Emergent BioSolutions Inc.
Form 10-K
March 05, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K
(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2009

OR

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

Commission file number: 001-33137

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

Delaware	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 ¨ No ý

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

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 ý No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant Rule 405 of Regulation S-T during the

preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

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

Large accelerated filer ¨ Accelerated filer ý 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 ý

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

EMERGENT BIOSOLUTIONS INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2009
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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," "wou expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our ability to perform under our contracts with the U.S. government for sales of BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, including the timing of deliveries;
- our plans for future sales of BioThrax, including our ability to obtain new contracts with the U.S. government;
- our plans to pursue label expansions and improvements for BioThrax;
- our ability to win a development award with the U.S. government for our recombinant protective antigen anthrax vaccine product candidate;
- our ability to win an award with the U.S. government for the scale-up, qualification and validation of our new manufacturing facility in Lansing, Michigan for the manufacture of BioThrax;
- our plans to expand our manufacturing facilities and capabilities;
- the rate and degree of market acceptance and clinical utility of our products;
- our ongoing and planned development programs, preclinical studies and clinical trials;
- our ability to identify and acquire or in-license products and product candidates that satisfy our selection criteria;
- the potential benefits of our existing collaborations and our ability to selectively enter into additional collaborative arrangements;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property portfolio; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

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

You should read this annual report, including the documents that we have incorporated by reference herein or filed as exhibits hereto, completely and with the understanding that our actual future results may be materially different from what we expect. We disclaim any obligation to update any forward-looking statements.

PART I

ITEM 1. BUSINESS

Overview

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

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

Anthrax

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

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

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

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

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

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

Tuberculosis

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

Typhoid

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

Influenza

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

Chlamydia

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

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

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

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

Our Strategy

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

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

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

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

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

Market Opportunity

Vaccines have long been recognized as a safe and cost-effective method for preventing infection caused by various bacteria and viruses. Because of an increased emphasis on preventative medicine in industrialized countries, vaccines are now well recognized as an important part of effective public health management. According to a 2008 report issued by Kalorama Information, a market research organization, the world market for preventative vaccines in 2007 totaled $16.3 billion, up from $11.7 billion in 2006. The Kalorama report estimates that the world vaccines market will grow at a compound annual rate of 13.1% from 2008 to 2013, and exceed $36 billion by 2013, as new product introductions continue and usage of current products expands further. New vaccine technologies, coupled with a greater understanding of how infectious microorganisms, or pathogens, cause disease are leading to the introduction of new vaccine products. Moreover, while existing marketed vaccines generally are designed to prevent infections, new vaccine technologies have also led to a focus on the development of vaccines for therapeutic purposes. Potential therapeutic vaccines extend beyond infectious diseases to cancer, autoimmune diseases and allergies.

Most non-pediatric commercial vaccines are paid for either directly by patients or paid for or reimbursed by managed care organizations, other private health plans or public insurers. With respect to certain diseases affecting general public health, particularly in developing countries, public health authorities or non-governmental organizations may fund the cost of developing vaccines against these diseases. According to a 2006 report issued by Frost & Sullivan, a market research organization, public purchases of vaccines, including immunization programs and government stockpiles, account for approximately 90% of the total volume of worldwide vaccine sales. Although private market purchases of vaccines represent only 10% of total worldwide vaccine sales in terms of volume, they accounted for approximately 60% of total worldwide vaccine revenues in 2005.

The market for biodefense countermeasures, including vaccines and antibody therapies, has grown dramatically as a result of the increased awareness of the threat of global terror activity in the wake of the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. Most U.S. government spending on biodefense programs is in the form of development funding from NIAID, BARDA and the DoD (including the Defense Advanced Research Projects Agency, or DARPA), and procurement of countermeasures by BARDA, the Centers for Disease Control, or CDC, and the DoD. The U.S. government is now the largest source of development and procurement funding for academic institutions and biotechnology companies conducting biodefense research or developing vaccines and immunotherapies directed at potential agents of bioterror or biowarfare.

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

The DoD, primarily through the Military Vaccine Agency, or MilVax, administers various vaccination programs for military personnel, including vaccines for common infectious diseases, such as influenza, and vaccines to protect against specific bioterrorism threats, such as anthrax and smallpox. The level of spending by the DoD for MilVax is a function of the size of the U.S. military and the DoD's protocols with respect to vaccine stockpile management and active immunization. The DoD provides development funding for biodefense vaccines through its Joint Vaccine Acquisition Program, or JVAP. The DoD procures doses of BioThrax from HHS, rather than from us directly, to satisfy ongoing requirements for its active immunization program in accordance with an October 2007 Presidential Directive that outlines the U.S. 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 we have had modest sales to these markets to date, we believe that they may comprise an important growth opportunity for the overall biodefense market in the future.

Scientific Background

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

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

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

patients.

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

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

Products

The following table summarizes key information about our marketed product, BioThrax, and our product candidates. We use multiple technologies to develop our product candidates, including bacterial fermentation, cell culture and recombinant DNA technologies. For each program, we select and apply the technology that we believe is best suited to address the particular disease based on our evaluation of factors such as safety, efficacy, manufacturing requirements, regulatory pathway and cost. We currently hold commercial rights to BioThrax and the product candidates listed below.

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

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

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

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

Anthrax

Disease overview. Anthrax is a potentially fatal disease caused by the spore forming bacterium Bacillus anthracis. Anthrax bacteria are naturally occurring, and spores are found in soil throughout the world. Anthrax spores can withstand extreme heat, cold and drought for long periods. Anthrax infections occur if the spores enter the body through a cut, abrasion or open sore, or by ingestion or inhalation. Once inside the body, anthrax spores germinate into anthrax bacteria that then multiply. Anthrax bacteria secrete three proteins: protective antigen, lethal factor and edema factor. Each of these proteins individually are non-toxic, but if allowed to interact on the surface of human or animal cells, they can form the highly potent toxins known as lethal toxin (protective antigen and lethal factor) or edema toxin (protective antigen and edema factor).

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

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

Inhalational anthrax is the most lethal form of anthrax. We believe that aerosolized anthrax spores are the most likely method to be used in a potential anthrax bioterrorism attack. Inhalational anthrax has been reported to occur from one to 43 days after exposure to aerosolized spores. Initial symptoms of inhalational anthrax are non-specific and may include sore throat, mild fever, cough, malaise, or weakness, lasting up to a few days. After a brief period of improvement, the release of anthrax toxins may cause an abrupt deterioration in the health of the infected person, with the sudden onset of symptoms, including fever, shock and respiratory failure as the lungs fill with fluids. Hemorrhagic meningitis is common. Death often occurs within 24 hours of the onset of advanced respiratory complications. The fatality rate for inhalational anthrax is estimated to be between 45% and 90%, depending on whether aggressive, early treatment is provided.

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

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

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

BioThrax and BioThrax Related Programs

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

As with any pharmaceutical product, the use of vaccines carries a risk of adverse health effects that must be weighed against the expected health benefit of the product. The adverse reactions that have been associated with the administration of BioThrax are similar to those observed following the administration of other adult vaccines and include local reactions, such as redness, swelling and limitation of motion in the inoculated arm, and systemic reactions, such as headache, fever, chills, nausea and general body aches. In addition, some serious adverse events have been reported to the vaccine adverse event reporting system, or VAERS, database maintained by the CDC and the FDA with respect to BioThrax. The report of any such adverse event to the VAERS database is not proof that the vaccine caused such an event. These putative serious adverse events, including diabetes, heart attacks, autoimmune diseases, Guillain-Barre syndrome, lupus, multiple sclerosis, lymphoma and death, have not been causally linked to the administration of BioThrax. In June 2009, we received approval from the FDA of our supplemental biologics license application, or BLA, to extend the expiry dating of BioThrax from three years to four years, which will allow BioThrax to be stockpiled for a longer period of time.

BioThrax Related Programs

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

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

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

In 2005, NIAID completed a proof-of-concept study in which rabbits infected with anthrax were treated with the antibiotic levofloxacin or with levofloxacin in combination with two doses of BioThrax in one of three dose amounts. One of the dose amounts tested was a dilution of BioThrax designed to elicit an immune response that is similar to the effect of an undiluted dose in humans. This is referred to as a humanized dose. Only 44% of the rabbits treated with antibiotics alone survived, while 100% of the rabbits treated with either humanized doses or undiluted doses of BioThrax in combination with levofloxacin survived. In the trial, there were statistically significant increases in

survival rates for rabbits treated with all dose amounts of BioThrax in combination with the antibiotic compared to rabbits treated with levofloxacin alone.

These results were consistent with an earlier animal test conducted by the U.S. Army Medical Research Institute of Infectious Diseases, or USAMRIID, involving the administration of BioThrax in combination with an antibiotic to non-human primates infected with anthrax. We have also completed pre-exposure active immunization studies in rabbits and non-human primates. We believe that the data from our planned non-clinical efficacy studies, together with the human immunogenicity data, if favorable, will be sufficient to support the filing with the FDA of a BLA supplement for marketing approval of BioThrax for the post-exposure indication. In February 2007, the FDA granted Fast Track designation for BioThrax as a post-exposure prophylaxis against anthrax disease. In September 2007, BARDA awarded us up to $11.5 million in development funding for this indication, $8.8 million of which was paid in the fourth quarter of 2007. We are currently engaged in discussions with the FDA regarding further steps to secure a post-exposure prophylaxis indication.

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

The immunogenicity parameters for the Phase I clinical trial of BioThrax combined with CpG 7909 were the mean peak antibody concentration and the median time to achieve mean peak immune response in trial participants who received BioThrax combined with CpG 7909 as compared to trial participants who received BioThrax alone. In this trial, the mean peak concentration of antibodies to anthrax protective antigen in participants who received the product candidate was approximately 6.3 times higher than in participants who received BioThrax alone. This result was statistically significant, with a P value of less than 0.001. Participants who received BioThrax alone achieved a mean peak geometric anti-PA IgG concentration approximately 42.5 days after first injection. Participants who received BioThrax combined with CpG 7909 achieved this same mean antibody concentration approximately 21 days earlier. This result was statistically significant, with a P value of less than 0.001. In this trial, there was a slightly higher frequency of moderate injection site reactions and systemic adverse events in the volunteers who received the product candidate as compared to volunteers who received BioThrax alone or CpG 7909 alone. One volunteer withdrew from this trial because of an adverse event. There were no serious adverse events reported that the trial investigators considered related to the product candidate, to BioThrax or to CpG 7909.

