or a life-threatening, seriously debilitating; or (ii) a serious and chronic condition in the European Community for which, without incentives, it is unlikely that the marketing of the product in the European Community would generate sufficient return to justify the necessary investment. In either case, the applicant must also demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition. 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 Community for an orphan product, no similar product may be approved for a period of ten years. At the end of the fifth year, however, any member state can initiate proceedings to restrict that period to six years if it believes the criteria for orphan designation no longer apply, for example, because the prevalence of disease has increased or the manufacturer is earning an unreasonable profit. In addition, competitive products can be approved during the marketing exclusivity period if they are not similar to the original product or even if they are similar, are safer, more effective or otherwise clinically superior to it.

Our tuberculosis vaccine product candidate has been designated as an orphan drug.

**Reimbursement and Pricing Controls**

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

In the United States, there is 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 Veterans Administration, DoD, and the 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 and biologics to enable them to be eligible for reimbursement. Vaccines are generally exempt from these rebate requirements, vaccines for Medicaid-eligible children 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 and biologics 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 and biologic prices, including by disfavoring higher priced products and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products.

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

Most non-pediatric commercial vaccines are purchased and paid for, or reimbursed by, managed care organizations, other private health plans or public insurers or paid for directly by patients. In the United States, pediatric vaccines are funded by a variety of federal entitlements and grants, as well as state appropriations. The CDC currently distributes pediatric grant funding on a discretionary basis under the Public Health Service Act. Federal and state governments purchase the majority of all pediatric vaccines produced in the United States, primarily through the 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.

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

**Regulations Regarding Government Contracting**

Our status as a government contractor in the United States and elsewhere means that we are also subject to various statutes and regulations, including the Federal Acquisition Regulation, which govern the procurement of goods and services by agencies of the United States and other countries. These governing statutes and regulations can impose stricter penalties than those normally applicable to commercial contracts, such as criminal and civil damages liability and suspension and debarment from future government contracting. In addition, pursuant to various statutes and regulations, our government contracts can be subject to unilateral termination or modification by the government for convenience in the United States and elsewhere, detailed auditing requirements 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 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 involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS and the DoD.

The Public Health Security and Bioterrorism Preparedness and Response Act and the Agricultural Protection Act require us to register with the CDC and the Department of Agriculture our possession, use or transfer of select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires increased safeguards and security measures for these select agents and toxins, including controlled access 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 addition to the FDA, including the Centers for Medicare and Medicaid Services; other divisions of HHS, such as the Office of Inspector General: the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice and state and local governments. For example, sales, marketing and scientific and educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provisions of the Health Insurance Portability and Accountability Act and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. 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 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, 2008, we had 587 employees, including 169 employees engaged in product development, 269 employees engaged in manufacturing, 11 employees engaged in sales and marketing and 138 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. 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 waive 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 and the 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. In 2006, 2007 and 2008, we derived substantially all of our revenue from our BioThrax contracts with HHS or the DoD. We are currently party to two contracts with HHS to supply doses of BioThrax for placement into the SNS. We are not currently party to a procurement contract with the 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. HHS has issued a Request For Proposals for contracts to develop and procure a recombinant protective antigen based anthrax vaccine which we may not win. Additionally, procurement by HHS of a recombinant protective antigen based anthrax vaccine could reduce demand for BioThrax. 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;
- the risk that the government will issue a request for proposal to which we would not be eligible to respond;
- the risk that third parties may submit protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- the expenses that we might incur and the delays that we might suffer if our competitors protest or challenge contract awards made to us pursuant to competitive bidding, and the risk that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract.

The U.S. government may choose to award future contracts for the supply of anthrax vaccines and other biodefense product candidates that we are developing to our competitors instead of to us. If we are unable to win particular contracts, we may not be able to operate in the market for products that are provided under those contracts for a number of years. For example, BARDA has issued a request for proposal for a recombinant protective antigen anthrax vaccine for the SNS. We have submitted a proposal responding to this request for proposal. We expect that our ability to secure an award will depend primarily on the technical merits of our rPA vaccine candidate. The U.S. government may purchase another company s product candidate instead of our rPA vaccine candidate. 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. Purchases by the U.S. government of an rPA vaccine candidate, whether from us or another company, may reduce demand for BioThrax, perhaps significantly.

***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 new 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.

Our agreements with HHS to supply doses of BioThrax to HHS for placement into the SNS provide that if we receive FDA approval of an application to extend the expiry dating of BioThrax from three years to four years, HHS will increase the price per dose under the agreements. The regulatory approval process is complex and uncertain, and there is no guarantee that we will receive approval of four-year expiry dating. If approved, BioThrax will be the first vaccine to receive FDA approval of four-year dating. If we do not receive FDA approval of four-year expiry dating during the term of either agreement, we will not be entitled to receive the increased price per dose under that agreement and our revenues and operating results may suffer.

***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, such as our potential pending development and procurement contract for rPA, 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 specified in a contract;
- decline to exercise an option to purchase the maximum amount 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.

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***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.***

Future 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 FDA did not make a clear error of judgment in reaffirming the safety and efficacy of BioThrax. In April 2008, the plaintiffs filed a notice of appeal of this decision, and that appeal remains pending.

Although we are not a party to any lawsuits challenging the DoD s mandatory use of the vaccine, 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. In addition, lawsuits brought directly against us by third parties, even if not successful, 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 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 the timing of our fulfilling orders from the U.S. government. 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, 2008, we had $57.2 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. 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 are committed to substantial capital expenditures in connection with our facility expansion in Lansing and may undertake additional facility projects in the future.

As of December 31, 2008, we had $91.5 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 new facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to our new manufacturing facility in Lansing, Michigan and, if we proceed, the build out of our manufacturing facilities in Frederick, Maryland;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, other product candidates that we may pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the 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 our anthrax immune globulin therapeutic product candidate, anthrax monoclonal antibody therapeutic candidate and advanced anthrax vaccine candidate. 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 agreements is subject to our satisfaction of specified conditions. Additional equity or debt financing, grants, or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

**Risks Related to Manufacturing and Manufacturing Facilities**

***We 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 are currently evaluating 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 are spending significant amounts on our new 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. We also own two buildings in Frederick, Maryland that are available to address our future manufacturing requirements and have initiated initial engineering design and preliminary utility build out for these facilities.

Constructing and preparing a facility for manufacturing is a significant project. For example, the process for qualifying and validating the new Lansing facility 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 cGMP regulations or similar regulatory requirements for sales of our products outside the U.S., may be significant. If qualification and validation activities of our new facility in Lansing are delayed, we may not be able to meet our obligations to the U.S. government, 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 candidate. This could require approval from the FDA of change-over procedures. If approval of such change over procedures is delayed or not obtained, our ability to grow BioThrax revenues could be limited.

***BioThrax and our vaccine and immune-related 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 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. 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 redundancy. In developing redundancy, we may face significant regulatory hurdles. In the event of a problem with this strain, if we have not developed redundancy, we would not be able to provide the FDA with required potency testing.

In addition, under our contacts with HHS, 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 profitability. HHS has notified us that we must develop new shipping protocols regarding temperature controls during shipping before we may make additional shipments of BioThrax. If approval of those protocols is delayed, our revenues could be reduced, perhaps dramatically. 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. For example, in the fourth quarter of 2008, three lots that we intended to ship were delayed in the completion of final testing, caused by the failure of a piece of replacement equipment.

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. We do not carry business interruption insurance.

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

We have outsourced the operation for filling BioThrax into vials to a single company, Hollister-Stier Laboratories LLC. Our contract with Hollister-Stier expires on December 31, 2010. We have not established internal redundancy for our filling functions. 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. 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 obtain FDA approval for filling BioThrax at its facilities. 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 or products in sufficient quantities and at an acceptable cost or in compliance with regulatory requirements and specifications, the development and commercialization of our product candidates could be delayed, prevented or impaired.***

We currently rely on third parties to manufacture the supplies of our vaccine and immune-related therapeutic product candidates that we require for preclinical and clinical development, including our anthrax immune globulin therapeutic, anthrax monoclonal therapeutic, Typhella vaccine, tuberculosis vaccine, hepatitis B therapeutic vaccine, and chlamydia vaccine 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, the manufacturer of our anthrax monoclonal therapeutic recently informed us it is discontinuing contract manufacturing operations and we will need to secure alternative manufacture resources. Although we recently commissioned a new pilot plant manufacturing facility on our Lansing campus for production of preclinical and clinical supplies of our product candidates, we expect that we will continue to use third parties for these purposes.

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In addition, we expect that we will rely on third parties for a portion of the manufacturing process for commercial supplies of product candidates that we successfully develop, including fermentation for some of our vaccine product candidates, plasma fractionation and purification for our anthrax immune globulin therapeutic product candidate 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 could 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 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 adequate 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. The general liability policy currently has a $15,000 per occurrence deductible. 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 a $2 million annual aggregate limit and a $25,000 per claim deductible. We hold product liability insurance policies for each clinical trial that we are conducting, in amounts we deem appropriate to the product candidate and the scope of the applicable trial.

These policies are subject to deductibles, exclusions and coverage limitations. Additionally, we do not carry business interruption insurance. 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 effect 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 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 immune- related 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.

***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.

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 immune-related therapeutic product candidates in humans. If we are not successful in completing the development and commercialization of our vaccine and immune-related 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 administer our product candidate as a monotherapy, causing us to cease enrollment in this trial. If we are unable to recommence this trial in a region in which our enrollment efforts are successful, we will be unable to progress the clinical program for this candidate. In addition, because some of our current and future vaccine candidates contain live attenuated viruses, our testing of these vaccine 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 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 may 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 new and undeveloped, and we may not be successful in generating meaningful sales of BioThrax to these potential customers. To date, we have made only modest sales to these customers. In particular, we have supplied small amounts of BioThrax directly to several foreign governments. Foreign governments in the past have requested that we submit an FDA certification of compliance. Until we reach final resolution of the issues raised in connection with the FDA s March 2008 inspection described below under Risks Related to Regulatory Approval 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, such a certification may be difficult to obtain, potentially limiting our ability to make sales to foreign customers. In 2006, 2007 and 2008, 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 controls 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.

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 facility in Lansing to manufacture BioThrax

for sale to U.S. government customers. To prepare for the event that we do obtain significant orders for BioThrax from customers other than the U.S. government, we are exploring 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 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 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 compliance 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 immune-related 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, or GAO, 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.

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.

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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. Lawsuits or publicity campaigns could limit the demand for BioThrax and our biodefense product candidates and harm our future business.

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

To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We currently market and sell BioThrax 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 marketing and sales force for sales of biodefense product candidates to customers other than the U.S. government or for sales of our commercial product candidates. If we are not successful in our efforts to expand our internal sales and marketing capability, our ability to independently market and sell BioThrax and any other product candidates that we successfully develop will be impaired. 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 immune-related 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 immune-related therapeutic are a number of pharmaceutical companies that have vaccine programs, including Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Wyeth and Novartis, as well as smaller more focused companies engaged in vaccine and immune-related therapeutic development, such as Crucell, Cangene, Human Genome Sciences, Dor BioPharma, Dynaport Vaccine Company L.L.C., Elusys, Bavarian Nordic and PharmAthene.

Any vaccine and immune-related therapeutic product candidate that we successfully develop and commercialize is likely to compete with currently marketed products, including antibiotics, and with other product candidates that are in development for the same indications. In many cases, the currently marketed products have well known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. In addition, we are aware of product candidates of third parties that are in development, which, if approved, would compete against product candidates for which we 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 a monoclonal antibody to anthrax as a post-exposure therapeutic for anthrax infection. Several companies have botulinum vaccines in early clinical or preclinical development. 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 candidates in addition to ours, any of which could present competitive risks. Numerous companies have vaccine 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. However, a willful misconduct action could be brought against us if any individuals exhausted their remedies under the compensation program and thereby expose us to liability. 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 would 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 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. Also, the U.S. government may not honor its indemnification obligations. 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.

***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 can not insure 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. 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 $10 million annual aggregate limit with a deductible of $75,000 per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. 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 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.

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

***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 to 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, chief executive officer and chairman of our Board of Directors and Daniel J. Abdun-Nabi, 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.

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**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 Foreign Corrupt Practices Act;

- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

In addition, *qui tam* lawsuits have been brought against us in which the plaintiffs argued that we defrauded the U.S. government by distributing non-compliant doses of BioThrax. Although we ultimately prevailed in this litigation, we spent significant time and money defending the litigation. 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 added costs on our business. Any changes in applicable laws and regulations could restrict our ability to maintain our existing contracts and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our revenues and results of operations.

***We rely on property and equipment owned by the 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 existing GFE from the government on terms to be negotiated with the government. If the 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 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 U.S. 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 U.S., 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 application with substantial evidence of the product s safety and effectiveness in treating the targeted indication based on data derived from adequate and well controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted. However, our biodefense product candidates require slightly different treatment. Specifically, because humans are rarely exposed to anthrax or botulinum toxins under natural conditions, and cannot be intentionally exposed, statistically significant effectiveness of our biodefense product candidates cannot be demonstrated in humans, but instead must be demonstrated, in part, by utilizing animal models before they can be approved for marketing.

We intend to use the FDA animal rule in pursuit of FDA approval for BioThrax as a post-exposure prophylaxis, our anthrax immune globulin therapeutic candidate, our recombinant botulinum vaccine candidate, our rPA anthrax vaccine, our anthrax monoclonal antibody therapeutic, and our advanced anthrax vaccine. We cannot guarantee that FDA will permit us to proceed with any of our products or product candidates under the animal rule. Even if we are able to proceed pursuant to the animal rule, 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 immune-related 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 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 and May 2006. Following each of these inspections, the FDA issued inspectional observations on Form FDA 483. We responded to the FDA regarding the inspectional observations relating to each inspection and, where necessary, implemented corrective action. In December 2005, the FDA stated in its final order on BioThrax that at that time we were in 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 March 2008. Following this inspection, the FDA issued inspectional observations on Form FDA 483. Some of the observations noted on the Form FDA 483 were significant. All observations from our 2008 inspection were closed out in November 2008. 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.