Additional Anthrax Product Candidates

- rPA vaccine. We are developing a recombinant form of the protective antigen protein as an anthrax vaccine. This vaccine contains purified rPA formulated with an aluminum hydroxide adjuvant and is designed to induce antibodies that neutralize anthrax toxins in a manner similar to BioThrax. The vaccine product candidate is based on development work at USAMRIID. Our rPA vaccine product candidate has been the subject of two research and development grants from NIAID totaling approximately $100 million. It has also been evaluated in one Phase II clinical trial, but this trial did not achieve statistically significant results due to product stability issues. We believe these stability issues have since been resolved, and that future trials will not be adversely affected by stability concerns. In December 2009, BARDA cancelled a previously issued procurement request for proposal, or RFP, for an rPA vaccine for the SNS in favor of a Broad Agency Announcement, or BAA, for rPA vaccine development. We submitted a proposal responding to the BAA in January 2010 to develop our product candidate.

- Double-mutant rPA vaccine. We are developing an anthrax vaccine product candidate based on a double-mutant form of rPA, or dmPA, combined with CpG 7909 and Alhydrogel, an aluminum hydroxide adjuvant. In September 2009, we received an award from NIAID under the American Recovery and Reinvestment Act that included funding for development of a dry powder formulation and for the manufacture of bulk drug substance and final drug product in a current Good Manufacturing Practice, or cGMP, environment. We expect our development efforts for this product candidate to continue throughout 2010.

- Immune globulin therapeutic. We are developing a human anthrax immune globulin, or AIG, therapeutic product candidate, which is a polyclonal antibody therapeutic, as a treatment for patients who have been exposed to anthrax spores and who present with symptoms of anthrax disease. We expect that, if approved, this product candidate would be prescribed as an intravenous infusion either as a monotherapy or in conjunction with a regimen of antibiotics. We are developing our anthrax immune globulin therapeutic product candidate using plasma produced by healthy donors who have been immunized with BioThrax. We have engaged Talecris Biotherapeutics, Inc. to fractionate, purify and fill our AIG at its FDA-approved facilities, and have manufactured three full-scale lots under cGMP conditions using the validated and approved process at Talecris. We plan to rely on the FDA's animal rule to support approval of this product candidate.

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

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

Tuberculosis

Disease overview. Tuberculosis, or TB, is an infection caused by 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 World Health Organization, or WHO, TB is the world's second leading cause of death from infectious disease in adults, after HIV/AIDS.

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

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

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

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

To date, the MVA85A vaccine has been evaluated in seven Phase I clinical trials. These trials were conducted in an aggregate of 126 healthy adults (BCG-naive, BCG-vaccinated, or latently infected with TB) and 12 BCG vaccinated adolescents living in the UK, The Gambia or South Africa. All trials evaluated the safety and immunogenicity of

various intradermal doses of MVA85A, first in healthy adults, both BCG-vaccinated and BCG-naive, and then also in special populations such as adolescents and TB/HIV-infected adults. The key findings from these clinical trials were that the MVA85A vaccine was well tolerated, with no significant safety concerns, and previous vaccination with BCG did not affect the safety profile. Additionally, MVA85A was effective at increasing cellular immune responses to antigen 85A in individuals previously vaccinated with BCG.

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

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

Typhoid

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

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

One oral typhoid vaccine and one injectable typhoid vaccine are currently approved for administration in both the United States and Europe and are primarily sold for use in the travelers market. The approved oral typhoid vaccine is available in liquid and capsule formulations. Both formulations require multiple doses to generate a protective immune response. The capsule formulation requires a booster every five years thereafter. The liquid formulation has been reported to provide 77% of recipients in clinical trials with protection three years after vaccination. The approved injectable vaccine requires only a single dose. However, it is not effectively immunogenic in children, requires a booster dose every three years thereafter and was effective in only 55% to 75% of recipients in clinical trials. Both approved vaccines have good safety profiles with relatively few adverse events reported. Antibiotics are used to treat typhoid after infection and usually lead to recovery commencing within four days. Without antibiotic therapy, the CDC estimates that the mortality rate for typhoid could be as high as 20%. Although vaccines are available, the WHO has stated that improved vaccines against typhoid fever are desirable, especially for children 2 years of age and older.

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

We have completed the following clinical trials of Typhella in the United States and Europe:

- An open-label, non-placebo controlled, pilot study conducted in the United Kingdom in nine healthy adult volunteers. The purpose of this study was to evaluate the safety and immunogenicity of our vaccine product candidate. In this study, Typhella was immunogenic, eliciting both cell mediated and humoral immune responses, and well tolerated.
    - A double-blind, placebo controlled, single dose escalating Phase I clinical trial conducted in the United States in 60 healthy adult volunteers. The purpose of this trial was to evaluate the safety, tolerability and immunogenicity of three dose levels of our vaccine product candidate. In this trial, Typhella was immunogenic and well tolerated at all dose levels.
- An open-label, non-placebo controlled, single dose Phase I clinical trial conducted in the United States in 32 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of two different presentations of Typhella, one using bottled water and another using tap water for reconstitution before administration. We vaccinated 16 subjects with each presentation. Because the two presentations were similarly immunogenic and both were well tolerated by trial participants, we selected the tap water presentation for further development based on its relative convenience.
- A single-blind, placebo controlled Phase I clinical trial of Typhella in Vietnam in 27 healthy adult volunteers using the dose and regimen established in our Phase I clinical trials in the United States. The Wellcome Trust provided funding for the Phase I trial in Vietnam. The purpose of the trial was to evaluate the safety and immunogenicity of Typhella when administered as a single oral dose in adults living in an endemic area. The primary immunogenicity endpoint for this trial was the proportion of trial participants with an immune response to Salmonella typhi following administration of a single oral dose of Typhella. Based on initial data from this trial, Typhella met the criterion for immunogenicity, with approximately 68% of subjects who received the vaccine product candidate mounting a humoral antibody response. Typhella was well tolerated by trial participants, with no serious adverse events reported.
- A single-blind randomized, placebo controlled, Phase II clinical trial of Typhella in Vietnam in 151 healthy children between the ages of 5 and 14 years. A total of 101 children received Typhella and 50 children received placebo. This was our first trial involving a pediatric population. We conducted this trial in collaboration with the Wellcome Trust, Oxford University and the Hospital for Tropical Diseases, Ho Chi Minh City, Vietnam. The Wellcome Trust provided funding for this trial. The purpose of this trial was to evaluate the safety and immunogenicity of Typhella in children in an endemic area. The immunogenicity parameter for this trial was the percentage of trial participants with an immune response to Salmonella typhi following administration of a single oral dose of Typhella. In this trial, 93% of the children receiving a vaccine dose developed an immune response as measured by increases in serum Salmonella typhi LPS-specific IgG antibody levels, 94% of the children receiving a vaccine dose developed an immune response as measured by increase in serum Salmonella typhi LPS-specific IgA antibody levels, and 97% of the children receiving a vaccine dose developed an immune response, which was statistically significantly greater than the percentage of children receiving placebo who developed an immune response. Typhella was well tolerated by trial participants, with no serious adverse events reported.
- A randomized, double blind, placebo controlled, single dose, dose escalating Phase II clinical trial conducted in the United States in 187 healthy adult volunteers. The purpose of this trial was to determine the immunogenicity, safety and tolerability of the vaccine product candidate manufactured at a new facility at dose levels across the range of the proposed manufacturing potency specification. The primary immunogenicity endpoint for this trial was the proportion of trial participants with an immune response to Salmonella typhi following administration of a single oral dose of Typhella. In this trial, the vaccine was immunogeneic and well tolerated across the range of doses tested.

In these six clinical trials, Typhella demonstrated immunogenicity response levels following a single drinkable dose similar to those seen with multiple doses of the currently approved oral vaccine. As a result of these trials, we were able to establish the safety and immunogenicity of a single dose regimen at an appropriate dose level in populations in both endemic and non-endemic areas.

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

- Phase II clinical trial. We plan to conduct a Phase II clinical trial in India in children under five years of age as a step towards conducting a Phase III clinical trial in an area where the incidence of disease is prevalent. The purpose of this Phase II trial is to evaluate the safety and immunogenicity of Typhella in this endemic population in preparation for our planned Phase III clinical trial.
- Challenge study. We plan to initiate a vaccine protection study using a human challenge model, pending the provision of funding by Oxford to establish that model.
- Disease surveillance study. We plan to conduct a disease surveillance study in India to confirm that a sufficient number of subjects will be included in our planned Phase III clinical trial. The Wellcome Trust has provided funding for a portion of this surveillance study.
- Phase III clinical trial. We plan to conduct a single-blind Phase III clinical trial in India, where typhoid is endemic. The purpose of this trial will be to evaluate the efficacy of Typhella in children who are likely to be exposed to the typhoid bacterium. We expect to undertake the primary analysis of the data from the trial after approximately one year, which, if the results are favorable, we plan to use the data to support the filing with the FDA of a BLA for marketing approval of Typhella. We plan to continue to monitor the incidence of typhoid in the trial participants for several years after vaccination. We are currently seeking external funding to support this trial.
- Tolerability and immunogenicity study. Concurrently with our planned Phase III clinical trial in India, we plan to conduct a Phase III clinical trial in the United States or Europe in healthy volunteers. The purpose of this trial will be to evaluate the safety and immunogenicity of Typhella to support marketing approval in the United States and Europe. It is not practicable to demonstrate clinical efficacy in travelers from the United States or Europe due to the prohibitively large number of subjects that would be needed. We will seek to establish an immune correlate of protection in the Phase III efficacy trial to allow us to extrapolate efficacy to developed world populations. The currently approved typhoid vaccines relied on similar clinical trials for regulatory approval.

Influenza

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

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

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

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

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

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

Chlamydia

Disease overview. Chlamydia, caused by infection with the bacterium Chlamydia trachomatis is the most prevalent sexually transmitted bacterial disease in the world. Chlamydia trachomatis can cause urogenital and reproductive tract disorders such as 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 antibiotic treatments have been effective at containing Chlamydia trachomatis in the United States and Europe. Although Chlamydia trachomatis infection can be treated with antibiotics, control measures based on antimicrobial treatment alone are difficult due to the incidence of infection, the percentage of asymptomatic infections and deficiencies in diagnosis.

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

Manufacturing

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

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

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

Hollister-Stier Laboratories LLC performs contract filling for BioThrax at its FDA-approved facility located in Spokane, Washington. Hollister-Stier has agreed to meet all of our firm purchase orders for contract filling of BioThrax based on a good faith annual estimate that we provide prior to each calendar year. In addition, Hollister-Stier has agreed to accommodate fill requests in excess of our annual estimate, subject to its available production capacity. Our contract with Hollister-Stier expires December 31, 2010. We have also entered into an agreement for contract filling operations with JHP Pharmaceuticals, LLC, which must now be qualified and licensed by the FDA to fill BioThrax at its facilities.

Talecris Biotherapeutics, Inc. has agreed to perform plasma fractionation and purification and contract filling of our anthrax immune globulin therapeutic candidate at its FDA-approved facilities located in Melville, New York and Clayton, North Carolina. Subject to limited exceptions, we have agreed to obtain all manufacturing requirements for our anthrax immune globulin therapeutic product candidate exclusively from Talecris. While our agreement with Talecris remains in effect, Talecris has agreed not to market, sell or acquire any competing product that contains anthrax immune globulin as an active ingredient. We have agreed to pay Talecris mid-single digit royalties on net sales on a country-by-country basis for commercial product manufactured by Talecris. Our contract with Talecris expires December 31, 2014, and we have the option to extend the term for an additional five-year period upon notice to Talecris at least 12 months prior to the expiration of the initial term. Our contract also provided for the commencement of commercial manufacturing activities as of January 1, 2010, which would have triggered an obligation on our part to purchase a significant amount of source plasma per year for a five-year term. Because our anthrax immune globulin therapeutic product candidate is not currently ready for commercial-scale manufacturing, we recently agreed to extend commencement of the commercial term to April 1, 2010, and are in negotiations with Talecris for a longer-term resolution regarding commercial production. In the event that we are not able to negotiate a satisfactory resolution, we may be required to explore other options for our anthrax immune globulin program. Under the existing agreement, after three years following initiation of commercial manufacturing, either party may terminate the contract upon two years' advance notice. We have the right to terminate the contract, under specified circumstances, including if we discontinue our production of anthrax immune globulin source plasma or the development of our anthrax immune globulin therapeutic product candidate.

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

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

Marketing and Sales

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

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

We expect to increase our sales and marketing resources to market and sell commercial products for which we retain commercialization or co-commercialization rights. We anticipate that our internal marketing and sales organization

will be complemented by selective co-promotion and other arrangements with leading pharmaceutical and biotechnology companies, especially in situations in which the collaborator has particular expertise or resources for the commercialization of our products or product candidates or access to particular markets.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience, and resources provide us with competitive advantages, we face potential competition from many different sources, including commercial pharmaceutical and biotechnology companies, academic institutions, government agencies and private and public research institutions. Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Novartis and Wyeth generated over 90% of the total worldwide vaccine revenues in 2007. The concentration of the industry reflects a number of factors, including:

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

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

Many of our competitors, including those named above, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring products, product candidates and technologies complementary to, or necessary for, our programs. Smaller or more narrowly focused companies, including Aeras, Crucell, Cangene, Human Genome Sciences, Soligenix, Dynport Vaccine Company LLC, Elusys, Bavarian Nordic, Panacea and PharmAthene, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or through significant development or procurement contracts with governmental agencies or philanthropic organizations.

Our biodefense product candidates face significant competition for U.S. government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. In addition, we may not be able to compete effectively if our products and product candidates do not satisfy government procurement requirements, particularly requirements of the U.S. government with respect to biodefense products. Our opportunity to succeed in this industry could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop.

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

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

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

Intellectual Property and Licenses

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

As of February 26, 2010, we owned or licensed exclusively a total of 20 U.S. patents and 34 U.S. patent applications relating to our biodefense and commercial product candidates, as well as numerous foreign counterparts to many of these patents and patent applications. Our patent portfolio includes patents and patent applications with claims directed to compositions of matter, pharmaceutical formulations and methods of use.

We consider the patent rights that we own or exclusively licensed from USAMRIID relating to our rPA vaccine product candidate and from OETC relating to our tuberculosis vaccine product candidate to be important.

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

- Typhella (typhoid vaccine). We hold four U.S. patents relating to Typhella. These patents have claims to the composition of matter of the vaccine product candidate and methods of use of live attenuated Salmonella typhi bacteria as vaccines for the treatment and prevention of typhoid and for the delivery of vaccine antigens. In addition, we have two pending U.S. patent applications with claims to additional compositions and methods of therapy that are generally related to Typhella. Our issued U.S. patents expire, and, if issued, our U.S. patent applications would expire, between 2015 and 2020. We hold 107 foreign counterpart patents to our issued U.S. patents relating to Typhella, including counterparts under the European Patent Convention and in Japan, that expire, and 14 foreign patent applications that, if issued, would expire, between 2015 and 2020. Additional patents relating to Typhella and delivery of vaccine antigens are discussed below under “STM technology.”

- STM technology. We own four U.S. patents with claims to methods for the identification of virulence genes using our signature tagged mutagenesis, or STM, technology, which we used to identify and develop the gene mutations that form the basis of our typhoid vaccine product candidate. In addition, we have one pending U.S. patent application with additional claims to methods for identifying virulence genes using our STM technology. We also own 50 foreign counterpart patents, including counterparts under the European Patent Convention and in Japan. These patents relating to the STM method will expire in 2015. We also hold 14 foreign patent applications that, if issued would expire in 2015. Our rights under these patents are licensed on a limited non-exclusive basis to third parties to practice the STM method with respect to specific microorganisms, not including Salmonella typhi or hepatitis virus.

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

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

We are a party to a number of license agreements under which we license patents, patent applications, and other intellectual property. We enter into these agreements to augment our own intellectual property. These agreements impose various diligence and financial payment obligations on us. We expect to continue to enter into these types of license agreements in the future. The only existing licenses that we consider to be material to our current product portfolio or development pipeline are our agreements with USAMRIID and OETC, which are described below. We also have a license agreement with the Bavarian State Ministry of the Environment and Public Health, or StMUG, relating to our MVA vector technology that we may use in the development of future product candidates, which is also described below.

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

Under the license agreement, we are required to pay USAMRIID a small annual license fee, aggregate payments of up to $535,000 upon the achievement of specified development and regulatory milestones and mid single-digit royalties on sales of licensed products to non-U.S. government customers. Our obligation to pay royalties continues on a product-by-product and country-by-country basis until the later of seven years from first commercial sale of the first licensed product in that country and the expiration of the last-to-expire licensed patent in that country. In addition, we are required to pay USAMRIID a specified fee per dose for any sales by us to a U.S. government agency.

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

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

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

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

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

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

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

MVA platform technology. In July 2006, in connection with our acquisition of ViVacs GmbH, or ViVacs, a German limited liability company, we acquired a license agreement with StMUG that provides us the non-exclusive, worldwide right to develop and produce viruses and viral products, including recombinant viral vectors, using MVA. Under the license agreement, we are required to pay StMUG low single digit royalties based on the net amounts or license fees that we receive from third-party licensees who use MVA to develop products that are used for research or diagnostic purposes and a mid-teens royalty based on the license fees that we receive from products developed using MVA that are licensed as starting material for the production of a smallpox vaccine.

The license agreement does not have a specified term. In addition, StMUG may terminate the license agreement upon the insolvency or liquidation of our wholly owned subsidiary, Emergent Product Development GmbH, formerly ViVacs GmbH. Our MVA platform technology, which is based on these licensed rights, could potentially be used as a viral vector for delivery of multiple vaccine antigens for different disease-causing organisms using recombinant technology. We are currently exploring potential product candidates based on our MVA platform, including a broadly cross protective influenza vaccine candidate.

Government Regulation

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

U.S. Government Regulation

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

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

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

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

Preclinical Studies and the IND

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

must provide informed consent for their participation in a clinical trial. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various ground, including a finding that the study subjects are being exposed to an unacceptable health risk or that the proposed clinical trials will not yield sufficient data to support licensure or approval of the product.

Clinical Trials

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

- In a Phase I clinical trial, the drug or biologic is initially administered into healthy human subjects or subjects with the target condition and tested for safety, dosage tolerance, absorption, distribution, metabolism and excretion.
- In a Phase II clinical trial, the drug or biologic is administered to a limited subject population to identify possible adverse effects and safety risks, and preliminary information related to the efficacy of the product for specific targeted diseases, dosage tolerance and optimal dosage.
- A Phase III clinical trial is undertaken if a Phase II clinical trial demonstrates that a dosage range of the drug has the potential to be effective and appears to potentially have an acceptable safety profile. In a Phase III clinical trial, the drug or biologic is administered to an expanded population, often at geographically dispersed clinical trial sites, to further evaluate the dosage amount(s), clinical efficacy, and safety. Prior to commencing Phase III clinical trials , many sponsors elect to meet with FDA officials to discuss the conduct and design of the proposed trial or trials.

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

In the case of product candidates that are intended to treat rare life-threatening diseases, such as infection caused by exposure to the anthrax toxin, conducting controlled clinical trials to determine efficacy may be unethical or infeasible. Under regulations issued by the FDA in 2002, often referred to as “the animal rule,” under some circumstances approval of such products can be based on clinical data from trials in healthy subjects that demonstrate adequate safety, and immunogenicity and efficacy data from adequate and well controlled animal studies. Among other requirements, the animal studies must establish that the drug or biological product is reasonably likely to produce clinical benefits in humans. Because the FDA must agree that data derived from animal studies may be extrapolated to establish safety and effectiveness in humans, these studies add complexity and uncertainty to the testing and approval process. In addition, products approved under the animal rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

Marketing Approval

In the United States, if a product is regulated as a drug, an NDA must be submitted and approved before commercial marketing may begin. If the product is regulated as a biologic, a BLA must be submitted and approved before commercial marketing may begin. The NDA or BLA must include a substantial amount of data and other information concerning the safety and effectiveness and, in the case of a biological product, the purity and potency of the product candidate. Both NDAs and BLAs must contain data and information on the finished product, including manufacturing, product stability and proposed product labeling.

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

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

Fast Track Designation

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

Post-Marketing Regulation

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

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

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

The FDCA and the FDA's rules for advertising and promotion require, among other things, that we not promote our products for unapproved uses and that our promotion be fairly balanced and adequately substantiated. We must also

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

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

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

- restrictions on the marketing or manufacturing of a product;
- Warning Letters or Untitled Letters from the FDA asking us, our collaborators or third party contractors to take or refrain from taking certain actions;
- withdrawal of the product from the market;
- FDA's refusal to approve pending applications or supplements to approved applications;
- voluntary or mandatory product recall;
- fines or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

BioThrax Lot Release and FDA Review

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

Regulation of Immune Globulin Products

Products derived from humans, including our anthrax immune globulin therapeutic candidate, are subject to additional regulation. The FDA regulates the screening and vaccination of human donors and the process of collecting source plasma. FDA regulations require that all donors be tested for suitability and provide informed consent prior to vaccination or collection of source plasma for the immune globulin. The vaccination and collection of source plasma may also be subject to IRB approval or to an IND, depending on factors such as whether donors are to be vaccinated

according to the vaccine's approved schedule. The FDA also regulates the process of testing, storage and processing of source plasma, which is used to manufacture immune globulin candidates for use in clinical trials and, after approval by the FDA, for commercial distribution.