***We may not be able to obtain orphan drug exclusivity for any or all our products. If our competitors are able to obtain orphan drug exclusivity for their products that are the same as our products, we may not be able to have competing products approved by the applicable regulatory 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. None of our products or product candidates has been designated as orphan drugs 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 BioThrax as a post-exposure prophylaxis against anthrax infection may not actually lead to a faster development or regulatory review or approval process.***

We have obtained a Fast Track designation from the FDA for BioThrax as a post-exposure prophylaxis against anthrax infection. However, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw our Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical development program. Our 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 U.S. 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 U.S., 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 for ourselves or entering into collaboration arrangements with leading pharmaceutical or biotechnology companies or non-governmental organizations. We expect that we will selectively pursue collaboration arrangements in situations in which the collaborator has particular expertise or resources for the development or commercialization of our products and product candidates or 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 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 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 trials required to obtain regulatory approval for our products. We depend on independent clinical investigators, contract research organizations and other third party service providers to conduct the clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical trials, but do not exercise day-to-day control over their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, 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 interim trial report provided to us by the CDC from its ongoing clinical trial. We currently are awaiting the final data from the CDC trial. These government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. In addition, government entities depend on annual Congressional appropriations to fund these development efforts. In prior years, there has been some uncertainty whether Congress would choose to fund the CDC trial. Although the trial has been funded to date, Congress may not continue to fund the completion of all study reports.

**Risks Related to Our Intellectual Property**

***Protection of our intellectual property rights could be costly, and if we fail to do so, 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 patent situation in the field of vaccine and immune-related therapeutic and other pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions.

We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Changes in patent laws or administrative patent office rules or changes in interpretations

of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the 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, under our licenses with HPA relating to our recombinant botulinum vaccine candidate, HPA is responsible for prosecuting and maintaining patent rights, although we have the right to support the continued prosecution or maintenance of the patent rights if HPA fails to do so. In addition, we have the first right to pursue claims against third parties for infringement of the patent rights and assume the defense of any infringement claims that may arise.

***If we 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 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. 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 manufacture of the modified vaccinia Ankara virus, or MVA, as a smallpox vaccine for biodefense use by the U.S. government. We have a strain of MVA that we are evaluating as a platform technology and a tuberculosis vaccine candidate that is based on another strain of MVA, both of which are distinct from the Acambis strain. 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. That litigation was terminated by a settlement and consent order filed by the parties with the U.S. International Trade Commission, or ITC, in August 2007 and subsequently published in the U.S. Federal Register. According to the published terms of the consent order, Acambis agreed not to import or sell within the U.S. its ACAM 3000 vaccine product, and further agreed not to challenge the validity or enforceability of certain Bavarian Nordic patents. Bavarian Nordic 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® which is an MVA-based therapeutic cancer vaccine. The original lawsuit against Oxford BioMedica was dismissed in January 2009. However, Bavarian Nordic has recently filed a new lawsuit against Oxford BioMedica that remains outstanding. Bavarian Nordic also has filed legal proceedings against the Bavarian State Ministry of the Environment, Public Health and Consumer Protection, or StMUGV, in which Bavarian Nordic is challenging StMUGV s ownership rights to the MVA in its possession. We have licensed from StMUGV 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 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. We are also party to a trademark invalidation proceeding in a foreign trademark office and 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 and vaccine development and production know-how from the Michigan Biologic Products Institute. We acquired a significant portion of our pipeline of vaccine and therapeutic product candidates through our acquisition of ViVacs GmbH in 2006 and Microscience Limited in 2005 and our acquisition of substantially all of the assets of Antex Biologics, Inc. in 2003.

In the future, we may be unable to license or acquire suitable products or product candidates from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical and biological products is a competitive area. A number of more established companies are also pursuing strategies to license or acquire products in the vaccine and immune-related 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 immune-related 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 27, 2009, Mr. El-Hibri was the beneficial owner of approximately 46% 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 February 27, 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. Moreover, holders of an aggregate of approximately 13.7 million shares of our common stock outstanding as of December 31, 2008 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:

| Location | Use | Segment | Approximate square feet | Owned/leased |
|---|---|---|---|---|
| Lansing, Michigan | Manufacturing operations facilities, office space and laboratory space | Biodefense | 264,000 | Owned |
| Frederick, Maryland | Future manufacturing facilities and office and laboratory space | Biodefense/Commercial | 290,000 | Owned |
| Gaithersburg, Maryland | Office and laboratory space | Biodefense/ Commercial | 36,000 | Lease expires 2009 |
| Rockville, Maryland | Office space | Biodefense/Commercial | 23,000 | Lease expires 2016 |
| Wokingham, England | Office and laboratory space | Commercial | 29,000 | Leases expire 2016 |
| Munich, Germany | Office and laboratory space | Commercial | 5,000 | Lease expires 2009 |

*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 form a commercial leader. The facility serves as collateral for this financial obligation. 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.

*Frederick, Maryland.* We own two buildings of approximately 145,000 square feet each on a 15-acre site in Frederick, Maryland. We financed the purchase of these buildings with a forgivable loan from the Department of Business and Economic Development of the State of Maryland and mortgage loans from commercial lenders. These buildings serve as collateral for these financing obligations.

We are considering building out this site for product development and a portion of our potential future product manufacturing requirements and are in the preliminary phase of establishing plans to do so. We expect that we would complete the build out of this site in several stages. Our preliminary plans contemplate a build out of one of the two buildings on this site to accommodate laboratory space, product development, pilot plant initial product launch capabilities and administrative office space. We have incurred costs of approximately $4 million through December 2008 related to initial engineering design and preliminary utility build out of these facilities. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that would be necessary to complete this project. Moving forward with these plans will be contingent on progress of our existing development programs or the acquisition of new product candidates. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project. We may elect to lease or sell one or both of these facilities to third parties.

*Other.* We lease three separate product development facilities. Our facility in Gaithersburg, Maryland is approximately 36,000 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 5,000 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.

**ITEM 3. LEGAL PROCEEDINGS**

*Litigation against Protein Sciences Corporation.* In July 2008, we filed a lawsuit against Protein Sciences Corporation, or PSC, Daniel D. Adams, PSC s Chief Executive Officer, and Manon M.J. Cox, PSC s Chief Operating Officer, in the Supreme Court of the State of New York asserting claims related to a letter of intent, a loan agreement, and an asset purchase agreement that PSC and the Company entered into in 2008. On September 12, 2008, a stipulation of discontinuance was filed with the court regarding the claims against Mr. Adams and Ms. Cox, and, on October 3, 2008, we filed a separate suit against Mr. Adams and Ms. Cox in the United States District Court for the District of Connecticut, alleging fraud and unfair trade practices and seeking compensatory and punitive damages. On September 12, 2008, we filed an amended complaint against PSC, which remains pending in the New York state court, alleging fraud, breach of the letter of intent, loan agreement, and asset purchase agreement, breach of the duty of good faith and fair dealing, unjust enrichment, and unfair business practices. We are seeking from PSC money damages of no less than $13 million, punitive damages, declaratory judgment that we have no further funding obligations to PSC, injunctive relief to protect the collateral for our loan, and other appropriate relief. PSC has moved to dismiss the New York action, and Mr. Adams and Ms. Cox have moved to dismiss the Connecticut action. Those motions remain pending. PSC, Mr. Adams, and Ms. Cox have not yet asserted any counterclaims against us, 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, which would include a $1.5 million reverse break-up fee under the asset purchase agreement as a setoff to the loan.

Between March 2008 and June 2008, we provided PSC with $10 million in funding under a loan agreement between the parties to enable PSC to continue operations through June 24, 2008, the anticipated closing date of the asset purchase transaction. Under the loan agreement, PSC was obligated to repay the $10 million principal plus interest and costs of collection the earlier of December 31, 2008, or an event of default under the loan agreement. In the lawsuit against PSC, we allege that an event of default occurred under the loan agreement and that the loan was due and payable as of June 2008. Subsequent to filing the lawsuit, we discussed with PSC a potential alternative transaction. In connection with those discussions, effective December 31, 2008, we and PSC entered into a forbearance agreement, pursuant to which we agreed not to foreclose on the collateral or to pursue other remedies relating to the loan prior to January 26, 2009. On January 5, 2009, we notified PSC that we would not be pursuing the proposed alternative transaction. On January 6, 2009, we issued a press release stating that we had ended all activities related to our planned acquisition of PSC and that we would pursue full repayment of the $10 million loan, which is secured by substantially all of PSC s assets, and settlement of the outstanding litigation. Since January 26, 2009, when the forbearance period expired, we have been negotiating the terms of an extended forbearance agreement with PSC, but, as of the date of this report, have not been successful in reaching such an agreement. If we are unsuccessful in reaching an agreement, we intend to seek to enforce our rights, which may include initiating a foreclosure action with respect to the collateral for the loan.

*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.

We believe that we are entitled to indemnification under our prior contract with the DoD for legal fees associated with the BioThrax product liability cases brought by military personnel.

*Insurance coverage litigation.* On December 26, 2006, we were named as a defendant in a lawsuit brought by Evanston Insurance Company in the U.S. District Court for the Western District of Michigan captioned *Evanston Insurance Company v. BioPort Corporation and Robert C. Myers.* Evanston issued a general liability policy to us in 2000, and we made a claim for coverage under that policy for defense and indemnity costs incurred as a result of the claims asserted in the BioThrax product liability litigation discussed above and the thimerosal litigation discussed below. In its complaint, Evanston asserted a number of purported bases for the court to void or reduce its obligation to defend or indemnify us, including a claim that we failed to disclose on our insurance application our alleged knowledge of incidents, conditions, circumstances, effects or suspected defects which may result in claims. Evanston sought rescission or reformation of the policy to exclude a duty to defend or indemnify us for the claims asserted in the BioThrax product liability litigation and the thimerosal litigation. Evanston also sought a refund of the approximately $331,000 that it had reimbursed us for defense costs. In October 2008, the litigation with Evanston was resolved, and the lawsuit was dismissed with prejudice.

*Mil Vax litigation.* In 2003, six unidentified plaintiffs filed suit in the U.S. District Court for the District of Columbia against the U.S. government seeking to enjoin the Anthrax Vaccine Immunization Program administered under MilVax under which all military personnel were required to be vaccinated with BioThrax. In October 2004, the District Court enjoined the DoD from administering BioThrax to military personnel on a mandatory basis without their informed consent or a Presidential waiver. This ruling was based in part on the District Court s finding that the FDA, as part of its review of all biological products approved prior to 1972, had not properly issued a final order determining that BioThrax is safe and effective and not misbranded. In December 2005, the FDA issued a final order determining that BioThrax is safe and effective and not misbranded. In February 2006, the U.S. Court of Appeals for the District of Columbia, on appeal of the injunction by the government, ruled that the injunction had dissolved by its own terms as a result of the FDA s final order. In October 2006, the DoD announced that it was resuming a mandatory vaccination program for BioThrax for designated military personnel and emergency DoD civilian personnel and contractors.

In December 2006, the same counsel who represented the plaintiffs in the 2003 litigation filed a new lawsuit against the government in the same federal court, on behalf of unnamed service members and the DoD civilian employees or contractors and purportedly on behalf of a class of similarly situated individuals. The suit contends on various grounds that the FDA's 2005 final order should be set aside as substantively and procedurally flawed and that BioThrax is not properly approved for use in the DoD s vaccination program. The plaintiffs seek a declaration that BioThrax is improperly licensed and is not approved for use against inhalation anthrax, an order vacating the FDA s 2005 final order, and an injunction prohibiting the DoD from using BioThrax in a mandatory vaccination program. In February 2008, the federal court in which that case was pending dismissed the action, concluding that FDA did not make a clear error of judgment in reaffirming the safety and efficacy of BioThrax. In April 2008, the plaintiffs filed a notice of appeal of this decision, and that appeal remains pending. Although we are not a party to the lawsuits challenging DoD s mandatory anthrax vaccination program, if the District Court were to enjoin the mandatory use of BioThrax by DoD, the amount of future purchases of BioThrax by the U.S. government could be affected.

*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 40 lawsuits pending in two jurisdictions: three 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. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

None.

**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, 2008 and 2007:

| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
|---|---|---|---|---|
| **Year Ended December 31, 2008** | | | | |
| High | $ 9.17 | $ 11.14 | $ 15.17 | $ 26.40 |
| Low | $ 4.93 | $ 8.22 | $ 9.62 | $ 11.22 |
| **Year Ended December 31, 2007** | | | | |
| High | $ 17.75 | $ 14.85 | $ 12.67 | $ 10.70 |
| Low | $ 10.50 | $ 8.33 | $ 7.67 | $ 4.40 |

As of February 27, 2009, the closing price per share of our common stock on the New York Stock Exchange was $19.31 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**

On November 20, 2006, we completed an initial public offering of 5,000,000 shares of our common stock pursuant to a registration statement on Form S-1 (File No. 333-136622), which was declared effective by the SEC on November 14, 2006. We received net proceeds from the offering of approximately $54.2 million, after deducting underwriting discounts and commissions and other offering expenses.

Through December 31, 2008, we have used all of the net proceeds from our initial public offering. We used approximately $27.2 million of the net proceeds from the offering to fund development of our product candidates, comprised of approximately $4.2 million for label expansions and improvements for BioThrax, approximately $2.3 million for an advanced anthrax vaccine candidate, approximately $6.0 million for our anthrax immune globulin therapeutic candidate, approximately $8.5 million for Typhella and approximately $6.2 million for our hepatitis B therapeutic vaccine candidate. We used approximately $27.0 million of the net proceeds from the offering to fund a portion of the construction, installation, validation and qualification activities costs for our new manufacturing facility in Lansing. We did not use any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10 percent or more of our common stock or to any affiliate of ours.

**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, 2008, 2007 and 2006 and the consolidated balance sheet data as of December 31, 2008 and 2007 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, 2005 and 2004 and the consolidated balance sheet data as of December 31, 2006, 2005 and 2004 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.