Legislation and Regulation Related to Bioterrorism Counteragents and Pandemic Preparedness

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

Project BioShield

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

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

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

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

Safety Act

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

Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act, or PREP Act, enacted by Congress in 2005 provides immunity to manufacturers from all claims under state or federal law for "loss" arising out of the administration or use of a "covered countermeasure." However, injured persons may still bring a suit for "willful misconduct" against the manufacturer under some circumstances. "Covered countermeasures" include security countermeasures and "qualified pandemic or epidemic products," including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or "credible risk" of a future public health emergency. In October 2008, the Secretary of HHS issued a declaration that BioThrax and our anthrax immune globulin therapeutic have been included as covered countermeasures under the PREP Act. We cannot predict whether Congress will fund the relevant PREP Act compensation programs or whether the necessary prerequisites for immunity would be triggered with respect to our product or product candidates.

Changing Legal and Regulatory Landscape

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

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

Foreign Regulation

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

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

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

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

European Union member states generally do not have separate rules or review procedures for biological products and vaccines. Regulators apply broadly consistent principles and standards when reviewing applications, although they accept that the nature of the efficacy data supporting a vaccine application is likely to differ from the data that would support applications for the majority of therapeutic products. However, there are special procedures for some types of vaccine products. For example, influenza vaccines are subject to accelerated review and approval each year following the release by the WHO of the annual influenza strains. European Union member states have the discretion to require that marketing authorization holders submit samples of live vaccines or other immunological products for examination and formal batch release by a government control laboratory prior to release onto the market.

Orphan Drugs

In the United States, under the Orphan Drug Act, special incentives exist for sponsors to develop drug and biological products for rare diseases or conditions, which are defined to include those diseases or conditions that affect fewer than 200,000 people in the United States or one that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the drug for the disease or condition will be recovered from sales of the drug in the United States. A vaccine also can receive these incentives if it is expected to be administered to fewer than 200,000 persons per year. Requests for orphan drug designation must be submitted prior to submission of an application for marketing authorization for a rare disease or condition. Biologics may qualify for designation as an orphan drug.

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

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

In the European Union, a product can be designated as an orphan drug if it is intended for either (i) a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the European Union when the application is made; or (ii) a serious and chronic condition in the European Union for which, without incentives, it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the necessary investment. In either case, the applicant must also demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition. The COMP assesses the orphan status at both the time of first designation and also in parallel with the review of every marketing authorization application for an orphan medicine.

After a marketing authorization has been granted in the European Union for an orphan product, no similar product may be approved for a period of ten years. At the end of the fifth year, however, any member state can initiate proceedings to restrict that period to six years if it believes the criteria for orphan designation no longer apply, for example, because the prevalence of disease has increased or the manufacturer is earning an unreasonable profit. In addition, competitive products can be approved during the marketing exclusivity period if they are not similar to the original product, or even if they are similar, if they are safer, more effective or otherwise clinically superior to it.

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

Reimbursement and Pricing Controls

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

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

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

become a potent force in the market place and exerts additional downward pressure on the prices of pharmaceutical products.

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

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

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

Regulations Regarding Government Contracting

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

Vaccine Injury Compensation Program

Because the cost of vaccine related litigation had reduced significantly the number of manufacturers willing to sell childhood vaccines, the U.S. Congress enacted the National Childhood Vaccine Injury Act, or Vaccine Injury Act, in 1986. The Vaccine Injury Compensation Program established under the Vaccine Injury Act is a no-fault compensation program funded by an excise tax on each dose of a covered vaccine and is designed to streamline the process of seeking compensation for those injured by childhood vaccines. The Vaccine Injury Act requires all individuals injured by certain vaccines to go through the compensation program, as administered by the U.S. Court of Federal Claims, before pursuing other remedies. Although claimants can reject decisions issued under the compensation program and

pursue subsequent legal action through the courts, the Vaccine Injury Act determines the circumstances under which a manufacturer of a covered vaccine may be found liable in a civil action. The Vaccine Injury Act may not reduce or limit our liability arising out of product liability claims.

Hazardous Materials and Select Agents

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

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

In particular, this legislation and related regulations require that we:

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

Other Regulations

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

All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws. In addition, we are subject to the Export Administration Regulations implemented by the Bureau of Industry and Security governing the export of BioThrax and technology for the development and use of pathogens and toxins in the development and manufacture of BioThrax and our product candidates. In connection with our international sales activity, we are also subject to export regulations and other sanctions imposed by the Office of Foreign Assets Control of the U.S. Department of the Treasury, the antiboycott provisions of the Export Administration Act and the Internal Revenue Code and the Foreign Corrupt Practices Act. Outside the United States, advertising and promotion of medicinal products, along with associated commercial practices, are often subject to significant government regulation by local authorities.

Personnel

As of December 31, 2009, we had 652 employees, including 172 employees engaged in product development, 310 employees engaged in manufacturing, 11 employees engaged in sales and marketing and 159 employees engaged in general and administrative activities. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees are represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

Available Information

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

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

ITEM 1A. RISK FACTORS

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

We have derived substantially all of our revenue from sales of BioThrax under contracts with HHS or the DoD. If HHS or DoD demand for BioThrax is reduced, our business, financial condition and operating results could be materially harmed.

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

Our existing and prior contracts with HHS and the DoD do not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government. The success of our business and our operating results for the foreseeable future are substantially dependent on the price per dose, the number of doses and the timing of deliveries for BioThrax sales to the U.S. government.

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

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

- the need to devote substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- that we may be ineligible to respond to a request for proposal issued by the government;
- that third parties could submit protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- that we may incur or could suffer expenses or delays if our competitors protest or challenge contract awards made to us pursuant to competitive bidding and that any such protest or challenge would result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract.

The U.S. government may choose to award future contracts for the supply of anthrax vaccines and other biodefense product candidates that we are developing to our competitors instead of to us. If we are unable to win particular contracts, we may not be able to operate in the market for products that are provided under those contracts for a number of years. For example, in December 2009, BARDA cancelled a previously issued procurement RFP for an rPA vaccine for the SNS in favor of BAA for rPA vaccine development. We submitted a proposal responding to the BAA in January 2010 to develop our rPA vaccine product. Additionally, if we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition and operating results could

be materially adversely affected.

Our U.S. government contracts for BioThrax require ongoing funding decisions by the government. Reduced or discontinued funding of these contracts could cause our financial condition and operating results to suffer materially.

Our principal customer for BioThrax is the U.S. government. In addition, we anticipate that the U.S. government will be the principal customer for any other biodefense products that we successfully develop. Over its lifetime, a U.S. government program may be implemented through the award of many different individual contracts and subcontracts. The funding of some government programs is subject to Congressional appropriations, generally made on a fiscal year basis even though a program may continue for several years. Our government customers are subject to stringent budgetary constraints and political considerations. For example, the sale of most supplied doses under our most recent contract with HHS is subject to the annual appropriations process. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, our business, revenues and operating results may suffer.

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

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

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

In addition, before awarding us any future contracts, the U.S. government could require that we respond satisfactorily to a request to substantiate our commercial viability and industrial capabilities. Compliance with these obligations increases our performance and compliance costs. Failure to comply with these regulations and requirements could lead to suspension or debarment, for cause, from government contracting or subcontracting for a period of time. The termination of a government contract or relationship as a result of our failure to satisfy any of these obligations would have a negative impact on our operations and harm our reputation and ability to procure other government contracts in the future.

The pricing under our fixed price government contracts is based on estimates of the time, resources and expenses required to perform those contracts. If our estimates are not accurate, we may not be able to earn an adequate return or may incur a loss under these contracts.

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

Unfavorable provisions in government contracts, some of which may be customary, may harm our business, financial condition and operating results.

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

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including equitable price adjustments;
- cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- decline to exercise an option to renew a contract;
- exercise an option to purchase only the minimum amount, if any, specified in a contract;
- decline to exercise an option to purchase the maximum amount, if any, specified in a contract;
- claim rights to products, including intellectual property, developed under the contract;
- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- suspend or debar the contractor from doing business with the government or a specific government agency;
- pursue criminal or civil remedies under the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

Generally, government contracts, including our HHS contracts for BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the government's convenience. Under general principles of government contracting law, if the government terminates a contract for convenience, the terminated company may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination.

If the government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. One or more of our government contracts could be terminated under these circumstances. Some government contracts grant the government the right to use, for or on behalf of the U.S. government, any technologies developed by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the government.

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

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

the Administrative Procedure Act in connection with its December 19, 2005 Final Order classifying BioThrax as safe and effective. The plaintiffs' petition for writ of certiorari in the United States Supreme Court was denied on March 1, 2010.

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

Risks Related to Our Financial Position and Need for Additional Financing

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

We commenced operations in 1998, and the FDA approved the manufacture of BioThrax at our renovated facilities in Lansing, Michigan in December 2001. Although we were profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. Our profitability is substantially dependent on revenues from BioThrax product sales. Revenues from BioThrax product sales have fluctuated significantly in recent quarters, and we expect that they will continue to fluctuate significantly from quarter to quarter based on several factors, including the timing of our fulfilling orders from the U.S. government. Additionally, our profitability may be adversely affected as we progress through various stages of ongoing or planned clinical trials for our product candidates. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

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

As of December 31, 2009, we had $65.7 million principal amount of debt outstanding. We may seek to raise substantial external debt financing to provide additional financial flexibility. Our leverage could have significant adverse consequences, including:

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

We may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. In addition, a failure to comply with the covenants under our existing debt instruments could result in an event of default under those instruments. In the event of an acceleration of amounts due under our debt instruments as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness. In addition, the covenants under our existing debt instruments and the pledge of our existing assets as collateral limit our ability to obtain additional debt financing.

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

We expect our development expenses to increase in connection with our ongoing activities, particularly as we conduct additional and later stage clinical trials for our product candidates. We also expect our commercialization expenses to increase in the future as we seek to broaden the market for BioThrax and if we receive marketing approval for additional products. We also may undertake additional facility projects in the future.

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

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

Our committed external sources of funds consist of the borrowing availability under our revolving line of credit with Fifth Third Bank and grant and development funding of some of our candidates. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Difficult economic conditions may make it difficult to obtain financing on attractive terms or at all. Lenders may be able to impose covenants on us that could be difficult to satisfy, which could put us at increased risk of defaulting on debt. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

Our ability to borrow additional amounts under our loan agreement is subject to our satisfaction of specified conditions. Additional equity or debt financing, grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

Risks Related to Manufacturing and Manufacturing Facilities

We are in the process of expanding our manufacturing facilities and entering into arrangements with contract manufacturing organizations. Delays in completing facilities, or delays or failures in obtaining regulatory approvals for new manufacturing facility projects or new contract manufacturing partners, could limit our potential revenues and growth.