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| **(in thousands, except share and per share data)** | **2008** | **2007** | **2006** | **2005** | **2004** |
| **Statements of operations data:** | | | | | |
| Revenues: | | | | | |
| Product sales | $ 169,124 | $ 169,799 | $ 147,995 | $ 127,271 | $ 81,014 |
| Contracts and grants | 9,430 | 13,116 | 4,737 | 3,417 | 2,480 |
| Total revenues | 178,554 | 182,915 | 152,732 | 130,688 | 83,494 |
| Operating expenses (income): | | | | | |
| Cost of product sales | 34,081 | 40,309 | 24,125 | 31,603 | 30,102 |
| Research and development | 59,470 | 53,958 | 45,501 | 18,381 | 10,117 |
| Selling, general & administrative | 55,076 | 55,555 | 44,601 | 42,793 | 30,323 |
| Purchased in-process research and development | - | - | 477 | 26,575 | - |
| Settlement of State of Michigan Obligation | - | - | - | - | (3,819) |
| Litigation settlement | - | - | - | (10,000) | - |
| Total operating expenses | 148,627 | 149,822 | 114,704 | 109,352 | 66,723 |
| Income from operations | 29,927 | 33,093 | 38,028 | 21,336 | 16,771 |
| Other income (expense): | | | | | |
| Interest income | 1,999 | 2,809 | 846 | 485 | 65 |
| Interest expense | (47) | (71) | (1,152) | (767) | (241) |
| Other income (expense), net | 134 | 156 | 293 | 55 | 6 |
| Total other income (expense) | 2,086 | 2,894 | (13) | (227) | (170) |
| Minority interest in subsidiary | 724 | - | - | - | - |
| Income before provision for income taxes | 32,737 | 35,987 | 38,015 | 21,109 | 16,601 |
| Provision for income taxes | 12,055 | 13,051 | 15,222 | 5,325 | 5,129 |
| Net income | $ 20,682 | $ 22,936 | $ 22,793 | $ 15,784 | $ 11,472 |
| Earnings per share basic | $ 0.69 | $ 0.79 | $ 0.99 | $ 0.77 | $ 0.61 |
| Earnings per share diluted | $ 0.68 | $ 0.77 | $ 0.93 | $ 0.69 | $ 0.56 |
| Weighted average number of shares basic | 29,835,134 | 28,995,667 | 23,039,794 | 20,533,471 | 18,919,850 |
| Weighted average number of shares diluted | 30,458,098 | 29,663,127 | 24,567,302 | 22,751,733 | 20,439,252 |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| **(in thousands)** | **2008** | **2007** | **2006** | **2005** | **2004** |
| **Balance Sheet Data:** | | | | | |
| Cash and cash equivalents | $ 91,473 | $ 105,730 | $ 76,418 | $ 36,294 | $ 6,821 |
| Working capital | 98,658 | 88,649 | 82,990 | 29,023 | 7,509 |
| Total assets | 290,788 | 273,508 | 238,255 | 100,332 | 69,056 |
| Total long-term liabilities | 37,418 | 46,688 | 35,436 | 10,502 | 11,921 |
| Total stockholders equity | 199,349 | 171,159 | 138,472 | 59,737 | 22,949 |

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**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 vaccine and immune-related therapeutic 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 therapeutics for use against biological agents that are potential weapons of bioterrorism or biowarfare. Our product candidates in this segment are focused on two specific biological agents: anthrax and botulinum. Within our anthrax product portfolio, we manufacture and market BioThrax® (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 anthrax, or rPA, vaccine an advanced BioThrax vaccine, an anthrax immune globulin therapeutic and a recombinant anthrax monoclonal antibody therapeutic. Within our botulinum product portfolio, we are developing a recombinant botulinum vaccine.

Our commercial segment focuses on vaccines and therapeutics 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 typhoid vaccine, a tuberculosis vaccine, a hepatitis B therapeutic 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 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 $169.1 million and $169.8 million for the years ended December 31, 2008 and 2007, 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:

| Product or Product Candidate | Funding Source |
|---|---|
| BioThrax post-exposure prophylaxis | HHS |
| Advanced BioThrax vaccine | Biomedical Advanced Research and Development Authority and National Institute of Allergy and Infectious Dis |
| Anthrax immune globulin therapeutic | National Institute of Allergy and Infectious Diseases |
| Anthrax monoclonal antibody therapeutic | Biomedical Advanced Research and Development Authority and National Institute of Allergy and Infectious Dis |
| Typhella vaccine | The Wellcome Trust |
| Recombinant botulinum vaccine | National Institute of Allergy and Infectious Diseases |

Additionally, our tuberculosis vaccine 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.

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

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

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We have generated BioThrax sales revenues under U.S. government contracts with HHS and the DoD. Under previous DoD contracts, we invoiced the DoD for progress payments upon reaching contractually specified stages in the manufacture of BioThrax. We recorded as deferred revenue the full amount of each progress payment invoice that we submitted to 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, we segregated the product for later shipment and recognized as period revenue all deferred revenue related to the released product in accordance with the bill and hold sale requirements under SAB 104. At that time, we also invoiced the DoD for the final progress payment and recognized the amount of that invoice as period revenue.

Under previous contracts with HHS, we 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 our current contracts 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.

Under a collaboration agreement that we entered into with Sanofi Pasteur in May 2006 for our meningitis B vaccine candidate, we received an upfront license fee and were entitled to additional payments for development work under the collaboration. We evaluated the various components of the collaboration in accordance with Emerging Issues Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables,* or EITF No. 00-21, which addresses whether, for revenue recognition purposes, there is one or several units of accounting in an arrangement. We concluded that under EITF No. 00-21, the license fee and the development work under our agreement with Sanofi Pasteur should be accounted for as a single unit of accounting. We recognized amounts received under this agreement over the estimated development period as we perform services. We recorded the amount of the upfront license fee as deferred revenue. Prior to the termination of this agreement in December 2008, we recognized this revenue over the estimated development period under the contract, estimated at seven years. Under the collaboration agreement, we were entitled to payments up to specified levels for development work we performed on behalf of Sanofi Pasteur. We invoiced Sanofi Pasteur monthly in arrears, and recognized revenue in the period in which the associated costs were incurred.

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 in connection with specific development activities and may also be entitled to additional fees. We record the reimbursement of our costs and any associated fees as contracts and grants revenue and the associated costs as research and development expense. We issue invoices and recognize revenue upon incurring the reimbursable costs.

**Accounts Receivable**

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. 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**

We account for income taxes in accordance with Statement of Financial Accounting Standards, or SFAS, No. 109, *Accounting for Income Taxes,* or SFAS No. 109. Under the asset and liability method of SFAS No. 109, 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 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.

We account for uncertainty in income taxes in accordance with Financial Accounting Standards Board, or FASB, Interpretation 48, *Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109, Accounting for Income Taxes*or FIN 48. FIN 48 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. Under FIN 48, 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**

We adopted SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS No. 123(R), on January 1, 2006. SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their estimated 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 SFAS No. 123(R) on net income (loss) and net income (loss) 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**

Between May 2005 and February 2007, we supplied 10.0 million doses of BioThrax to HHS for inclusion in the Strategic National Stockpile, or SNS, under a base contract for 5.0 million doses for a fixed price of $123 million and a contract modification for an additional 5.0 million doses for a fixed price of $120 million. We completed delivery of all doses to HHS under the base contract and the contract modification in February 2007.

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 SNS. The term of the agreement is from September 25, 2007 through September 24, 2010. The first 5.5 million doses delivered under this contract were sold to HHS at a discounted price, as specified in the contract, due to the limited remaining shelf-life for those specific doses. This discounted price does not apply to the final 13.25 million doses under the contract. The firm fixed price for the 18.75 million doses, including the discount, is $400 million in the aggregate. Through December 31, 2008, we have delivered approximately 13.8 million doses under this contract. If we receive FDA approval of our pending supplement to our biologics license application, or BLA, to extend the expiry dating of BioThrax from three years to four years, HHS has agreed to increase the price per dose under the agreement for 13.25 million doses sold under this contract. In that event, HHS would make a lump sum payment to us reflecting an increase in the price per dose for specified doses delivered prior to such approval and pay an increased price per dose for doses delivered following the date of such approval. The aggregate value of such price adjustment is approximately $34 million. If we do not receive FDA approval of four-year expiry dating during the term of the agreement there will be no adjustment in the price per dose under the agreement. In December 2006, based on data generated from our ongoing stability studies, we submitted a supplement to our BLA for BioThrax to extend the expiry dating. We have received a complete response from the FDA which posed a number of questions. In responding to those questions, we submitted a separate supplement in December 2008 and submitted a response to the FDA's complete response in February 2009. We believe that our application will be approved in 2009.

Under this agreement, we have also 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 approximately $2.2 million. We invoice HHS for each delivery upon acceptance of BioThrax doses delivered into the SNS. The agreement also provides 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 invoiced HHS for $8.8 million. We received this payment from HHS and revenue was recognized in November 2007.

On September 30, 2008, we entered into an agreement with HHS to supply up to an additional 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 will commence immediately following the anticipated completion of deliveries under our current 18.75 million dose supply contract with HHS, currently anticipated in September 2009, and continue through September 2011. Funds for the procurement of the first 5.7 million doses of BioThrax have been committed. Procurement of the remaining 8.8 million doses will be funded through the annual appropriations process for the SNS. If the FDA approves our pending application to extend the shelf life of BioThrax from three years to four years, and if four-year dated lots of BioThrax are available at the time of delivery of a particular lot or shipment, we must deliver four-year dated product to the SNS. In the event the FDA has not approved four-year expiry dating at the time of such delivery, we may instead deliver three-year dated product to the SNS. Four-year dated product will be invoiced at a higher price than three-year dated product. The total purchase price for the 14.5 million doses will be between $362.7 million and $402.8 million, depending on product dating. Under the 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 will invoice HHS under the agreement upon acceptance of each delivery of BioThrax doses to the SNS.

Pursuant to two supply agreements for BioThrax with the DoD, we have supplied approximately 10 million doses of BioThrax for immunization of military personnel from 1997 through 2007. As a result of 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, the DoD is procuring additional doses of BioThrax to satisfy ongoing requirements for its active immunization program directly from the SNS. Consequently, we are not currently party to a procurement contract with the DoD.

In September 2007, we received a development contract from National Institute of Allergy and Infectious Disease, or NIAID, valued at up to $9.5 million, in support of non-clinical and clinical studies of our anthrax immune globulin therapeutic candidate. Under the terms of the development contract, we are using the funds to conduct various studies on this product candidate, including non-clinical efficacy studies and clinical trials. In July 2008, we were awarded two grants from NIAID, totaling over $4.5 million, to support development of our recombinant botulinum vaccine and advanced anthrax vaccine candidates. In September 2008, we received a $24 million development contract from NIAID and Biomedical Advanced Research and Development Authority, or BARDA, to fund continued development of our anthrax monoclonal antibody therapeutic candidate, and a development contract with NIAID and BARDA, valued at up to approximately $30 million, to fund development of our advanced BioThrax vaccine candidate.

In May 2006, we entered into a collaboration agreement with Sanofi Pasteur, which was amended in June 2008, under which we granted Sanofi Pasteur an exclusive, worldwide license under a proprietary technology to develop and commercialize a meningitis B vaccine candidate and received a $3.8 million upfront license fee. This agreement also provided for payments for development work under the collaboration. In December 2008, we and Sanofi Pasteur determined that the joint efforts on this collaboration had not identified a promising product candidate, and we mutually terminated the collaboration. Upon termination we recognized as revenue the unamortized portion of the upfront license fee.

On December 5, 2008, we entered into an agreement with Pfizer Inc. whereby Pfizer acquired from us technology, materials and related documentation pertaining to our Pertussis, or whooping cough, product candidate. Under the terms of the agreement, Pfizer paid $1.8 million for all Pertussis technology, product material, data, technical and scientific information, intellectual property, know-how, expertise and trade secrets, as well as standard operating procedures, batch records, historical manufacturing records and regulatory documentation relating to the technology. In addition, Pfizer will pay us a future milestone payment of up to $750,000, pending the results of ongoing work with the technology.

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 cost 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 the ongoing studies with BioThrax being 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 and certain University of Oxford researchers to conduct clinical trials in the advancement of a vaccine candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium. 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 *Mycobacterium tuberculosis* in humans in developed countries. We anticipate contributing approximately $20 million to the joint venture over the next three years to support 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. The University of 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 and cash equivalents, and we incur interest expense on our indebtedness. We capitalize interest expense in accordance with SFAS No. 34, *Capitalization of Interest Cost,* based on the cost of major ongoing projects which have not yet been placed in service, such as our new manufacturing facility. Our total interest cost will increase in future periods as compared to prior periods as a result of the term loan that we entered into in June 2007, as well as any borrowings under our revolving line of credit. In addition, some of our existing debt arrangements provide for increasing amortization of principal payments in future periods. See Liquidity and Capital Resources Debt Financing for additional information.

**Results of Operations**

**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, $3.5 million on product candidates categorized in the commercial segment, and $436,000 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 enhancements was related to preparing for and conducting clinical and non-clinical efficacy studies to support applications for marketing approval of these enhancements. The spending for the recombinant protective antigen anthrax vaccine was related primarily to the purchase of this vaccine candidate from VaxGen in May 2008 and continued advancement of this product candidate. The increase in spending in our advanced anthrax vaccine program resulted from feasibility studies and formulation development of product candidates, including our advanced BioThrax vaccine candidate. 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 candidate and related technology in March 2008 and continued advancement of this product candidate. The decrease in spending for our botulinum vaccine candidates resulted from enhanced spending in 2007 from advancing 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 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 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 decrease in spending for our hepatitis B therapeutic vaccine 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 montherapy. The spending for our group B streptococcus vaccine candidate resulted from preparing for Phase I clinical trials for two of the protein components of the vaccine candidate. We have decided not to proceed with these trials and, as a result, we expect that spending for our group B streptococcus vaccine candidate will be significantly reduced in the future. The spending for our tuberculosis vaccine 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 decrease in spending for our chlamydia vaccine candidate, which is in preclinical development, is related to slowing development while seeking external funding.

The increase in other research and development expenses was primarily attributable to spending associated the development of technology platforms.

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 |
|---|---|---|
| **Biodefense:** | | |
| BioThrax enhancements | $ 6,039 | $ 5,175 |
| Recombinant protective antigen anthrax vaccine | 6,563 | - |
| Advanced anthrax vaccines | 3,660 | 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 |
| **Commercial:** | | |
| Typhella | 15,431 | 9,641 |
| Hepatitis B therapeutic vaccine | 3,010 | 5,370 |
| Group B streptococcus vaccine | 6,539 | 6,790 |
| Tuberculosis vaccine | 2,145 | - |
| Chlamydia vaccine | 1,220 | 3,146 |
| Meningitis B vaccine | 1,313 | 1,212 |

| | | |
|---|---|---|
| Total commercial | 29,658 | 26,159 |
| Other | 3,491 | 3,055 |
| **Total** | $ 59,470 | $ 53,958 |

***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.

***Minority Interest in Subsidiary***

Minority interest in subsidiary 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.

***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 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.

**Year Ended December 31, 2007 Compared to Year Ended December 31, 2006**

***Revenues***

Product sales revenues increased by $21.8 million, or 15%, to $169.8 million for 2007 from $148.0 million for 2006. This increase in product sales revenues was primarily due to a 41% increase in the number of doses of BioThrax delivered, offset by a 19% decrease 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 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. Product sales revenues in 2006 consisted of BioThrax sales to HHS of $109.8 million, sales to the DoD of $37.4 million and aggregate international and other sales of $763,000.

Contracts and grant revenues increased by $8.4 million, or 177%, to $13.1 million in 2007 from $4.7 million in 2006. 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. Contracts and grant revenues for 2006 consisted of $3.2 million in upfront and development program revenue from the Sanofi Pasteur collaboration and $1.5 million in grant revenue from the Wellcome Trust.

***Cost of Product Sales***

Cost of product sales increased by $16.2 million, or 67%, to $40.3 million for 2007 from $24.1 million for 2006. This increase was attributable to a 41% increase in the number of doses of BioThrax delivered, coupled with increased costs associated with our annual production shut-down, the related impact on production yield, and the write-off of waste during the period.

***Research and Development Expenses***

Research and development expenses increased by $8.5 million, or 19%, to $54.0 million for 2007 from $45.5 million for 2006. This increase reflects additional personnel and contract service costs, and includes increased expenses of $2.5 million on product candidates that are categorized in the biodefense segment, $3.7 million on product candidates categorized in the commercial segment, and $2.2 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 candidates in the biodefense and commercial segments, detailed in the table below, was attributable to increased efforts on various programs as we completed various studies and began subsequent studies and trials. The spending for BioThrax enhancements is related to preparing for and conducting animal efficacy studies to support applications for marketing approval of these enhancements. The spending for the advanced anthrax vaccine programs resulted from feasibility studies and formulation development of product candidates. The spending for our anthrax immune globulin therapeutic candidate development program related primarily to costs associated with the plasma collection and fractionation program. The spending for the botulinum vaccine programs resulted from advancing this program to the process development stage and the manufacture of clinical trial material. We continue to assess, and may alter, our future development plans for our products based on the interest of the U.S. government or other non-governmental organizations in providing funding for further development or procurement.

The spending in 2007 for Typhella resulted from the ongoing Phase II study in Vietnam, which commenced in the first quarter of 2007. The spending in 2006 for Typhella resulted from ongoing work for the Phase I clinical trial in Vietnam, which we completed in the second quarter of 2006. The spending in 2007 for our hepatitis B therapeutic vaccine candidate resulted from preparing for and initiating our Phase II clinical trial, which commenced in the first quarter 2007. The spending in 2007 for our group B streptococcus vaccine candidate resulted from preparing for Phase I clinical trials for two of the protein components of the vaccine candidate. Both our chlamydia and meningitis B vaccine candidates are in preclinical development.

The increase in other research and development expenses was primarily attributable to spending associated with product development programs that we acquired in the acquisition of ViVacs in July 2006.

Our principal research and development expenses for 2007 and 2006 are shown in the following table:

| (in thousands) | Year ended December 31, 2007 | 2006 |
|---|---|---|
| **Biodefense:** | | |
| BioThrax enhancements | $ 5,175 | $ 7,232 |
| Advanced anthrax vaccines | 2,719 | 1,088 |
| Anthrax immune globulin therapeutic | 7,717 | 7,373 |

| | | |
|---|---|---|
| Botulinum vaccines | 9,133 | 6,526 |
| Total biodefense | 24,744 | 22,219 |
| **Commercial:** | | |
| Typhella | 9,641 | 9,642 |
| Hepatitis B therapeutic vaccine | 5,370 | 4,058 |
| Group B streptococcus vaccine | 6,790 | 3,759 |
| Chlamydia vaccine | 3,146 | 1,991 |
| Meningitis B vaccine | 1,212 | 2,975 |
| Total commercial | 26,159 | 22,425 |
| Other | 3,055 | 857 |
| **Total** | $ 53,958 | $ 45,501 |

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

Selling, general and administrative expenses increased by $11.0 million, or 25%, to $55.6 million for 2007 from $44.6 million for 2006. The increase in selling, general and administrative expenses was driven by an increase in our headquarters and staff organization to support our operations as a public company and to support the overall growth of our business, and is primarily attributable to an increase of approximately $9.0 million resulting from the addition of personnel and increased legal and other professional services for our headquarters organization and an increase of $2.1 million in sales and marketing expenses related to the growth of our staff and an increase in our selling and marketing activities. The majority of the expense is attributed to the biodefense segment, in which selling, general and administrative expenses increased by $7.4 million, or 21%, to $43.0 million for 2007 from $35.6 million for 2006. Selling, general and administrative expenses related to our commercial segment increased by $3.6 million, or 40%, to $12.5 million for 2007 from $9.0 million for 2006.

***Purchased In-process Research and Development***

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

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

Total other income (expense) increased by $2.9 million to income of $2.9 million for 2007 from expense of $13,000 for 2006. This increase resulted primarily from an increase in interest income of $2.0 million as a result of higher investment return on increased average cash balances, including the net proceeds of our initial public offering, and a decrease in interest expense of $1.1 million due to the capitalization of interest costs related to the construction of our new building in Lansing.

***Income Taxes***

Provision for income taxes decreased by $2.2 million, or 14%, to $13.1 million for 2007 from $15.2 million for 2006. 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 provision for income taxes for 2006 resulted primarily from our income before provision for income taxes of $38.0 million and an effective annual tax rate of 40%. The decrease in the effective annual tax rate is due primarily to a reduction in state valuation allowances related to the expected utilization of net operating losses. The provision for income taxes also reflects research and development tax credits of $880,000 for 2007 and $759,000 for 2006.

**Liquidity and Capital Resources**

***Sources of Liquidity***

We require cash to meet our operating expenses and for capital expenditures, acquisitions and principal and interest payments on our debt. We have funded our cash requirements from inception through December 31, 2008 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases, revenues under our collaboration agreement with Sanofi Pasteur, development funding from government entities and non-government and philanthropic organizations, the net proceeds from our initial public offering and, to a lesser extent, from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the years in the three year period ended December 31, 2008.

As of December 31, 2008, we had cash and cash equivalents of $91.5 million.

***Cash Flows***

The following table provides information regarding our cash flows for the years ended December 31, 2008, 2007 and 2006.

| | Year ended December 31, | | |
|---|---|---|---|
| **(in thousands)** | **2008** | **2007** | **2006** |
| Net cash provided by (used in): | | | |
| Operating activities(1) | $ 7,588 | $ 54,790 | $ (4,258) |
| Investing activities | (30,813) | (43,969) | (41,446) |
| Financing activities | 8,968 | 18,491 | 85,828 |
| **Total net cash provided (used in)** | $ (14,257) | $ 29,312 | $ 40,124 |

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

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 the 2007 income tax liability and estimated tax payments related to the 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 $7.8 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 operating activities of $4.3 million in 2006 resulted principally from our net income of $22.8 million, an increase in income taxes payable of $11.5 million due to the timing of payment of the 2006 income tax liability, an increase in accounts payable of $5.8 million related to increased research and development and selling, general and administrative expenses, and the impact of non-cash depreciation and amortization expense of $4.7 million, offset by an increase in accounts receivable of $40.8 million due from HHS and the DoD reflecting amounts billed in December 2006 that were still outstanding at year end, and an increase in inventory of $8.3 million reflecting the value of work in process for BioThrax lots being manufactured or awaiting delivery.

Net cash used in investing activities for the years ended December 31, 2008, 2007 and 2006 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 2008 include $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. Capital expenditures in 2006 relate primarily to $25.7 million for construction of our new building in Lansing, $10.2 million related to the acquisition of our second facility in Frederick, Maryland, and approximately $5.3 million in infrastructure investments and other equipment.

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 long-term 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 consist of $5.0 million in restricted cash deposits in conjunction with our June 2007 HSBC term loan.

Net cash provided by financing activities of $85.8 million in 2006 resulted primarily from $54.2 million in proceeds from our initial public offering, $15.0 million in proceeds related to financing a portion of the costs related to the construction of our new building in Lansing, $8.5 million in proceeds from notes payable related to the financing of the purchase of our Frederick facility in April 2006, and $8.9 million in proceeds from our revolving line of credit.

***Contractual Obligations***

The following table summarizes our contractual obligations at December 31, 2008:

| | Payments due by period | | | | | | |
|---|---|---|---|---|---|---|---|
| **(in thousands)** | **Total** | **2009** | **2010** | **2011** | **2012** | **2013** | **After 2013** |
| **Contractual obligations:** | | | | | | | |
| Long-term indebtedness including current portion | $ 25,683 | $ 6,248 | $ 3,792 | $ 15,643 | $ - | $ - | $ - |
| Operating lease obligations | 11,073 | 1,972 | 1,317 | 1,300 | 1,268 | 1,288 | 3,928 |
| Contractual settlement liabilities | - | - | - | - | - | - | - |
| **Total contractual obligations** | $ 36,756 | $ 8,220 | $ 5,109 | $ 16,943 | $ 1,268 | $ 1,288 | $ 3,928 |

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

***Debt Financing***

As of December 31, 2008, we had $57.2 million principal amount of debt outstanding, comprised primarily of the following:

- $2.5 million outstanding under a forgivable loan from the Department of Business and Economic Development of the State of Maryland used to finance eligible costs incurred to purchase the first facility in Frederick, Maryland;
- $6.4 million outstanding under a mortgage loan from PNC Bank used to finance the remaining portion of the purchase price for the first Frederick facility;
- $7.8 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance the purchase price for the second facility on the Frederick site;
- $25.5 million outstanding under a term loan from HSBC Realty Credit Corporation used to finance a portion of the costs of our facility expansion in Lansing, Michigan; and
- $15.0 million outstanding under a $15.0 million revolving line of credit with Fifth Third Bank. This balance was repaid in February 2009.

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

- Under our forgivable loan from the State of Maryland, we are not required to repay the principal amount of the loan if beginning December 31, 2009 and through 2012 we maintain a specified number of employees at the Frederick site, by December 31, 2009 we have invested at least $42.9 million in total funds toward financing the purchase of the buildings on the site and for related improvements and operation of the facility, and we occupy the facility through 2012.
- Under our 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, we are required to maintain on an annual basis a book leverage ratio of less than 1.25. In addition, we are required to maintain on a quarterly basis a debt coverage ratio of not less than 1.25 to 1.00 or maintain $5.0 million in a cash collateral account.
- 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 is scheduled to be adjusted to a fixed annual rate equal to 3.20% over the yield on U.S. government securities adjusted to a constant maturity of two years.

Under our mortgage loan from HSBC Realty Credit Corporation, we are required to make monthly principal payments. A residual principal repayment of approximately $7.0 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 3.0%.

Under our term loan with HSBC Realty Credit Corporation, we are required to make monthly payments in the amount of $250,000 in principal plus accrued interest, with a residual principal payment due upon maturity in June 2012. Interest on the loan accrues at an annual rate equal to the 30-day LIBOR plus 2.75%.

Under our revolving line of credit with Fifth Third Bank, any outstanding principal is due upon maturity in June 2009. The principal amount outstanding at any time under the line of credit may not exceed 75% of total eligible accounts receivable under HHS and the DoD contracts. Consistent with the terms of this agreement, we repaid $15.0 million of outstanding principal under the line of credit in February 2009. Interest is payable monthly and accrues at an annual rate equal to the 30-day LIBOR plus 2.0%.

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***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 $75 million planned 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 to raise 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 our anthrax immune globulin therapeutic product candidate, recombinant botulinum vaccine candidate, anthrax monoclonal antibody therapeutic candidate and advanced BioThrax vaccine candidate. Our ability to borrow additional amounts under our loan agreements is subject to our satisfaction of specified conditions.

Our future capital requirements will depend on many factors, including:

- the level and timing of BioThrax product sales and cost of product sales;
- the timing of, and the costs involved in qualification and validation activities related to our new manufacturing facility in Lansing, Michigan and, if we proceed, the build out of our manufacturing facility in Frederick, Maryland;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, other product candidates that we may pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- the extent to which we acquire or invest in businesses, products and technologies;
- our ability to obtain development funding from government entities and non-government and philanthropic organizations; and
- our ability to establish and maintain collaborations.

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 November 2008, the EITF issued EITF Issue No. 08-8, *Accounting for an Instrument (or an Embedded Feature) with a Settlement Amount That Is Based on the Stock of an Entity s Consolidated Subsidiary*, or EITF No. 08-8. EITF No. 08-8 applies to freestanding financial instruments (and embedded features) for which the payoff to the counterparty is based, in whole or in part, on the stock of a consolidated subsidiary. EITF No. 08-8 applies to those instruments (and embedded features) in the consolidated financial statements of the parent, whether the instrument was entered into by the parent or the subsidiary. Freestanding financial instruments (and embedded features) for which the payoff to the counterparty is based, in whole or in part, on the stock of a consolidated subsidiary are not precluded from being considered indexed to the entity's own stock in the consolidated financial statements of the parent if the subsidiary is a substantive entity. If the subsidiary is not a substantive entity, the instrument or embedded feature would not be considered indexed to the entity's own stock. EITF No. 08-8 is effective for fiscal years beginning on or after December 15, 2008, and interim periods within those fiscal years. Early adoption is not permitted. We anticipate that the adoption of this EITF will not have a material impact on our financial statements.

In November 2008, the EITF issued EITF Issue No. 08-7, *Accounting for Defensive Intangible Asset,* or EITF No. 08-7. EITF No. 08-7 applies to acquired intangible assets in situations in which an entity does not intend to actively use the asset but intends to hold or lock up the asset to prevent others from obtaining access to the asset (a defensive intangible asset), except for intangible assets that are used in research and development activities. EITF No. 08-7 states that a defensive intangible asset should be accounted for as a separate unit of accounting. It should not be included as part of the cost of an entity's existing intangible asset(s) because the defensive intangible asset is separately identifiable. EITF No. 08-7 applies to intangible assets acquired on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The provisions of EITF No. 08-7 will impact our financial statements to the extent that we acquire a defensive intangible asset after EITF No. 08-7 has been adopted.