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

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

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

BioThrax and our vaccine and therapeutic product candidates are complex to manufacture and ship, which could cause us to experience delays in revenues or shortages of products.

BioThrax and all our product candidates are biologics. Manufacturing biologic products, especially in large quantities, is complex. The products must be made consistently and in compliance with a clearly defined manufacturing process. Accordingly, it is essential to be able to validate and control the manufacturing process to assure that it is reproducible. Slight deviations anywhere in the manufacturing process, including maintaining master seed banks and preventing drift, obtaining materials, seed growth, fermentation, filtration, filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures or manufacturing shut-down, delay in the release of lots, product recalls, spoilage or regulatory action. Success rates can vary dramatically at different stages of the manufacturing process, which can lower yields and increase costs. From time to time we experience deviations in the manufacturing process that may take significant time and resources to resolve and if unresolved may affect manufacturing output and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation or regulatory action against us, or cause the FDA to cease releasing product until the deviations are explained and corrected, any of which could be costly to us and negatively impact our business.

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

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

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

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

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

- equipment malfunctions or failures;
- technology malfunctions;
- work stoppages or slow downs;
- protests, including by animal rights activists;
- damage to or destruction of the facility;
- regional power shortages; or
- product tampering.

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

In addition, providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. For example, the U.S. government has designated our Lansing facility as a facility requiring additional security to protect against potential terrorist threats to the facility. Any disruption that impedes our ability to manufacture and ship BioThrax in a timely manner could reduce our revenues and materially harm our business, financial condition and operating results.

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

We have outsourced the operation for filling BioThrax into vials to a single company, Hollister-Stier Laboratories LLC, or Hollister-Stier. Our contract with Hollister-Stier expires on December 31, 2010. We have not established internal redundancy for our filling functions, however, we have identified and contracted with an additional provider that we believe can handle our filling needs. Before this party may perform filling services for us, it must be qualified and licensed by the FDA. Such qualification and licensure may require use of a significant number of doses of BioThrax for consistency lots and stability testing that we may not be able to sell in the future once testing is complete. If Hollister-Stier is unable to perform filling services for us, we would need to obtain FDA approval of our

potential substitute filler, engage, qualify and license an alternative filling company or develop our own filling capabilities. Any new contract filling company or filling capabilities that we acquire or develop will need to be approved by the FDA. Identifying and engaging a new contract filling company or developing our own filling capabilities and obtaining FDA approval could involve significant time and cost. As a result, we might not be able to deliver BioThrax orders on a timely basis and our revenues could decrease.

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

The timing and amount of customer demand is difficult to predict. We may not be able to scale-up our production quickly enough to fill any new customer orders on a timely basis. This could cause us to lose new business and possibly existing business. For example, we may not be able to scale-up manufacturing processes for our product candidates to allow production of commercial quantities at a reasonable cost or at all. Furthermore, if we overestimate customer demand, or choose to commercialize products for which the market is smaller than we anticipate, we could incur significant unrecoverable costs from creating excess capacity. In addition, if we do not successfully develop and commercialize any of our product candidates, we may never require the production capacity that we expect to have available.

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

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

In addition, we expect that we will rely on third parties for a portion of the manufacturing process for commercial supplies of product candidates that we successfully develop, including fermentation for some of our vaccine product candidates, plasma fractionation and purification and contract fill and finish operations and we rely on those manufacturers to comply with a wide variety of rules and regulations. If our contract manufacturers are unable to scale-up production to generate enough materials for commercial launch, if manufacturing is of insufficient quality, or if the costs of manufacturing are prohibitively high, the success of those products may be jeopardized. For example, we are currently evaluating manufacturing alternatives for Typhella in countries in which we believe manufacturing costs will be economical. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our ability to develop product candidates and commercialize any products that receive regulatory approval on a timely and competitive basis.

Third party manufacturers under short-term supply agreements are not obligated to accept any purchase orders we may submit. If any third party terminates its agreement with us, based on its own business priorities, or otherwise fails to fulfill our purchase orders, we would need to rely on alternative sources or develop our own manufacturing capabilities to satisfy our requirements.

If alternative suppliers are not available or are delayed in fulfilling our requirements, or if we are unsuccessful in developing our own manufacturing capabilities, we may not be able to obtain adequate supplies of our product candidates on a timely basis. A change of manufacturers would require review and approval from the FDA and the applicable foreign regulatory agencies. This review may be costly and time consuming. There are a limited number of manufacturers that operate under the FDA’s cGMP requirements and that are both capable of manufacturing for us and willing to do so.

We currently rely on third parties for regulatory compliance and quality assurance with respect to the supplies of our product candidates that they produce for us. We also will rely for these purposes on any third party that we use for production of commercial supplies of product candidates that we successfully develop. Manufacturers are subject to

ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP regulations and other governmental regulations and corresponding foreign standards.

We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the U.S. We do not control compliance by manufacturers with these regulations and standards. If we or these third parties fail to comply with applicable regulations, sanctions could be imposed on us, which could significantly and adversely affect supplies of our product candidates. The sanctions that might be imposed include:

- fines, injunctions and civil penalties;
- refusal by regulatory authorities to grant marketing approval of our product candidates;
- delays, suspension or withdrawal of regulatory approvals, including license revocation;
- seizures or recalls of product candidates or products;
- operating restrictions; and
- criminal prosecutions.

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

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

Our development and manufacturing processes involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we are subject to federal, state, local and foreign laws and regulations governing the use, manufacture, distribution, storage, handling, disposal and recordkeeping of these materials. We are also subject to a variety of environmental laws in Michigan regarding underground storage tanks. One such tank on our Lansing campus has leaked in the past. The State of Michigan removed the tank, continues to monitor the situation and has agreed to indemnify us for any resulting liabilities. In the event that the State of Michigan does not indemnify us, or if our insurance does not cover the exposure of any remediation that may be necessary, we may be required to spend significant amounts on remediation efforts. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the Centers for Disease Control and Prevention, or CDC, HHS and the DoD.

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

We also are subject to export control regulations governing the export of BioThrax and technology and materials used to develop and manufacture BioThrax and our product candidates. These laws and regulations may limit the countries in which we may conduct development and manufacturing activities. If we fail to comply with environmental, occupational health and safety, biosafety and export control laws, we could be held liable for fines, penalties and damages that result, and any such liability could exceed our assets and resources. In addition, we could be required to cease immediately all use of a select agent or toxin, and we could be prohibited from exporting our products, technology and materials or we could be suspended from the right to do business with the U.S. government.

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

We hold a number of insurance policies in an effort to protect ourselves against extraordinary or unanticipated costs. Our general liability and excess insurance policies provide for coverage up to annual aggregate limits of $12 million, with coverage of $1 million per occurrence and $2 million in the aggregate for general liability and $10 million per occurrence and in the aggregate for excess liability. Both policies exclude coverage for liabilities relating to the release of pollutants. We do not currently hold insurance policies expressly providing for coverage relating to our use of hazardous materials other than storage tank liability insurance for our Lansing facility with coverage of $1 million per occurrence and $2 million annual aggregate limit and a $25,000 per claim deductible. We hold product liability and clinical trial liability insurance policies for our commercial products and each clinical trial we are conducting in amounts we deem appropriate.

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

Risks Related to Product Development

Our business depends significantly on our success in completing development and commercialization of our product candidates at acceptable costs. If we are unable to commercialize these product candidates, or experience significant delays or unanticipated costs in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of our vaccines and therapeutic product candidates. In addition to BioThrax product sales, our ability to generate near term revenue is dependent on the success of our development programs, on the U.S. government’s interest in providing development funding for or procuring our product candidates, on the interest of non-governmental organizations in providing grant funding for development of our product candidates and on the commercial viability of those product candidates. The commercial success of our product candidates will depend on many factors, including accomplishing the following in an economical manner:

- successful development, formulation and cGMP scale-up of biological manufacturing that meets FDA requirements;
- successful development of animal models by the U.S. government;
- successful completion of non-clinical development, including studies in approved animal models;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- successful completion of clinical trials;
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities;
- a determination by the Secretary of HHS that our biodefense product candidates should be purchased for the SNS prior to FDA approval;
- establishing commercial manufacturing processes of our own or arrangements with contract manufacturers;
- manufacturing stable commercial supplies of product candidates, including materials based on recombinant technology;
- launching commercial sales of the product, whether alone or in collaboration with others; and
- acceptance of the product by potential government customers, physicians, patients, healthcare payors and others in the medical community.

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

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

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive preclinical studies and clinical trials to establish proof of concept, safety and efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete, and the outcome of such trials is uncertain. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results.

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

We expect to rely on FDA regulations known as the “animal rule” to obtain approval for our biodefense product candidates. The animal rule permits the use of animal efficacy studies together with human clinical safety and immunogenicity trials to support an application for marketing approval. These regulations are relatively new, and we have limited experience in the application of these rules to the product candidates that we are developing. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our vaccine and therapeutic product candidates in humans. If we are not successful in completing the development and commercialization of our vaccine and therapeutic product candidates, or if we are significantly delayed in doing so, our business will be materially harmed.

A failure of one or more of our clinical trials or animal efficacy studies can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial or animal efficacy study process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;

- the cost of our clinical trials could escalate and become cost prohibitive;

- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

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

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

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

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

Under the Project BioShield Act, the Secretary of HHS can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA. However, our product candidates might not be selected by the Secretary under this authority. Moreover, this authority could result in increased competition for our products and product candidates.

Risks Related to Commercialization

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

An element of our business strategy is to establish a market for sales of BioThrax to customers in addition to the U.S. government. These potential customers include foreign governments and state and local governments, which we expect will be interested in BioThrax to protect emergency responders such as police, fire and emergency medical personnel, multinational companies, non-governmental organizations and hospitals.

The market for sales of BioThrax to customers other than the U.S. government is undeveloped, and we may not be successful in generating meaningful sales of BioThrax to these potential customers. To date, we have made only

modest sales to these customers. In particular, we have supplied small amounts of BioThrax directly to several foreign governments. In 2007, 2008 and 2009, our sales of BioThrax to customers other than the U.S. government represented a small portion of our revenue. If we fail to significantly increase our sales of BioThrax to these customers, our business and opportunities for growth could be materially harmed.