In June 2008, the FASB issued EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*, or EITF No. 07-5. EITF No. 07-5 supersedes EITF Issue No. 01-6, *The Meaning of 'Indexed to a Company's Own Stock',* and provides guidance in evaluating whether certain financial instruments or embedded features can be excluded from the scope of SFAS 133, *Accounting for Derivatives and Hedging Activities* or SFAS 133. EITF No. 07-5 sets forth a two-step approach that evaluates an instrument's contingent exercise and settlement provisions for the purpose of determining whether such instruments are indexed to an issuer's own stock (a requirement necessary to comply with the scope exception under SFAS 133). EITF No. 07-5 will be effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We anticipate that the adoption of this statement will not have a material impact on our financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles,* or SFAS No. 162. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the U.S. SFAS No. 162 is effective 60 days following the Securities and Exchange Commission approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles.* We anticipate

that the adoption of this statement will not have a material impact on our financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an Amendment of FASB Statement No. 133,* or SFAS No. 161. SFAS No. 161 states that entities are required to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations and how derivative instruments and related hedged items affect an entity s financial position, financial performance, and cash flows. The provisions of SFAS No. 161 are effective for fiscal years beginning on or after November 15, 2008, with early adoption encouraged. We anticipate that the adoption of this statement will not have a material impact on our financial statements.

In February 2008, the FASB issued a one-year deferral for non-financial assets and liabilities to comply with SFAS No. 157, *Fair Value Measurements,* or SFAS No. 157. We adopted SFAS No. 157 for financial assets and liabilities effective January 1, 2008. There was no material effect upon adoption of this accounting pronouncement on our consolidated results of operations or financial position. We do not expect the adoption of SFAS No. 157 as it pertains to non-financial assets and liabilities to have a material impact on our financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an Amendment of ARB No. 51,* or SFAS No. 160. SFAS No. 160 clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements, requires consolidated net income (loss) to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest, establishes a single method of accounting for changes in a parent s ownership interest in a subsidiary that do not result in deconsolidation, and requires that a parent recognize a gain or loss in net income (loss) when a subsidiary is deconsolidated. The provisions of SFAS No. 160 are effective for fiscal years beginning on or after December 15, 2008. We anticipate that the adoption of this statement will not have a material impact on our financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations,* or SFAS No. 141(R). SFAS No. 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values, changes the recognition of assets acquired and liabilities assumed arising from contingencies, changes the recognition and measurement of contingent consideration, and requires the expensing of acquisition-related costs as incurred. In accordance with the provisions of SFAS No. 141(R), in January 2009 we 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. SFAS No. 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and it may not be applied before that date. The provisions of SFAS No. 141(R) will impact our financial statements to the extent that we are party to a business combination after the pronouncement has been adopted.

In November 2007, the EITF issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements,* or EITF No. 07-1. EITF No. 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The provisions of EITF No. 07-1 are effective for fiscal years beginning on or after December 15, 2008 and interim periods within those fiscal years. EITF No. 07-1 applies to all periods presented for all collaborative arrangements existing as of the effective date. We anticipate that the adoption of the EITF will not have a material impact on our financial statements.

**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. We currently do not hedge interest rate exposure or 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.

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

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders

Emergent BioSolutions Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. and Subsidiaries as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2008. These financial statements and schedule 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. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as 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, 2008 and 2007, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 10 to the consolidated financial statements, in 2007 the Company changed its method of accounting for uncertain tax provisions.

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, 2008, 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, 2009 expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

McLean, Virginia
March 5, 2009

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

| | December 31, 2008 | 2007 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 91,473 | $ 105,730 |
| Accounts receivable | 24,855 | 18,817 |
| Inventories | 19,728 | 16,897 |
| Note receivable | 10,000 | - |
| Prepaid expenses and other current assets | 6,623 | 2,866 |
| Total current assets | 152,679 | 144,310 |
| Property, plant and equipment, net | 124,656 | 110,218 |
| Deferred tax assets, net | 12,073 | 12,397 |
| Restricted cash | 208 | 5,200 |
| Other assets | 1,172 | 1,383 |
| Total assets | $ 290,788 | $ 273,508 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 18,254 | $ 20,257 |
| Accrued expenses and other current liabilities | 1,399 | 1,778 |
| Accrued compensation | 11,380 | 9,502 |
| Indebtedness under line of credit | 15,000 | 11,832 |
| Long-term indebtedness, current portion | 6,248 | 3,514 |
| Income taxes payable | 951 | 7,665 |
| Deferred tax liabilities, net | 557 | 211 |
| Deferred revenue, current portion | 232 | 902 |
| Total current liabilities | 54,021 | 55,661 |
| Long-term indebtedness, net of current portion | 35,935 | 42,588 |
| Deferred revenue, net of current portion | - | 2,473 |
| Other liabilities | 1,483 | 1,627 |
| Total liabilities | 91,439 | 102,349 |
| Commitments and contingencies | - | - |
| Stockholders equity: | | |
| Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2008 and 2007, respectively | - | - |
| Common stock, $0.001 par value; 100,000,000 shares authorized, 30,159,546 and 29,750,237 shares issued and outstanding at December 31, 2008 and 2007, respectively | 30 | 30 |
| Additional paid-in capital | 109,170 | 101,933 |
| Accumulated other comprehensive loss | (859) | (1,130) |
| Retained earnings | 91,008 | 70,326 |
| Total stockholders equity | 199,349 | 171,159 |
| Total liabilities and stockholders equity | $ 290,788 | $ 273,508 |

*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)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2008** | **2007** | **2006** |
| **Revenues:** | | | |
| Product sales | $ 169,124 | $ 169,799 | $ 147,995 |
| Contracts and grants | 9,430 | 13,116 | 4,737 |
| **Total revenues** | 178,554 | 182,915 | 152,732 |
| **Operating expense:** | | | |
| Cost of product sales | 34,081 | 40,309 | 24,125 |
| Research and development | 59,470 | 53,958 | 45,501 |
| Selling, general and administrative | 55,076 | 55,555 | 44,601 |
| Purchased in-process research and development | - | - | 477 |
| **Income from operations** | 29,927 | 33,093 | 38,028 |
| **Other income (expense):** | | | |
| Interest income | 1,999 | 2,809 | 846 |
| Interest expense | (47) | (71) | (1,152) |
| Other income, net | 134 | 156 | 293 |
| **Total other income (expense)** | 2,086 | 2,894 | (13) |
| Minority interest in subsidiary | 724 | - | - |
| **Income before provision for income taxes** | 32,737 | 35,987 | 38,015 |
| **Provision for income taxes** | 12,055 | 13,051 | 15,222 |
| **Net income** | $ 20,682 | $ 22,936 | $ 22,793 |
| **Earnings per share - basic** | $ 0.69 | $ 0.79 | $ 0.99 |
| **Earnings per share - diluted** | $ 0.68 | $ 0.77 | $ 0.93 |
| **Weighted-average number of shares - basic** | 29,835,134 | 28,995,667 | 23,039,794 |
| **Weighted-average number of shares - diluted** | 30,458,098 | 29,663,127 | 24,567,302 |

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

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2008** | **2007** | **2006** |
| **Cash flows from operating activities:** | | | |
| Net income | $ 20,682 | $ 22,936 | $ 22,793 |
| Adjustments to reconcile net income to net cash provided by (used in) operating activities (net of effects of acquisitions): | | | |
| Stock-based compensation expense | 2,510 | 2,541 | 723 |
| Depreciation and amortization | 4,964 | 4,817 | 4,715 |
| Deferred income taxes | 2,006 | 5,589 | 987 |
| Loss (gain) on disposal of property and equipment | (135) | 24 | 27 |
| Purchased in-process research and development | - | - | 477 |
| Excess tax benefits from stock-based compensation | (1,336) | (6,003) | (789) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (6,038) | 24,514 | (40,801) |
| Inventories | (2,831) | 7,825 | (8,280) |
| Income taxes | (6,714) | (5,169) | 11,463 |
| Prepaid expenses and other assets | (3,546) | (1,316) | (792) |
| Accounts payable | (457) | (12) | 7,105 |
| Accrued expenses and other liabilities | (523) | (1,557) | 209 |
| Accrued compensation | 1,878 | 2,312 | 1,013 |
| Deferred revenue | (3,143) | (1,054) | (2,911) |
| Net cash provided by (used in) operating activities | 7,317 | 55,447 | (4,061) |
| **Cash flows from investing activities:** | | | |
| Purchases of property, plant and equipment | (20,813) | (43,969) | (41,228) |
| Issuance of note receivable | (10,000) | - | - |
| Acquisitions, net of cash received | - | - | (218) |
| Net cash used in investing activities | (30,813) | (43,969) | (41,446) |
| **Cash flows from financing activities:** | | | |
| Restricted cash release (deposit) | 4,992 | (5,008) | (192) |
| Proceeds from borrowings on long term indebtedness and line of credit | 60,000 | 33,195 | 32,430 |
| Issuance of common stock in initial public offering (net of issuance cost) | - | - | 54,229 |
| Issuance of common stock subject to exercise of stock options | 3,391 | 2,471 | 590 |
| Redemption of Class B common stock | - | - | (192) |
| Principal payments on long term indebtedness, notes payable to employees, and line of credit | (60,751) | (18,015) | (1,569) |
| Excess tax benefits from stock-based compensation | 1,336 | 6,003 | 789 |
| Debt issuance costs | - | (155) | (257) |
| Net cash provided by financing activities | 8,968 | 18,491 | 85,828 |
| Effect of exchange rate changes on cash and cash equivalents | 271 | (657) | (197) |
| Net increase (decrease) in cash and cash equivalents | (14,257) | 29,312 | 40,124 |
| Cash and cash equivalents at beginning of year | 105,730 | 76,418 | 36,294 |
| Cash and cash equivalents at end of year | $ 91,473 | $ 105,730 | $ 76,418 |
| **Supplemental disclosure of cash flow information:** | | | |
| Cash paid during the year for interest | $ 3,216 | $ 3,094 | $ 1,681 |
| Cash paid during the year for income taxes | $ 16,788 | $ 14,329 | $ 2,788 |
| **Supplemental information on non-cash investing and financing activities:** | | | |
| Purchases of property, plant and equipment unpaid at year end | $ 2,510 | $ 4,056 | $ 11,140 |

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

**Emergent BioSolutions Inc. and Subsidiaries**
**Consolidated Statement of Changes in Stockholders' Equity**
**(in thousands, except share and per share data)**

| | Class A $0.001 Par Value Common Stock | | Class B $0.01 Par Value Common Stock | | $0.001 Par Value Common Stock | | Additional Paid-In Capital | Accumulated Other Comprehensive Loss | Retained Earnings | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | | | | |
| Balance at December 31, 2005 | 22,303,280 | $ 22 | 21,283 | $ - | - | $ - | $ 34,595 | $ (276) | $ 25,396 | $ 59,737 |
| Exercise of stock options | - | - | 95,858 | 1 | 175,828 | - | 589 | - | - | 590 |
| Redemption of common stock | - | - | - | - | - | - | - | - | (192) | (192) |
| Conversion of class A $0.001 and class B $0.01 ppar value common stock to $0.001 par value common stock | (22,303,280) | (22) | (117,141) | (1) | 22,420,421 | 23 | - | - | - | - |
| Issuance of common stock in initial public offering (net of issuance cost) | - | - | - | - | 5,000,000 | 5 | 54,224 | - | - | 54,229 |
| Stock-based compensation expense | - | - | - | - | - | - | 723 | - | - | 723 |
| Excess tax benefits from exercises of stock options | - | - | - | - | - | - | 789 | - | - | 789 |
| Net income | - | - | - | - | - | - | - | - | 22,793 | 22,793 |
| Foreign currency translation | - | - | - | - | - | - | - | (197) | - | (197) |
| Comprehensive income | - | - | - | - | - | - | - | - | - | 22,596 |
| 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 |

*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 immune-related therapeutics. 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 Emergent. 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, Antex as Emergent Product Development Gaithersburg Inc. and ViVacs 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, as defined by FASB Interpretation No. 46, *Consolidation of Variable Interest Entities, an Interpretation of Accounting Research Bulletin (ARB) No. 51*, as revised ( FIN No. 46(R) ), the Company would consolidate 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 $42.2 million and $42.0 million, respectively, at December 31, 2008 and $46.1 million and $45.6 million, respectively, at December 31, 2007.

**Restricted cash**

Restricted cash at December 31, 2008 and 2007 includes a certificate of deposit held by a bank as collateral for a letter of credit acting as a security deposit on a loan. Restricted cash at December 31, 2007 also includes $5.0 million in a pledged bank deposit account as collateral for a term loan, which was released to unrestricted cash in 2008 due to the Company s continued compliance with a debt coverage ratio covenant contained in a loan agreement with HSBC Realty Credit Corporation (USA) ( HSBC ). As of December 31, 2008 and 2007 the Company had restricted cash of $208,000 and $5.2 million, respectively.

**Significant customers and accounts receivable**

For the years ended December 31, 2008, 2007 and 2006, 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 year ended December 31, 2008, revenues from HHS and HHS agencies comprised 96% of total revenues. For the years ended December 31, 2007 and 2006, revenues from the DoD, HHS and HHS agencies comprised 97% and 96%, respectively, of total revenues. As of December 31, 2008 and 2007, the Company s receivable balances were comprised of 83% and 84%, respectively, from these customers. Unbilled accounts receivable, included in accounts receivable, totaling $1.9 million and $1.1 million as of December 31, 2008 and 2007, 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, 2008 and 2007, 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**

The Company has entered into a loan and security agreement with Protein Sciences Corporation ( PSC ) to provide a loan to PSC of 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 intellectual property. Under this loan agreement and a related promissory note, PSC had drawn $10 million as of December 31, 2008, and the Company has recorded this as a note receivable. The note bears interest at an annual rate of 8%. The note was originally due and payable on the earlier of December 31, 2008 or when the amount becomes due and payable under the terms of the note. As of December 31, 2008, the Company has recorded accrued interest on the note receivable of $538,000, included in prepaid expenses and other current assets.