Government regulations may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, many foreign governments require licensure of BioThrax in their jurisdiction before they will consider procuring doses. Additionally, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of BioThrax and related technology, the U.S. government may decide, particularly in the current environment of elevated concerns about global terrorism, to increase the scope of export prohibitions. These prohibitions could limit our sales of BioThrax to foreign governments and other foreign customers. In addition, U.S. government demand for anthrax vaccine may limit supplies of BioThrax available for sale to non-U.S. government customers. For example, our efforts to develop domestic commercial and international sales may be impeded by the DoD's right under the Defense Production Act to require us to deliver doses that we do not currently anticipate. Furthermore, the DoD's sale of BioThrax to foreign governments under the Foreign Military Sales program has and may continue to have an adverse effect on our ability to sell BioThrax internationally.

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

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

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

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

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

jurisdiction in which we are contemplating future expansion where we will need to exercise caution to ensure our compliance with the FCPA.

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

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

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

Any products that we bring to the market may not gain or maintain market acceptance by potential government customers, physicians, patients, healthcare payors and others in the medical community. In particular, our biodefense vaccine and therapeutic products and product candidates are subject to the product criteria that may be specified by potential U.S. government customers. The product specifications in any government procurement request may prohibit or preclude us from participating in the government program if our products or product candidates do not satisfy the stated criteria.

In addition, notwithstanding favorable findings regarding the safety and efficacy of BioThrax by the FDA in its final ruling in December 2005, the Government Accountability Office reiterated concerns regarding BioThrax in Congressional testimony in May 2006 that it had previously identified beginning in 1999. These concerns include the then-licensed six-dose regimen and annual booster doses, questions about the long-term and short-term safety of the vaccine, including how safety is affected by gender differences, and uncertainty about the vaccine's efficacy against inhalational anthrax. Continued reiteration of these concerns could have a detrimental effect on the market acceptance of BioThrax.

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

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

- the prevalence and severity of any side effects;

- the efficacy and potential advantages over alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- the relative convenience and ease of administration;

- the willingness of the target patient population to try new products and of physicians to prescribe these products;
- the strength of marketing and distribution support; and
- the sufficiency of coverage or reimbursement by third parties.

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

Products developed to treat diseases caused by or to combat the threat of bioterrorism will be subject to changing political and social environments. The political and social responses to bioterrorism have been highly charged and unpredictable. Political or social pressures or changes in the perception of the risk that military personnel or civilians could be exposed to biological agents as weapons of bioterrorism may delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, which would harm our business.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Furthermore, lawsuits brought against us by third parties or activists, even if not successful, require us to spend time and money defending the related litigation. The need to address political and social issues may divert our management's time and attention from other business concerns. For example, between 2001 and 2006, members of the military and various activist groups who oppose mandatory inoculation with BioThrax petitioned the FDA and the federal courts to revoke the license for BioThrax and to terminate the DoD program for the mandatory administration of BioThrax to military personnel. Although the DoD has prevailed in those challenges to date, the actions of these groups have created negative publicity about BioThrax.

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

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

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

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

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

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

Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. We believe that our most significant competitors in the area of vaccine and therapeutics are a number of pharmaceutical companies that have vaccine programs, including Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Pfizer, and Novartis, as well as smaller more focused companies engaged in vaccine and therapeutic development, such as Aeras, Crucell, Cangene, Human Genome Sciences, Soligenix, Dynport Vaccine Company, Elusys, Bavarian Nordic and PharmAthene.

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

Although BioThrax is the only anthrax vaccine approved by the FDA for the prevention of anthrax infection, the government is funding the development of new products that could compete with BioThrax, and could eventually procure those new products in addition to, or instead of, BioThrax, potentially reducing our BioThrax revenues. We also face competition for our biodefense product candidates. For example, HHS has awarded a development and SNS procurement contract to a competitor for an anthrax immune globulin therapeutic and is assisting this company in its production efforts by providing it with BioThrax doses that we delivered for placement into the SNS so that it can immunize donors and obtain plasma for its anthrax immune globulin therapeutic product candidate. HHS has awarded another development and SNS procurement contract to another competitor for an anthrax monoclonal antibody as a post-exposure therapeutic for anthrax infection. One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the U.S. and Europe. The Aeras Global Tuberculosis Vaccine Foundation is developing or supporting the development of five tuberculosis vaccine product candidates in addition to ours, any of which could present competitive risks. Numerous companies have vaccine product candidates in development that would compete with any of our commercial product candidates for which we are seeking to obtain marketing approval.

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

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

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

The Public Readiness and Emergency Preparedness Act, or PREP Act, which was signed into law in December 2005, creates immunity for manufacturers of biodefense countermeasures when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is meant to provide immunity from all claims under state or federal law for loss arising out of the administration or use of a covered countermeasure. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct. Upon a declaration by the Secretary of HHS, a compensation fund is created to provide “timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure.” The “covered injuries” to which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer only after they have exhausted their remedies under the compensation program. Therefore, a willful misconduct action could be brought against us if any individuals exhausted their remedies under the compensation program and thereby expose us to liability. In October 2008, the Secretary of HHS issued a PREP Act declaration identifying BioThrax and our anthrax immune globulin therapeutic candidate as covered countermeasures. We do not know, however, whether the PREP Act will provide adequate protection or survive anticipated legal challenges to its validity.

In August 2006, the Department of Homeland Security approved our application under the Support Anti-Terrorism by Fostering Effective Technology Act, or Safety Act, enacted by the U.S. Congress in 2002 for liability protection for sales of BioThrax. The Safety Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. In addition, the Safety Act provides a process by which an anti-terrorism technology may be certified as an “approved product” by the Department of Homeland Security and therefore entitled to a rebuttable presumption that the government contractor defense applies to sales of the product. The government contractor defense, under specified circumstances, extends the sovereign immunity of the U.S. to government contractors who manufacture a product for the government. Specifically, for the government contractor defense to apply, the government must approve reasonably precise specifications, the product must conform to those specifications and the supplier must warn the government about known dangers arising from the use of the product. Although we are entitled to the benefits of the Safety Act, it may not provide adequate protection from any claims made against us.

In addition, although our prior contracts with the DoD and HHS provided that the U.S. government would indemnify us for any damages resulting from product liability claims, our current contracts with HHS do not contain such indemnification, and we may not be able to negotiate similar indemnification provisions in future contracts.

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

We face an inherent risk of product liability exposure related to the sale of BioThrax and any other products that we successfully develop and the testing of our product candidates in clinical trials. For example, we have been a defendant in lawsuits filed on behalf of military personnel who alleged that they were vaccinated with BioThrax by the DoD and claimed damages resulting from personal injuries allegedly suffered because of the vaccinations. The plaintiffs in these lawsuits claimed different injuries and sought varying amounts of damages. Although we successfully defended these lawsuits, we cannot ensure that we will be able to do so in the future.

Under our prior BioThrax contracts with the DoD and HHS, the U.S. government indemnified us against claims by third parties for death, personal injury and other damages related to BioThrax, including reasonable litigation and settlement costs, to the extent that the claim or loss results from specified risks not covered by insurance or caused by our grossly negligent or criminal behavior. As required under such contracts, we have notified the DoD of personal injury claims that have been filed against us as a result of the vaccination of U.S. military personnel with BioThrax and are seeking reimbursement from the DoD for uninsured costs incurred in defending these claims; however, the DoD has not acted on our requests for reimbursement. The collection process can be lengthy and complicated, and there is no guarantee that we will be able to recover these amounts from the U.S. government.

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

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

We currently have product liability insurance for coverage up to a $15 million annual aggregate limit with a deductible of $75,000 per claim up to $375,000 in aggregate. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Product liability insurance is difficult to obtain and increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. For example, from 2002 through February 2006, we were unable to obtain product liability insurance for sales of BioThrax on commercially reasonable terms. We do not believe that the amount of insurance we have been able to obtain for BioThrax is sufficient to manage the risk associated with the potential large scale deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on statutory protections in addition to insurance to mitigate our liability exposure for BioThrax.

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

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

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

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

Even when a payor determines that a product is covered, the payor may impose limitations that preclude payment for some uses that are approved by the FDA or comparable authorities but are determined by the payor to not be medically reasonable and necessary. Moreover, eligibility for coverage does not imply that any product will be covered in all cases or that reimbursement will be available at a rate that permits the health care provider to cover its costs of using the product.

We expect that the success of some of our commercial vaccine product candidates for which we obtain marketing approval will depend on inclusion of those product candidates in government immunization programs. Most non-pediatric commercial vaccines are purchased and paid for, or reimbursed by, managed care organizations, other private health plans or public insurers or paid for directly by patients. In the U.S., pediatric vaccines are funded by a variety of federal entitlements and grants, as well as state appropriations. Foreign governments also commonly fund pediatric vaccination programs through national health programs. In addition, with respect to some diseases affecting the public health generally, particularly in developing countries, public health authorities or non-governmental, charitable or philanthropic organizations fund the cost of vaccines.

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

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

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

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

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

In some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental

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

Legislation has been introduced into Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the U.S., which may include re-importation from foreign countries where the drugs are sold at lower prices than in the U.S. Such legislation, or similar regulatory changes, could decrease the price we receive for any approved products which, in turn, could adversely affect our operating results and our overall financial condition.

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

Our success depends on our continued ability to attract, retain and motivate highly qualified managerial and key scientific personnel. We consider Fuad El-Hibri, chairman of our Board of Directors and our chief executive officer, and Daniel J. Abdun-Nabi, a member of our Board of Directors and our president and chief operating officer, to be key to our BioThrax operations and our efforts to develop and commercialize our product candidates. Both of these key employees are at will employees and can terminate their employment at any time. We do not maintain “key person” insurance on any of our employees.

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

Additional Risks Related to Sales of Biodefense Products to the U.S. Government

Our business is subject to audit by the U.S. government and a negative audit could adversely affect our business.

U.S. government agencies such as the Defense Contract Audit Agency, or the DCAA, routinely audit and investigate government contractors. These agencies review a contractor’s performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The DCAA also reviews the adequacy of, and a contractor’s compliance with, its internal control systems and policies, including the contractor’s purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

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

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

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

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

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

In addition, qui tam lawsuits have been brought against us in which the plaintiffs argued that we defrauded the U.S. government by distributing non-compliant doses of BioThrax. Although we ultimately prevailed in this litigation, we spent significant time and money defending the litigation. U.S. States, many municipalities and foreign governments typically also have laws and regulations governing contracts with their respective agencies. These domestic and foreign laws and regulations affect how we and our customers conduct business and, in some instances, impose additional costs on our business. Any changes in applicable laws and regulations could restrict our ability to maintain our existing contracts and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our revenues and results of operations.

We rely on property and equipment owned by the U.S. government in the manufacturing process for BioThrax.