On July 9, 2008, the Company initiated a lawsuit against PSC and PSC s senior management, alleging fraudulent conduct by PSC s senior management and breach of the terms of PSC s agreements with the Company. Based on the event of default alleged by the Company, the promissory note was accelerated and became due and payable immediately. The Company has agreed to extend the due date of the note to January 26, 2009, and is currently in discussions with PSC to further extend this due date. The Company has concluded that, according to the provisions of Statement of Financial Accounting Standards ( SFAS ) No. 114, *Accounting by Creditors for Impairment of a Loan,* the $10 million note receivable is not impaired as of December 31, 2008, and has not recorded a reserve against this note.

**Property, plant and equipment**

Property, plant and equipment are stated at cost. Depreciation is computed using the straight-line method over the following estimated useful lives:

| | |
|---|---|
| Buildings | 39 years |
| Furniture and equipment | 3-7 years |
| Software | Lesser of 3 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 in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* ( SAB No. 104 ). SAB No. 104 requires recognition of revenues from product sales that require no continuing performance by the Company if four basic criteria have been met:

there is persuasive evidence of an arrangement;

delivery has occurred and title has passed to the Company s customer;

the fee is fixed and determinable and no further obligation exists; and

collectibility is reasonably assured.

All revenues from product sales are recorded net of applicable allowances for sales returns, rebates, special promotional programs, and discounts. For arrangements where the risk of loss has not passed to the customer, the Company defers the recognition of revenue until such time that risk of loss has passed. Also, the cost of revenue associated with amounts recorded as deferred revenue is recorded in inventory until such time as risk of loss has passed.

Under 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 is segregated for later shipment, and all deferred revenue related to the released product is recognized in accordance with the bill and hold requirements under SAB No. 104.

In December 2005, the Securities and Exchange Commission released an interpretation with respect to the accounting for sales of vaccines and bioterror countermeasures to the federal government for placement into the Strategic National Stockpile ( SNS ). This interpretation provides for revenue recognition for specifically identified products purchased for the SNS in the event that all requirements for revenue recognition, as specified in Statement of Financial Accounting Concepts No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises,* are not met. 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 in accordance with Emerging Issues Task Force ( EITF ) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* ( EITF No. 00-21 ), 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 items(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 in the discussion of SAB No. 104 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.

Payments received by the Company for the reimbursement of expenses for research and development activities are recorded in accordance with EITF Issue No. 99-19, *Reporting Revenue Gross as Principal Versus Net as an Agent* ( EITF No. 99-19 ). Pursuant to EITF No. 99-19, for transactions in which the Company acts as principal, with discretion to choose suppliers, bears credit risk and performs a substantive part of the services, revenue is recorded at the gross amount of the reimbursement. Costs associated with these reimbursements are reflected as a component of research and development expenses.

**Impairment of long-lived assets**

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal 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 has recorded no impairment losses for the years ended December 31, 2008, 2007 and 2006.

**Research and development**

Research and development costs are expensed as incurred. Research and development costs primarily consist of salaries, materials and related expenses for personnel and facility expenses. Other research and development expenses include fees paid to consultants and outside service providers and the costs of materials used in clinical trials and research and development.

**Purchased in-process research and development**

The Company accounts for purchased in-process research and development in accordance with SFAS No. 2, *Accounting for Research and Development Costs* along with Financial Accounting Standards Board ( FASB ) Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method an interpretation of FASB Statement No. 2*. Under these standards, the Company is required to determine whether the technology relating to a particular research and development project acquired through an acquisition has an alternative future use. If the determination is that the technology has no alternative future use, the acquisition amount assigned to assets to be used in the particular research and development project is expensed. Otherwise, the Company capitalizes and amortizes the costs incurred over

the estimated useful lives of the technology acquired.

**Comprehensive income**

SFAS No. 130, *Reporting Comprehensive Income,* requires the presentation of the comprehensive income and its components as part of the financial statements. 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 in accordance with SFAS No. 34, *Capitalization of Interest Cost,* based on the cost of major ongoing capital projects which have not yet been placed in service. For the years ended December 31, 2008, 2007 and 2006, the Company incurred interest expense of $3.0 million, $3.2 million and $1.9 million, respectively. Of these amounts, the Company capitalized $3.0 million, $3.1 million and $759,000, 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 has 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.

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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, 2008 | 2007 | 2006 |
|---|---|---|---|
| Numerator: | | | |
| Net income | $ 20,682 | $ 22,936 | $ 22,793 |
| Denominator: | | | |
| Weighted-average number of shares basic | 29,835,134 | 28,995,667 | 23,039,794 |
| Dilutive securities stock options | 622,964 | 667,460 | 1,527,508 |
| Weighted-average number of shares diluted | 30,458,098 | 29,663,127 | 24,567,302 |
| Earnings per share-basic | $ 0.69 | $ 0.79 | $ 0.99 |
| Earnings per share-diluted | $ 0.68 | $ 0.77 | $ 0.93 |

For the years ending December 31, 2008, 2007 and 2006, outstanding stock options to purchase approximately 494,000, 463,000, and 160,000 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, 2008, the Company has two stock-based employee compensation plans, the 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 9 Stockholders Equity.

Effective January 1, 2006, the Company adopted the fair value provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* ( SFAS No. 123(R) ). Under the fair value recognition provisions of SFAS No. 123(R), the Company recognizes stock-based compensation net of an estimated forfeiture rate. The Company accounts for equity instruments issued to non-employees in accordance with EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services.*

Compensation cost recognized in 2008, 2007 and 2006 includes: (1) compensation cost for all share-based payments granted prior to but not yet vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, and (2) compensation cost for all share-based payments granted and vested subsequent to December 31, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). Stock based compensation is recognized on a straight-line basis over the vesting period.

Based on options granted to employees as of December 31, 2008, total compensation expense not yet recognized related to unvested options is approximately $2.9 million, after tax. The Company expects to recognize that expense over a weighted average period of 1.6 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, | | |
|---|---|---|---|
| | **2008** | **2007** | **2006** |
| Expected dividend yield | 0% | 0% | 0% |
| Expected volatility | 65% | 50% | 50% |
| Risk-free interest rate | 1.63-2.75% | 2.99-5.09% | 4.58-5.21% |
| Expected average life of options | 3.0 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 89%, with an average estimated volatility of 68%. The Company used a rate of 65% for grants made in 2008, 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 guidance in SFAS No. 123(R), 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 accrued expenses and other current liabilities in the consolidated balance sheet as of December 31, 2007 have been reclassified as accounts payable to conform with current period presentation.

**Recent accounting pronouncements**

In November 2008, the EITF issued EITF Issue No. 08-8, *Accounting for an Instrument (or an Embedded Feature) with a Settlement Amount That Is Based on the Stock of an Entity s Consolidated Subsidiary* ( EITF No. 08-8 ). EITF No. 08-8 applies to freestanding financial instruments and embedded features for which the payoff to the counterparty is based, in whole or in part, on the stock of a consolidated subsidiary. EITF No. 08-8 applies to those instruments and embedded features in the consolidated financial statements of the parent, whether the instrument was entered into by the parent or the subsidiary. Freestanding financial instruments and embedded features for which the payoff to the counterparty is based, in whole or in part, on the stock of a consolidated subsidiary are not precluded from being considered indexed to the entity's own stock in the consolidated financial statements of the parent if the subsidiary is a substantive entity. If the subsidiary is not a substantive entity, the instrument or embedded feature would not be considered indexed to the entity's own stock. EITF No. 08-8 is effective for fiscal years beginning on or after December 15, 2008, and interim periods within those fiscal years. Early adoption is not permitted. The Company anticipates that the adoption of this statement will not have a material impact on its financial statements.

In November 2008, the EITF issued EITF Issue No. 08-7, *Accounting for Defensive Intangible Asset* ( EITF No. 08-7 ). EITF No. 08-7 applies to acquired intangible assets in situations in which an entity does not intend to actively use the asset but intends to hold or lock up the asset to prevent others from obtaining access to the asset ( a defensive intangible asset ). EITF No. 08-7 states that a defensive intangible asset should be accounted for as a separate unit of accounting. It should not be included as part of the cost of an entity's existing intangible asset(s) because the defensive intangible asset is separately identifiable. EITF No. 08-7 applies to intangible assets acquired on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The provisions of EITF No. 08-7 will impact the Company s financial statements to the extent that the Company acquires a defensive intangible asset after EITF No. 08-7 has been adopted.

In June 2008, the FASB issued EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* ( EITF No. 07-5 ). EITF 07-5 supersedes EITF Issue No. 01-6, *The Meaning of 'Indexed to a Company's Own Stock',* and provides guidance in evaluating whether certain financial instruments or embedded features can be excluded from the scope of SFAS 133, *Accounting for Derivatives and Hedging Activities* ( SFAS 133 ). EITF No. 07-5 sets forth a two-step approach that evaluates an instrument's contingent exercise and settlement provisions for the purpose of determining whether such instruments are indexed to an issuer's own stock (a requirement necessary to comply with the scope exception under SFAS 133). EITF No. 07-5 will be effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The Company anticipates that the adoption of this statement will not have a material impact on our financial statements.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ( SFAS No. 162 ). SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the U.S. SFAS No. 162 is effective 60 days following the Securities and Exchange Commission approval of the Public Company Accounting Oversight Board amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles.* The Company anticipates that the adoption of this statement will not have a material impact on its financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities an Amendment of FASB Statement No. 133* ( SFAS No. 161 ). SFAS No. 161 states that entities are required to provide enhanced disclosures about how and why an entity uses derivative instruments, how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations and how derivative instruments and related hedged items affect an entity s financial position, financial performance, and cash flows. The provisions of SFAS No. 161 are effective for fiscal years beginning on or after November 15, 2008. The Company anticipates that the adoption of this statement will not have a material impact on its financial statements.

In February 2008, the FASB issued a one-year deferral for non-financial assets and liabilities to comply with SFAS No. 157, *Fair Value Measurements* ( SFAS No. 157 ). The Company adopted SFAS No. 157 for financial assets and liabilities effective January 1, 2008. There was no material effect upon adoption of this accounting pronouncement on the Company s consolidated results of operations or financial position. The Company does not expect the adoption of SFAS No. 157 as it pertains to non-financial assets and liabilities to have a material impact on its financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an Amendment of ARB No. 51* ( SFAS No. 160 ). SFAS No. 160 clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements, requires consolidated net income (loss) to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest, establishes a single method of accounting for changes in a parent s ownership interest in a subsidiary that do not result in deconsolidation, and requires that a parent recognize a gain or loss in net income (loss) when a subsidiary is deconsolidated. The provisions of SFAS No. 160 are effective for fiscal years beginning on or after December 15, 2008. The Company anticipates that the adoption of this statement will not have a material impact on its financial statements.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* ( SFAS No. 141(R) ). SFAS No. 141(R) requires the acquiring entity in a business combination to record all assets acquired and liabilities assumed at their respective acquisition-date fair values, changes the recognition of assets acquired and liabilities assumed arising from contingencies, changes the recognition and measurement of contingent consideration, and requires the expensing of acquisition-related costs as incurred. In accordance with the provisions of SFAS No. 141(R), 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. SFAS No. 141(R) also requires additional disclosure of information surrounding a business combination, such that users of the entity's financial statements can fully understand the nature and financial impact of the business combination. SFAS No. 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and it may not be applied before that date. The provisions of SFAS No. 141(R) will impact the Company s financial statements to the extent that the Company is party to a business combination after the pronouncement has been adopted.

In November 2007, the EITF issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements* ( EITF No. 07-1 ). EITF No. 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The provisions of EITF No. 07-1 are effective for fiscal years beginning on or after December 15, 2008 and interim periods within those fiscal years. EITF No. 07-1 applies to all periods presented for all collaborative arrangements existing as of the effective date. The Company anticipates that the adoption of EITF No. 07-1 will not have a material impact on its financial statements.

**3. Acquisitions**

**ViVacs GmbH**

On July 13, 2006, Emergent International, Inc., a wholly owned subsidiary of the Company, incorporated in Delaware ( EII ), completed the acquisition of ViVacs, a German limited liability company, to expand the Company s commercial vaccine portfolio, pursuant to the terms and conditions of the Share Purchase and Assignment Agreement dated July 13, 2006 by and between EII and ViVacs. EII paid $150,000 in cash on the closing date of the agreement and agreed to pay $50,000 on each of the first and second anniversaries of the closing date. The acquisition agreement also provides for a potential variable earn-out purchase price of up to $220,000, based on future payments from third party licensees of the technology. As of December 31, 2008, the Company has not received any such payments from third party licensees. Because ViVacs was a development stage company and had not commenced its planned principal operations, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded.

Total purchase consideration consisted of:

| **(in thousands)** | |
|---|---|
| Cash (including future guaranteed cash payments of $100) | $ 250 |
| Direct acquisition costs | 180 |
| Total purchase consideration | $ 430 |

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

The purchase price was allocated as follows:

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

In connection with the transaction, the Company recorded a charge of $477,000 for acquired research projects associated with product candidates in development for which, at the acquisition date, technological feasibility had not been established and, for accounting purposes, no alternative future use existed.

**4. Accounts receivable**

Accounts receivable consist of the following:

| | December 31, | |
|---|---|---|
| **(in thousands)** | **2008** | **2007** |
| Billed | $ 23,005 | $ 17,741 |
| Unbilled | 1,850 | 1,076 |
| Total | $ 24,855 | $ 18,817 |

**5. Inventories**

Inventories consist of the following:

| | December 31, | |
|---|---|---|
| **(in thousands)** | **2008** | **2007** |
| Raw materials and supplies | $ 2,755 | $ 2,463 |
| Work-in-process | 14,459 | 11,483 |
| Finished goods | 2,514 | 2,951 |
| Total inventories | $ 19,728 | $ 16,897 |

**6. Property, plant and equipment**

Property, plant and equipment consist of the following:

| | December 31, | |
|---|---|---|
| **(in thousands)** | **2008** | **2007** |
| Land and improvements | $ 5,050 | $ 4,974 |
| Buildings and leasehold improvements | 28,119 | 26,410 |
| Furniture and equipment | 22,657 | 19,626 |
| Software | 6,423 | 5,866 |

| | | |
|---|---|---|
| Construction-in-progress | 82,518 | 71,129 |
| | 144,767 | 128,005 |
| Less: Accumulated depreciation and amortization | (20,111) | (17,787) |
| Total Property, plant and equipment, net | $ 124,656 | $ 110,218 |

Depreciation and amortization expense was $5.0 million, $4.8 million and $4.7 million for the years ended December 31, 2008, 2007 and 2006, respectively. For the years ended December 31, 2008, 2007 and 2006, depreciation and amortization expense included approximately $0, $1.0 million and $1.3 million, respectively, related to the amortization of internal-use software. As of December 31, 2008 and 2007, there was no unamortized internal use software-cost.

**7. Long-term debt**

The components of long term-debt are as follows:

| (in thousands) | December 31, 2008 | 2007 |
|---|---|---|
| Term loan dated June 2007; 30-day LIBOR plus 2.75%, due June 2012 | $ 25,500 | $ 28,750 |
| Term loan dated April 2006; three month LIBOR plus 3.0%, due April 2011 | 7,809 | 8,167 |
| Forgivable loan dated October 2004; 3.0%, due March 2013 | 2,500 | 2,500 |
| Term loan dated October 2004; 6.625%, due October 2011 | 6,369 | 6,671 |
| Other | 5 | 14 |
| Total long-term indebtedness | 42,183 | 46,102 |
| Less current portion of long-term indebtedness | (6,248) | (3,514) |
| Non-current portion of long-term indebtedness | $ 35,935 | $ 42,588 |

In June 2007, the Company entered into a loan agreement with HSBC, under which HSBC provided the Company with a term loan of $30 million. This loan replaced a prior loan arrangement with HSBC under which HSBC agreed to loan the Company $15 million, consisting of a $10 million term loan and a $5 million revolving line of credit. Under the new loan agreement, the Company is required to make monthly payments in the amount of $250,000 in principal plus accrued interest, with a residual principal payment due upon maturity in June 2012. 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 annual interest rate is based on the 30-day LIBOR plus 2.75% (3.83% as of December 31, 2008).

Under this term loan, the Company is required to maintain a book leverage ratio of less than 1.25. 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 or maintain a minimum balance of $5.0 million in a deposit account pledged to HSBC. 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, 2008.

In August 2006, the Company entered into a term loan with HSBC for $10 million and a revolving credit loan that provided for borrowings up to $5 million. Under the term loan, the Company was required to make monthly principal payments beginning in April 2007 and a residual principal payment of approximately $5.6 million upon maturity in August 2011. Under the revolving credit loan, the Company was not required to repay outstanding principal until October 2007. In October 2007, the outstanding principal under the revolving credit loan was to convert to a term loan with required monthly principal payments through maturity in August 2011. Interest was payable monthly and accrued at an annual rate equal to LIBOR plus 3.75%. Both the term loan and the revolving credit loan were replaced by the $30 million term loan discussed above.

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 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 annual interest rate is based on the three month LIBOR plus 3.0% (4.83% as of December 31, 2008). The loan is collateralized by the facility. The loan requires the Company to comply with certain non-financial covenants. The Company is in compliance with these covenants as of December 31, 2008.

In October 2004, the Company entered into a Secured Conditional Loan with the Maryland Economic Development Assistance Fund for $2.5 million. The proceeds of the loan were used to reimburse the Company for eligible costs it incurred to purchase a building in Frederick, Maryland. The loan is secured by a $1.3 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 principal and related accrued interest may 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. For the loan to be forgiven, the Company must employ at least 280 full-time employees at the Company s facilities in Frederick, Maryland as of December 31, 2009 and maintain at least 280 full-time employees through December 31, 2012. If as of December 31, 2009, 2010, 2011 or 2012 the Company employs fewer than 280 and more than 225 full-time employees at the Company s facilities in Frederick, Maryland, then the Company will be required to repay $9,000 of principal plus accrued interest for each position not filled below the target level of 280 employees. If as of December 31, 2009, 2010, 2011 or 2012 the Company employs fewer than 225 full-time employees at the Company s facilities in Frederick, Maryland, then the Company will be required to repay the entire outstanding principal amount of the loan plus accrued interest. The full $2.5 million outstanding under this loan is included in current portion of long-term indebtedness at December 31, 2008, as the first measurement date under the agreement is December 31, 2009

In connection with the 2004 purchase of the building in Frederick, Maryland discussed above, the Company entered into a loan agreement for $7 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, 2008.

Scheduled principal repayments and maturities on long-term debt as of December 31, 2008 are as follows:

| **(in thousands)** | | |
|---|---|---|
| 2009 | $ | 6,248 |
| 2010 | | 3,792 |
| 2011 | | 15,643 |
| 2012 | | 16,500 |
| 2013 | | - |
| 2014 and beyond | | - |
| | $ | 42,183 |

**8. 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 2009, 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 30-day LIBOR plus 2.0% (3.08% as of December 31, 2008). 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. At December 31, 2008 and 2007, $15.0 and $11.8 million, respectively, were outstanding under the line of credit. These amounts were repaid in February 2009 and January 2008, respectively.

**9. 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, 2008 and 2007, 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.

On September 20, 2006, the Company s board of directors recommended to the stockholders of the Company an amendment of the Company s amended and restated certificate of incorporation, which the stockholders approved on October 27, 2006, that, among other things, reclassified the Class A Common Stock as $0.001 par value per share Common Stock, increased the number of authorized shares of Common Stock to 100,000,000 shares and adjusted the par value of the Preferred Stock from $0.01 par value per share to $0.001 par value per share.

The amendment became effective on October 27, 2006. On September 20, 2006, the Company s board of directors also authorized the pricing committee of the board of directors to effect a stock split of both the Common Stock, in the form of a dividend of shares of Common Stock, and the Class B Common Stock, in the form of a dividend of shares of Class B Common Stock. The pricing committee subsequently declared a 2.8771-for-one stock split of the Common Stock and the Class B Common Stock effective as of October 27, 2006. The par values, the number of authorized shares and all share and per share amounts in the consolidated financial statements have been retroactively adjusted to give effect to the filing of the certificate of amendment of the Company s amended and restated certificate of incorporation and the stock split. The consolidated financial statements do not reflect the reclassification of the Class A Common Stock as Common Stock, other than the related adjustment to par value and the increase in the number of authorized shares.

On November 14, 2006, the Company completed its initial public offering ( IPO ), which resulted in the issuance of 5,000,000 shares of common stock at a price of $12.50 per share for gross proceeds of $62.5 million. Issuance costs related to the offering were $8.3 million, resulting in net proceeds from the offering of $54.2 million. In conjunction with the completion of the IPO, all outstanding shares of Class A and Class B common stock were converted into 22,420,421 shares of Common Stock at a conversion rate of one share of common stock for one share of Class A and Class B common stock.

**Stock options**

As of December 31, 2008, 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.

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The 2006 Plan, established in connection with the Company s initial public offering in November 2006, initially authorized the issuance of up to 1,089,461 shares of Common Stock. In addition, the 2006 Plan contains an evergreen provision that allows for increases in the number of shares authorized for issuance under the 2006 Plan in the first and third quarter of each year from 2007 through 2009. Each semi-annual increase in the number of shares will be equal to the lowest of: (1) a specified number of shares stipulated in the 2006 Plan; (2) a specified percentage of the aggregate number of shares outstanding; and (3) an amount determined by the Company s Board of Directors. The maximum specified number of shares per semi-annual increase ranges from 428,700 to 937,900. The maximum specified percentage of outstanding shares for each semi-annual increase ranges from 1.5% to 3.0%. As of December 31, 2008, an aggregate of 3,424,040 shares of Common Stock are authorized for issuance under the 2006 Plan, and a total of 756,922 options are available for issuance. The maximum number of options 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, 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 Number of Shares | | Weighted-Average Exercise Price | 2004 Plan Number of Shares | | Weighted-Average Exercise Price | Aggregate Intrinsic Value |
|---|---|---|---|---|---|---|---|
| Outstanding at December 31, 2007 | 1,380,111 | $ | 9.77 | 666,519 | $ | 6.04 | 743,995 |
| Exercisable at December 31, 2007 | 289,900 | $ | 10.27 | 507,802 | $ | 4.94 | 682,439 |
| Granted | 1,512,540 | | 7.96 | - | | - | |
| Exercised | (200,599) | | 9.86 | (208,710) | | 6.76 | |
| Forfeited | (225,533) | | 8.57 | (19,181) | | 10.28 | |
| 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 |

The weighted average remaining contractual term of options outstanding as of December 31, 2008 and 2007 was 5.7 and 5.5 years, respectively. The weighted average remaining contractual term of options exercisable as of December 31, 2008 and 2007 was 4.5 and 4.6 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2008, 2007 and 2006 was $3.53, $3.58 and $3.94, respectively. The total intrinsic value of options exercised during the years ended December 31, 2008, 2007 and 2006 was $4.0 million, $20.5 million and $2.3 million, respectively. The total fair value of options vested during 2008 was $1.9 million.

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

| (in thousands) | Years Ended December 31, 2008 | | 2007 |
|---|---|---|---|
| Cost of sales | $ | 100 | $ 82 |
| Research and development | | 520 | 377 |
| Selling, general and administrative | | 1,890 | 2,082 |
| Total stock-based compensation expense | $ | 2,510 | $ 2,541 |

A summary of the status of the Company s nonvested stock options at December 31, 2008 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, 2007 | 1,090,211 | $ 3.66 | 158,717 | $ 3.53 |
| Granted | 1,512,540 | 3.53 | - | - |
| Exercised | - | - | - | - |
| Vested | (419,747) | 3.69 | (103,575) | 3.26 |
| Forfeited | (203,633) | 3.42 | - | - |
| Nonvested at December 31, 2008 | 1,979,371 | $ 3.57 | 55,142 | $ 4.24 |
| Options expected to vest at December 31, 2008 | 1,309,957 | | 45,770 | |

During the years ended December 31, 2008, 2007 and 2006, the Company received a tax benefit from stock options exercised of approximately $1.3 million, $6.0 million and $789,000, respectively.

**10. Income taxes**

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

| (in thousands) | 2008 | 2007 | 2006 |
|---|---|---|---|
| Current | | | |
| Federal | $ 11,186 | $ 11,189 | $ 14,212 |
| State | 98 | 2,275 | 812 |
| International | 101 | - | - |
| Total current | 11,385 | 13,464 | 15,024 |
| Deferred | | | |
| Federal | (1,174) | 2,832 | 100 |
| State | 1,844 | (3,245) | 98 |
| Total preferred | 670 | (413) | 198 |
| Total provision for income taxes | $ 12,055 | $ 13,051 | $ 15,222 |

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

| | December 31, | |
|---|---|---|
| (in thousands) | 2008 | 2007 |
| Net operating loss carryforward | $ 8,458 | $ 6,361 |
| Research and development carryforward | 1,714 | 511 |
| Stock compensation | 730 | 523 |
| Foreign deferrals | 46,151 | 39,044 |
| Other | 1,902 | 1,508 |
| Deferred tax asset | 58,955 | 47,947 |
| Fixed assets | (851) | (756) |
| Other | (2,051) | (1,303) |
| Deferred tax liability | (2,902) | (2,059) |
| Valuation allowance | (44,537) | (33,702) |
| Net deferred tax asset | $ 11,516 | $ 12,186 |

Net operating loss carryforwards consist of approximately $158 million for state jurisdictions and $134 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:

| | Year ended December 31, | | |
|---|---|---|---|
| **(in thousands)** | **2008** | **2007** | **2006** |
| US | $ 66,326 | $ 62,016 | $ 56,698 |
| International | (33,589) | (26,029) | (18,683) |
| Earnings before taxes on income | $ 32,737 | $ 35,987 | $ 38,015 |
| | | | |
| Federal tax at statutory rates | $ 11,458 | $ 12,595 | $ 13,305 |
| State taxes, net of federal benefit | (2,118) | 701 | (395) |
| Impact of foreign operations | (8,384) | (7,106) | (6,050) |
| Change in valuation allowance | 10,835 | 6,419 | 6,605 |
| Effect of change in rates | - | 493 | - |
| Effect of foreign rates | (11) | 154 | 752 |
| Tax credits | (819) | (880) | (759) |
| Other differences | 185 | (617) | 1,044 |
| Permanent differences | 909 | 1,292 | 720 |
| Provision for income taxes | $ 12,055 | $ 13,051 | $ 15,222 |

The effective annual tax rate for the years ended December 31, 2008, 2007 and 2006 was 37%, 36% and 40%, respectively. The increase in the effective rate from 2007 to 2008 is due primarily to a reduction in state valuation allowance in 2007 related to the expected utilization of net operating losses, partially offset by a reduction in state and local taxes in 2008. The decrease in the effective rate from 2006 to 2007 was due primarily to a reduction in state valuation allowances related to the expected utilization of net operating losses.

In September 2006, the FASB issued FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109, Accounting for Income Taxes* ( FIN 48 ). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 requires that the Company recognize in its financial statements the impact of a tax position if that position is more likely than not to be sustained on audit based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure.

The Company adopted the provisions of FIN 48 on January 1, 2007. As a result of the implementation of FIN 48, the Company recognized, as a cumulative effect of change in accounting principle, a $607,000 increase in tax-related liabilities for unrecognized tax benefits and a $607,000 reduction to beginning retained earnings. 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 $44,000 and $27,000, respectively, for the payment of interest and penalties as of December 31, 2008 and 2007. Of the total unrecognized tax benefits recorded at December 31, 2008 and 2007, $160,000 and $33,000, respectively is classified as a current liability and $110,000 and $244,000, respectively is classified as a non-current liability on the balance sheet. As of December 31, 2008 and 2007, $0 and $33,000, respectively, of unrecognized tax benefits will reverse within the next twelve months.

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

| **(in thousands)** | | |
|---|---|---|
| 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 statue of limitations | | (426) |
| Gross unrecognized tax benefits at December 31, 2007 | | 277 |
| 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 statue of limitations | | (35) |
| Gross unrecognized tax benefits at December 31, 2008 | $ | 270 |

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 2007 to 2005 remain open to examination. The Company s tax returns in the United Kingdom remain open to examination for the tax years 2007 to 2001, and tax returns in Germany remain open indefinitely.

In July 2008, the Company was notified by the Internal Revenue Service that the federal income tax return for the 2006 tax year has been selected for a limited scope audit. 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.

**11. 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, 2008, 2007 and 2006, the Company made matching contributions of approximately $827,000, $682,000 and $573,000, respectively.

**12. Leases**

The Company leases laboratory and office facilities, office equipment and vehicles under various operating lease agreements. The Company leases office and laboratory space in Gaithersburg, Maryland under a non-cancelable operating lease that expires in November 2009. 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. For the years ended December 31, 2008, 2007 and 2006, total rent expense was $3.7 million, $3.4 million and $2.4 million, respectively.

Future minimum lease payments under operating lease obligations as of December 31, 2008 are as follows:

| **(in thousands)** | |
|---|---|
| 2009 | $ 1,972 |
| 2010 | 1,317 |
| 2011 | 1,300 |
| 2012 | 1,268 |
| 2013 | 1,288 |
| 2014 and beyond | 3,928 |
| Total minimum lease payments | $ 11,073 |

**13. Litigation**

In July 2008, the Company filed a lawsuit against Protein Sciences Corporation ( PSC ), Daniel D. Adams, PSC s Chief Executive Officer, and Manon M.J. Cox, PSC s Chief Operating Officer, in the Supreme Court of the State of New York asserting claims related to a letter of intent, a loan agreement, and an asset purchase agreement that PSC and the Company entered into in 2008. On September 12, 2008, a stipulation of discontinuance was filed with the court regarding the claims against Mr. Adams and Ms. Cox, and, on October 3, 2008, the Company filed a separate suit against Mr. Adams and Ms. Cox in the United States District Court for the District of Connecticut, alleging fraud and unfair trade practices and seeking compensatory and punitive damages. On September 12, 2008, the Company filed an amended complaint against PSC, which remains pending in the New York state court, alleging fraud, breach of the letter of intent, loan agreement, and asset purchase agreement, breach of the duty of good faith and fair dealing, unjust enrichment, and unfair business practices. The Company is seeking from PSC money damages of no less than $13 million, punitive damages, declaratory judgment that the Company has no further funding obligations to PSC, injunctive relief to protect the collateral for the loan, and other appropriate relief. PSC has moved to dismiss the New York action, and Mr. Adams and Ms. Cox have moved to dismiss the Connecticut action. Those motions remain pending. PSC, Mr. Adams, and Ms. Cox have not yet asserted any counterclaims, 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, which would include a $1.5 million reverse break-up fee under the asset purchase agreement as a setoff to the loan.

Between March 2008 and June 2008, the Company provided PSC with $10 million in funding under a loan agreement between the parties to enable PSC to continue operations through June 24, 2008, the anticipated closing date of the asset purchase transaction. Under the loan agreement, PSC was obligated to repay the $10 million principal plus interest and costs of collection the earlier of December 31, 2008, or an event of default under the loan agreement. In the lawsuit against PSC, the Company alleges that an event of default occurred under the loan agreement and that the loan was due and payable as of June 2008. Subsequent to filing the lawsuit, a potential alternative transaction was discussed with PSC. In connection with those discussions, effective December 31, 2008, the Company and PSC entered into a forbearance agreement, pursuant to which the Company agreed not to foreclose on the collateral or to pursue other remedies relating to the loan prior to January 26, 2009. On January 5, 2009, the Company notified PSC that it would not be pursuing the proposed alternative transaction, and on January 6, 2009, issued a press release stating that it had ended all activities related to the planned acquisition of PSC and would pursue full repayment of the $10 million loan, which is secured by substantially all of PSC s assets, and settlement of the outstanding litigation. Since January 26, 2009, when the forbearance period expired, the Company has been negotiating the terms of an extended forbearance agreement with PSC, but, as of the date of this report, has not been successful in reaching such an agreement. If an agreement is not reached, the Company intends to seek to enforce its rights, which may include initiating a foreclosure action with respect to the collateral for the loan.

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. For claims filed against the Company for use of BioThrax by the DoD, the Company expects to rely on contractual indemnification provisions with the DoD and statutory protections to limit our potential liability resulting from the pending lawsuits.

**14. Asset purchase agreement**

In May 2008, the Company and VaxGen, Inc. ( VaxGen ) entered into an asset purchase agreement in which the Company acquired all assets and rights related to a recombinant protective antigen anthrax vaccine product candidate and related technology from VaxGen, in exchange for consideration of $2 million upon execution of the definitive agreement, up to an additional $8 million in milestone payments, and specified percentages of future net sales. The $2 million was paid to VaxGen in May 2008, and a $1 million milestone payment was paid in August 2008. These amounts have been recorded as research and development expense.

**15. Joint venture**

In July 2008, the Company entered into a joint venture with the University of Oxford ( Oxford ) and certain University of Oxford researchers to conduct clinical trials in the advancement of a vaccine 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 the provisions of FIN No. 46(R) 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, 2008, assets of $514,000 and liabilities of $122,000 related to this entity are included within the Company s consolidated balance sheet. During the year ended December 31, 2008, the entity incurred a net loss of $2.1 million, of which $1.3 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 SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* and EITF Topic D-98, *Classification and Measurement of Redeemable Securities* (revised December 15, 2008). In accordance with this guidance, the Company has determined that the put option has a fair value of $0 as of December 31, 2008.

**16. Related party transactions**

The Company has engaged Wilmer Cutler Pickering Hale and Dorr LLP ("WilmerHale") to provide certain legal services to the Company. The Company's Senior Vice President, Legal Affairs and General Counsel is married to a former partner at WilmerHale, who did not participate in providing legal services to the Company. For the 2008 and 2007 periods during which the spouse of the General Counsel was partner at WilmerHale, the Company incurred fees for legal services of approximately $735,000 and $1.0 million, respectively. At December 31, 2008 and 2007, $0 and $131,000, remained in accounts payable for these services.

The Company entered into a marketing arrangement in 2009 with an entity controlled by family members of the Chief Executive Officer to market and sell BioThrax. The contract requires a payment of 17.5% and reimbursement of certain expenses on net sales of our biodefense products in Saudi Arabia, and 15% and reimbursement of certain expenses on net sales in Qatar and United Arab Emirates. No royalty payments under this agreement have been triggered for the year ended December 31, 2008. During the year ended December 31, 2008, the Company paid the same entity a $70,000 settlement related to a previously terminated agreement.

The Company has entered into a consulting arrangement with a member of the Company s Board of Directors. At December 31, 2008 and 2007, $7,000 and $15,000, respectively, remained in accounts payable for these services. During the years ended December 31, 2008 and 2007, the Company paid approximately $218,000 and $200,000, respectively, 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, 2008 and 2007, $3,000 remained in accounts payable for these services. During the years ended December 31, 2008 and 2007, the Company paid approximately $31,000 and $33,000, respectively, under this arrangement for transportation and logistical support.

**17. 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 immune-related therapeutics 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 immune-related therapeutics 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.

| | Reportable Segments | | | |
|---|---|---|---|---|
| **(in thousands)** | **Biodefense** | **Commercial** | **All Other** | **Total** |
| **Year Ended December 31, 2008** | | | | |
| External revenue | $ 174,061 | $ 4,346 | $ 147 | $ 178,554 |
| Intersegment revenue (expense) | - | - | - | - |
| Research and development | 26,321 | 29,658 | 3,491 | 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 |
| **Year Ended December 31, 2007** | | | | |
| External revenue | $ 179,738 | $ 3,177 | $ - | $ 182,915 |
| Intersegment revenue (expense) | - | - | - | - |
| Research and development | 24,744 | 26,159 | 3,055 | 53,958 |
| Interest revenue | - | - | 2,809 | 2,809 |
| Interest expense | - | - | (71) | (71) |
| Depreciation and amortization | 3,445 | 947 | 425 | 4,817 |
| Net income (loss) | 76,397 | (38,213) | (15,248) | 22,936 |
| Assets | 133,692 | 21,672 | 118,144 | 273,508 |
| Expenditures for long-lived assets | 38,880 | 1,991 | 3,098 | 43,969 |

**18. Quarterly financial data (unaudited)**

Quarterly financial information for the years ended December 31, 2008 and 2007 is presented in the following tables:

| | Three months ended | | | |
|---|---|---|---|---|
| **(in thousands)** | **March 31,** | **June 30,** | **September 30,** | **December 31,** |
| Fiscal year 2008 | | | | |
| 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 |
| Fiscal year 2007 | | | | |
| Revenue | $ 26,448 | $ 23,186 | $ 43,644 | $ 89,637 |
| Income (loss) from operations | (5,831) | (8,657) | 4,422 | 43,159 |
| Net income (loss) | (2,690) | (4,961) | 2,845 | 27,742 |
| Net income (loss) per share, basic | (0.10) | (0.17) | 0.10 | 0.93 |
| Net income (loss) per share, diluted | (0.10) | (0.17) | 0.10 | 0.93 |

**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, 2008. 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, 2008, 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, 2008. 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, 2008, 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, 2008, 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, 2008 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, 2008, 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, 2008, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Emergent BioSolutions Inc. and Subsidiaries as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2008 of Emergent BioSolutions Inc. and Subsidiaries and our report dated March 5, 2009 expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

McLean, Virginia

March 5, 2009

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**ITEM 9B. OTHER INFORMATION**

**Executive Compensation**

On March 5, 2009, cash bonuses were awarded to the following executives in the following amounts: Fuad El-Hibri, $323,250; Daniel J. Abdun-Nabi, $211,350; R. Don Elsey, $118,560; Kyle W. Keese, $96,460; and Robert G. Kramer, Sr., $78,815. Also on March 5, 2009, the following base salaries and target bonus percentages for the following executives were approved, all effective as of January 1, 2009: Fuad El-Hibri, $575,000 and 65%; Daniel J. Abdun-Nabi, $410,958 and 45%; R. Don Elsey, $315,666 and 45%; Kyle W. Keese, $286,624 and 40%; and Robert G. Kramer, Sr., $394,075 and 40%.

**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 2009 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 2009 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 2009 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. 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 from, 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 2009 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 2009 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 2009 Annual Meeting of Stockholders. Such information is incorporated herein by reference. The Compensation Committee Report contained in the Proxy Statement for our 2009 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 2009 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 2009 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 2009 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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**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, 2008 and 2007

Consolidated Statements of Operations for the years ended December 31, 2008, 2007 and 2006

Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006

Consolidated Statement of Changes in Stockholders Equity for the years ended December 31, 2008, 2007 and 2006

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, 2009

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.

| Signature | Title | Date |
|---|---|---|
| /s/Fuad El-Hibri<br>Fuad El-Hibri | Chief Executive Officer and Chairman of the Board of Directors<br>(Principal Executive Officer) | March 5, 2009 |
| /s/R. Don Elsey<br>R. Don Elsey | Senior Vice President Finance, Chief Financial Officer and Treasurer<br>(Principal Financial and Accounting Officer) | March 5, 2009 |
| /s/Joe Allbaugh<br>Joe Allbaugh | Director | March 5, 2009 |
| /s/Zsolt Harsanyi, Ph.D.<br>Zsolt Harsanyi, Ph.D. | Director | March 5, 2009 |
| /s/Jerome M. Hauer<br>Jerome M. Hauer | Director | March 5, 2009 |
| /s/Ronald B. Richard<br>Ronald B. Richard | Director | March 5, 2009 |

| | | |
|---|---|---|
| /s/Louis W.Sullivan, M.D. | | |
| Louis W.Sullivan, M.D. | Director | March 5, 2009 |
| /s/Dr. Sue Bailey | | |
| Dr. Sue Bailey | Director | March 5, 2009 |

**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 (SEC 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* | 2006 Stock Incentive Plan (Incorporated by reference to Exhibit 10.3 to Amendment No. 5 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on October 30, 2006) |
| 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* | 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 (SEC File No. 001-33137)) |
| 10.7 * | 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) |
| 10.8* | 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) |
| 10.9 | 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) |
| 10.10 | 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)) |
| 10.11 | Contract No. HHS0100200800091C 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 (SEC File No. 001-33137)) |
| 10.12 | 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) |
| 10.13 | 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)) |
| 10.14 | BT Vaccine License Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency (Incorporated by reference to Exhibit 10.11 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006) |
| 10.15 | BT Vaccine Development Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency (Incorporated by reference to Exhibit 10.12 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006) |
| 10.16 | |

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|---|---|
| | rBot Vaccine License Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency (Incorporated by reference to Exhibit 10.13 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006) |
| 10.17 | rBot Vaccine Development Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency (Incorporated by reference to Exhibit 10.14 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006) |
| 10.18 | 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 (SEC File No. 001-33137)) |

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| 10.19 | 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) |
| 10.20 | 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) |
| 10.21# | License Agreement between U.S. Army Medical Research Institute of Infectious Diseases and the Registrant dated October 7, 2003 |
| 10.22 | Exclusive Distribution Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency (Incorporated by reference to Exhibit 10.15 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006) |
| 10.23 | 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) |
| 10.24 | Consulting Services Agreement, dated March 1, 2006, between the Registrant and The Hauer Group (Incorporated by reference to Exhibit 10.19 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006) |
| 10.25# | Consulting Services Agreement effective March 30, 2008, between the Registrant and The Hauer Group |
| 10.26 | 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) |
| 10.27# | Amended and Restated Marketing Agreement entered into on February 10, 2009 between Emergent BioDefense Operations Lansing Inc.and Intergen N.V. |
| 10.28 | Lease, dated December 1, 1998, between ARE-QRS, Corp. and Antex Biologics Inc., as amended (Incorporated by reference to Exhibit 10.21 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006) |
| 10.29 | Second Amendment to Lease Agreement between ARE-QRS Corp. and Emergent Product Development Gaithersburg Inc. dated as of March 31, 2008 (Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (SEC File No. 001-33137)) |
| 10.30 | Third Amendment to Lease Agreement between ARE-QRS Corp. and Emergent Product Development Gaithersburg Inc. dated as of June 30, 2008 (Incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (SEC File No. 001-33137)) |
| 10.31 | 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) |
| 10.32 | 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) |
| 10.33 | 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)) |
| 10.34 | 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) |
| 10.35 | 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) |
| 10.36 | 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) |
| 10.37 | 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) |
| 10.38 | 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) |

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| 10.39 | 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) |
| 10.40 | 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) |
| 10.41 | 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) |

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| 10.42 | Loan Agreement, dated June 29, 2007, among the Registrant, Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and HSBC Realty Credit Corporation (USA) (Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137)) |
| 10.43 | Promissory Note, dated June 29, 2007, from Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, to HSBC Realty Credit Corporation (USA) (Incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137)) |
| 10.44 | 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)) |
| 10.45 | 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 (SEC File No. 001-33137)) |
| 10.46 | 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 (SEC 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.