We have the right to use certain property and equipment that is owned by the U.S. government, referred to as government furnished equipment, or GFE, at our Lansing, Michigan site in the manufacture of BioThrax. We have the option to purchase all or part of the existing GFE from the U.S. government on terms to be negotiated with the U.S. government. If the U.S. government modifies the terms under which we use the GFE in a manner that is unfavorable to us, including substantially increasing the usage fee, or we are unable to reach an agreement with the U.S. government concerning the terms of the purchase of that part of the GFE necessary for our business, our business could be harmed. If the U.S. government were to terminate or fail to extend all BioThrax supply contracts with us, we potentially could be required to rent or purchase that part of the GFE necessary for the continued production of BioThrax in our current manufacturing facility.

Risks Related to Regulatory Approvals

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

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

In the United States, BioThrax, our biodefense product candidates and our commercial product candidates are regulated by the FDA as biologics. To obtain approval from the FDA to market our product candidates, we will be required to submit to the FDA a biologics license application, or BLA. Ordinarily, the FDA requires a sponsor to support a BLA with substantial evidence of the product's safety and effectiveness in treating the targeted indication based on data derived from adequate and well controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted. However, our biodefense product candidates require slightly different treatment. Specifically, because humans are rarely exposed to anthrax toxins under natural conditions, and cannot be intentionally exposed, statistically significant effectiveness of our biodefense product candidates cannot be demonstrated in humans, but instead must be demonstrated, in part, by utilizing animal models before they can be approved for marketing. This is known as the FDA's animal rule.

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

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review for a submitted product application, may cause delays in the approval or rejection of an application.

The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

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

Any vaccine and therapeutic product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies. As an approved product, BioThrax is subject to these requirements and ongoing review.

These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. The FDA enforces its cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect manufacturing facilities without a warrant or prior notice at reasonable times and in a reasonable manner.

After we acquired BioThrax and related vaccine manufacturing facilities in Lansing, Michigan in 1998 from the Michigan Biologic Products Institute, we spent significant amounts of time and money renovating those facilities before the FDA approved a supplement to our manufacturing facility license in December 2001. The State of Michigan had initiated renovations after the FDA issued a notice of intent to revoke the FDA license to manufacture BioThrax in 1997. The notice of intent to revoke cited significant deviations by the Michigan Biologic Products

Institute from cGMP requirements, including quality control failures. In March 2007, the FDA notified us that our manufacturing facility license is no longer subject to the notice of intent to revoke.

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

The FDA conducted a routine, biannual inspection of the Lansing facility in December 2009. Following this inspection, the FDA issued inspectional observations on Form FDA 483. We are in the process of implementing corrective action where necessary and anticipate that all observations from the 2009 inspection will be successfully closed out in the near future. If in connection with this inspection or with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, or if the FDA is not satisfied with the corrective actions we take in connection with any such inspection, the FDA may undertake enforcement action against us.

Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products or manufacturing processes, or failure to comply with regulatory requirements, may result in:

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

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

If one of our competitors obtains orphan drug exclusivity for an indication for a product that competes with one of the indications for one of our product candidates before we obtain orphan drug designation, and if the competitor’s product is the same drug as ours, the FDA would be prohibited from approving our product candidate for the same orphan indication unless we demonstrate that our product is clinically superior or the FDA determines that the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the drug. We have obtained orphan drug status from the FDA and in the European Union for our anthrax immune globulin therapeutic product candidate and in the European Union for our tuberculosis vaccine product candidate; however, none of our other products or product candidates has been designated as an orphan drug and there is no guarantee that the FDA will grant such designation in the future. Even if we obtain orphan drug exclusivity for one or more indications for one of our product candidates, we may not be able to maintain it. For example, if a competitive product that is the same drug or biologic as our product is shown to be clinically superior to our product, any orphan drug exclusivity we may have obtained

will not block the approval of that competitive product.

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

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

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

We intend to have some or all of our products marketed outside the United States. To market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. With respect to some of our product candidates, we expect that a future collaborator will have responsibility to obtain regulatory approvals outside the United States, and we will depend on our collaborators to obtain these approvals. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval.

The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We and our collaborators may not be able to obtain regulatory approvals to commercialize our products in any market.

Risks Related to Our Dependence on Third Parties

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

For each of our product candidates, we plan to evaluate the merits of retaining commercialization rights or entering into collaboration arrangements with leading pharmaceutical or biotechnology companies or non-governmental organizations. We expect that we will selectively pursue collaboration arrangements in situations in which the collaborator has particular expertise or resources for the development or commercialization of our products and product candidates or for accessing particular markets.

If we are unable to reach agreements with suitable collaborators, we may fail to meet our business objectives for the affected product or program. We face, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements, or the arrangements that we establish may not turn out to be productive or beneficial for us. The terms of any collaboration or other arrangements that we establish may not be favorable to us.

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

collaborators. It is likely that our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations.

The risks that we are subject to in our current collaborations, and anticipate being subject to in future collaborations, include the following:

- our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach by us;
- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not do so, our ability to maintain and defend our intellectual property rights may be compromised by our collaborators' acts or omissions;
- our collaborators may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability; or
- our collaborators may decide not to continue to work with us in the development of product candidates.

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

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

We do not have the ability to independently conduct the clinical or non-clinical trials required to obtain regulatory approval for our products. We depend on independent clinical investigators, contract research organizations and other third party service providers to conduct the clinical and non-clinical trials of our product candidates and expect to continue to do so. We rely heavily on these third parties for successful execution of our clinical and non-clinical trials, but do not exercise day-to-day control over their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates. In addition, we encourage government entities and non-government organizations to conduct studies of, and pursue other development efforts for, our product candidates.

We expect to rely on data from clinical trials conducted by third parties seeking marketing approval for our product candidates. For example, our BLA supplement for a label expansion of BioThrax for a regimen of fewer doses is based on the results of a clinical trial conducted by the CDC. These government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. In addition, government entities depend on annual Congressional appropriations to fund these development efforts.

Risks Related to Our Intellectual Property

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

Our success, particularly with respect to our commercial business, will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property covering or incorporated into our technology and products. This protection is very costly. The patentability of technology in the field of vaccine and therapeutic development and other pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions.

We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the duration of patent protection we may have for our products. Changes in patent laws or administrative patent office rules or changes in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, or result in costly defense measures.

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

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not do so, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties.

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

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

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

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

We are a party to a number of license agreements and expect to enter into additional license agreements in the future. For example, we consider our license from the Oxford-Emergent Tuberculosis Consortium to our tuberculosis vaccine product candidate to be material to our business. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

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

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

These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

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

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

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

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology and pharmaceutical industries. For example, Bavarian Nordic sued Acambis for patent infringement and other claims arising out of Acambis' importation of an MVA-based smallpox vaccine for biodefense use by the U.S. government. Bavarian Nordic claimed that its patents broadly covered the manufacture of MVA-based biological products and that Bavarian Nordic had rights in the biological materials used by Acambis. The Acambis strain has a distinct lineage from the strains used by us. That litigation was terminated by a settlement and consent order. Bavarian Nordic subsequently sued Oxford BioMedica PLC, Oxford BioMedica Ltd. and Biomedica Inc., collectively Oxford BioMedica, alleging that Oxford BioMedica has infringed certain Bavarian Nordic U.S. patents by making, using, and importing, and inducing others to use Oxford BioMedica's experimental drug TroVax®, which is an MVA-based therapeutic cancer vaccine. The Oxford BioMedica strain also has a distinct lineage from the strain used by us. The lawsuit was settled by agreement between the parties. While the terms of the settlement have not been published, the parties have announced that Oxford BioMedica received a license for TroVax under Bavarian Nordic's MVA patents, and in return Bavarian Nordic received a license under Oxford BioMedica's patents on heterologous prime boost technology and a sublicense under certain patents licensed by Sanofi to Oxford BioMedica. Typically, patent infringement settlements are structured to specifically cover the alleged infringing product, and the settlement has no direct impact on other products in the field. Accordingly, we do not believe that the Acambis or Oxford BioMedica settlements will have any adverse effect on our plans for commercialization of our tuberculosis vaccine or our MVA platform. Bavarian Nordic also filed legal proceedings against the Bavarian State Ministry of the Environment and Public Health, or StMUG, in which Bavarian Nordic questioned StMUG's rights to convey MVA strains to third parties. This lawsuit was dismissed and an appeal by Bavarian Nordic was withdrawn in June 2009. We have licensed from StMUG rights to materials and technology related to MVA. Our MVA platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based in part on these rights.

Our ability to use our MVA platform technology, or to develop and manufacture MVA-based products such as our tuberculosis product candidate, could be negatively affected by pending or future patent infringement litigation or other legal actions brought by Bavarian Nordic or other parties challenging our rights to use MVA materials or technology. To protect our interests, we have filed oppositions in the European Patent Office against four of Bavarian Nordic's patents covering certain aspects of the MVA technology. The European Patent Office has called for hearings in one of these oppositions to be held in June 2010 and in an additional two of these proceedings in October 2010. We are also a party to a trademark invalidation proceeding in the U.S. and certain foreign trademark offices. In addition, we may in the future become party to additional trademark invalidation or interference proceedings. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Risks Related to Our Acquisition Strategy

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

Since our inception we have pursued an acquisition strategy to build our business. We commenced operations in September 1998 through an acquisition of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how from the Michigan Biologic Products Institute. We acquired a portion of our pipeline of vaccine and therapeutic product candidates through our acquisition of Microscience Limited in a share exchange in 2005 and our acquisitions of substantially all of the assets, for cash, of Antex Biologics, Inc. in 2003 and of ViVacs GmbH in 2006.

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

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

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

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

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

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

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

- challenges associated with managing an increasingly diversified business;
- prioritizing product portfolios;
- disruption of our ongoing business;
- difficulty and expense in assimilating and integrating the operations, products, technology, information systems or personnel of the acquired company;
- diversion of management’s time and attention from other business concerns;
- inability to maintain uniform standards, controls, procedures and policies;
- the assumption of known and unknown liabilities of the acquired company, including intellectual property claims;
- challenges and costs associated with reductions in work force; and
- subsequent loss of key personnel.

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

Risks Related to Our Common Stock

Fuad El-Hibri, chief executive officer and chairman of our Board of Directors, has substantial control over us, including through his ability to control the election of the members of our Board of Directors, and could delay or prevent a change of control.

Mr. El-Hibri has the ability to control the election of the members of our Board of Directors through his ownership interests among our significant stockholders. As of February 26, 2010, Mr. El-Hibri was the beneficial owner of approximately 39% of our outstanding common stock. Because Mr. El-Hibri has significant influence over the election of the members of our board, and because of his substantial control of our capital stock, Mr. El-Hibri will likely have the ability to delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause our stock price to decline.

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

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

These provisions include:

- the classification of our directors;
- limitations on changing the number of directors then in office;
- limitations on the removal of directors;
- limitations on filling vacancies on the board;
- limitations on the removal and appointment of the chairman of our Board of Directors;
- advance notice requirements for stockholder nominations for election of directors and other proposals;
- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval.

The affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. The affirmative vote of either a majority of the directors present at a meeting of our Board of Directors or holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws.

In addition, Section 203 of the General Corporation Law of Delaware prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns or within the last three years has owned 15% or more of our voting stock, for a period of three years

after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us.

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

Under a rights agreement that establishes our stockholder rights plan, we issue to each of our stockholders one preferred stock purchase right for each outstanding share of our common stock. Each right, when exercisable, will entitle its holder to purchase from us a unit consisting of one one-thousandth of a share of series A junior participating preferred stock at a purchase price of $150 in cash, subject to adjustments.

Our stockholder rights plan is intended to protect stockholders in the event of an unfair or coercive offer to acquire us and to provide our Board of Directors with adequate time to evaluate unsolicited offers. The rights plan may have anti-takeover effects. The rights plan will cause substantial dilution to a person or group that attempts to acquire us on terms that our Board of Directors does not believe are in our best interests and those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

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

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through December 31, 2009, our common stock has traded as high as $27.00 per share and as low as $4.40 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

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

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. For example, we have filed a registration statement that would permit us to issue

up to $100 million in common stock. Moreover, holders of an aggregate of approximately 11.2 million shares of our common stock outstanding as of February 26, 2010 have the right to require us to register these shares of common stock under specified circumstances.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

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

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

Lansing, Michigan. We own a multi-building campus on approximately 12.5 acres in Lansing, Michigan that includes facilities for bulk manufacturing of BioThrax, including fermentation, filtration and formulation, as well as for raw material storage and in-process and final product warehousing. It also includes our new 50,000 square foot manufacturing facility which we financed in part with a term loan from a commercial leader. The campus is secured through perimeter fencing, limited and controlled ingress and egress and 24-hour on-site security personnel. We acquired these facilities in 1998 from the Michigan Biologic Products Institute. In December 2001, the FDA approved a supplement to our manufacturing facility license for the manufacture of BioThrax at the renovated facilities.

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

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

approximately 23,000 square feet of office space, including our executive offices.

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

ITEM 3. LEGAL PROCEEDINGS

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

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

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

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

BioThrax product liability litigation. Between 2001 and 2003, over 100 individual plaintiffs filed a series of lawsuits in which they claimed damages resulting from personal injuries allegedly caused by vaccination with BioThrax by the DoD. In April 2006, the U.S. District Court for the Western District of Michigan entered summary judgment in our favor in four consolidated lawsuits brought by approximately 120 claimants. The District Court's ruling in these consolidated cases was based on two grounds. First, the District Court found that we were entitled to protection under a Michigan state statute that provides immunity for drug manufacturers if the drug was approved by the FDA and its labeling is in compliance with FDA approval, unless the plaintiffs establish that the manufacturer intentionally withheld or misrepresented information to the FDA and the drug would not have been approved, or the FDA would have withdrawn approval, if the information had been accurately submitted. Second, the District Court found that we were entitled to the immunity afforded by the government contractor defense, which, under specified circumstances, extends the sovereign immunity of the United States to government contractors who manufacture a product for the government. Specifically, the government contractor defense applies when the government approves reasonably precise specifications, the product conforms to those specifications and the supplier warns the government about known risks arising from the use of the product. The District Court found that we established each of those factors.

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

Other. We are, and may in the future become, subject to other legal proceedings, claims and litigation arising in the ordinary course of our business in connection with the manufacture, distribution and use of our products and product candidates. For example, Emergent BioDefense Operations Lansing Inc., or EBOL, is a defendant, along with many other vaccine manufacturers, in a series of lawsuits that have been filed in various state and federal courts in the United States alleging that thimerosal, a mercury-containing preservative used in the manufacture of some vaccines, caused personal injuries, including brain damage, central nervous system damage and autism. No specific dollar amount of damages has been claimed. EBOL is currently a named defendant in 38 lawsuits pending in two jurisdictions: one in California and 37 in Illinois. The products at issue in these lawsuits are pediatric vaccines. Because we are not currently and have not historically been in the business of manufacturing or selling pediatric vaccines, we do not believe that we manufactured the pediatric vaccines at issue in the lawsuits. Under a contractual obligation to the State of Michigan, we manufactured one batch of vaccine suitable for pediatric use. However, the contract required the State to use the vaccine solely for Michigan public health purposes. We no longer manufacture any products that contain thimerosal.

ITEMREMOVED AND RESERVED
4.

PART II

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

Market Information and Holders

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

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

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

Dividend Policy

We have not declared, or paid any cash dividends on our common stock since becoming a publicly traded company in November 2006. We currently intend to retain all of our future earnings to finance the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future.

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Not applicable.

Purchases of Equity Securities

Not applicable.

ITEMSELECTED CONSOLIDATED FINANCIAL DATA
6.

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

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

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

Weighted average number of shares — basic	30,444,485	29,835,134	28,995,667	23,039,794	20,533,471
Weighted average number of shares — diluted	31,375,305	30,458,098	29,663,127	24,567,302	22,751,733

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

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this annual report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Special Note Regarding Forward Looking Statements" and "Risk Factors" sections of this annual report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Product Portfolio

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

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

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

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

Product Sales

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

Contracts and Grants

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

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

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

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

Manufacturing Infrastructure

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

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

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

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

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, fair value of stock-based compensation and income taxes. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

We recognize revenues from product sales that require no continuing performance on our part if four basic criteria have been met:

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

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

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

Accounts Receivable

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

Inventories

Inventories are stated at the lower of cost or market, with cost being determined using a standard cost method, which approximates average cost. Average cost consists primarily of material, labor and manufacturing overhead expenses and includes the services and products of third party suppliers.

We analyze our inventory levels quarterly and write down in the applicable period inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand. We also write off in the applicable period the costs related to expired inventory. We capitalize the costs associated with the manufacture of BioThrax as inventory from the initiation of the manufacturing process through the completion of manufacturing, labeling and packaging.

Income Taxes

Under the asset and liability method of income tax accounting, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax basis of assets and liabilities and are measured using the tax rates and laws that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. A net deferred tax asset or liability is reported on the balance sheet. Our deferred tax assets include the unamortized portion of in-process research and development expenses, the anticipated future benefit of the net operating losses that we have incurred and other timing differences between the financial reporting and tax basis of assets and liabilities.

We have historically incurred net operating losses for income tax purposes in some states, primarily Maryland, and in some foreign jurisdictions, primarily the United Kingdom. The amount of the deferred tax assets on our balance sheet reflects our expectations regarding our ability to use our net operating losses to offset future taxable income. The applicable tax rules in particular jurisdictions limit our ability to use net operating losses as a result of ownership changes. In particular, we believe that these rules will significantly limit our ability to use net operating losses generated by Microscience Limited, or Microscience, and Antex Biologics, Inc., or Antex, prior to our acquisition of Microscience in June 2005 and our acquisition of substantially all of the assets of Antex in May 2003.

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

Uncertainty in income taxes is accounted for using a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We recognize in our financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position.

Stock-based Compensation

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

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

The effect of this accounting treatment on net income attributable to Emergent BioSolutions Inc. and earnings per share in any period is not necessarily representative of the effects in future years due to, among other things, the vesting period of the stock options and the fair value of additional stock option grants in future years.

Financial Operations Overview

Revenues

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

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

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

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

Our revenue, operating results and profitability have varied, and we expect that they will continue to vary on a quarterly basis, primarily because of the timing of our fulfilling orders for BioThrax and work done under new and existing contracts and grants.

Cost of Product Sales

The primary expense that we incur to deliver BioThrax to our customers is manufacturing costs, which are primarily fixed costs. These fixed manufacturing costs consist of facilities, utilities and salaries and personnel-related expenses for indirect manufacturing support staff. Variable manufacturing costs for BioThrax consist primarily of costs for materials, direct labor and contract filling operations.

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

Research and Development Expenses

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

- salaries and related expenses for personnel;
- fees to professional service providers for, among other things, preclinical and analytical testing, independently monitoring our clinical trials and acquiring and evaluating data from our clinical trials and non-clinical studies;
- costs of contract manufacturing services for clinical trial material;
- costs of materials used in clinical trials and research and development;
- depreciation of capital assets used to develop our products; and
- operating costs, such as the operating costs of facilities and the legal costs of pursuing patent protection of our intellectual property.

We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to be in a position to realize the potential of our product candidates. We expect that development spending for our product pipeline will increase as our product development activities continue based on ongoing advancement of our product candidates, and as we prepare for regulatory submissions and other regulatory activities. We expect that the magnitude of any increase in our research and development spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, the size, structure and duration of any follow-on clinical programs that we may initiate, costs associated with manufacturing our product candidates on a large scale basis for later stage clinical trials, and our ability to use or rely on data generated by government agencies, such as studies with BioThrax conducted by the Centers for Disease Control and Prevention, or CDC.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, sales and marketing, business development, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales or research and development expense and professional fees for legal and accounting services. We currently market and sell BioThrax directly to HHS with a small, targeted marketing and sales group. As we seek to broaden the market for BioThrax and if we receive marketing approval for additional products, we expect that we will increase our spending for marketing and sales activities.

Total Other Income (Expense)

Total other income (expense) consists primarily of interest income and interest expense. We earn interest income on our cash, cash equivalents and a note receivable, and we incur interest expense on our indebtedness. We capitalize interest based on the cost of major ongoing projects which have not yet been placed in service, such as new manufacturing facilities. Some of our existing debt arrangements provide for increasing amortization of principal payments in future periods. See "Liquidity and Capital Resources — Debt Financing" for additional information.

Results of Operations

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

Revenues

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

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

Cost of Product Sales

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

Research and Development Expenses

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

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

manufacture of master and working cell banks. We expect that spending for our botulinum vaccine candidates will decrease in the future, due primarily to reduced interest in and funding for these product candidates by the U.S. government.

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

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

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

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

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

Other	7,650	1,980
Total	$74,588	$59,470

Selling, General and Administrative Expenses

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

Total Other Income (Expense)

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

Income Taxes

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

Net Loss Attributable to Noncontrolling Interest

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

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

Revenues

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

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

Cost of Product Sales

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

Research and Development Expenses

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

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

The increase in spending on commercial product candidates, detailed in the table below, primarily reflects additional personnel and contracted services. The spending for our tuberculosis vaccine product candidate related to the formation of our joint venture with the University of Oxford in July 2008 and preparation for a Phase IIb clinical trial. The increase in spending for Typhella resulted from the manufacture of clinical material and initiating and conducting a Phase IIb study in the U.S., which commenced in the second quarter of 2008. The spending for our influenza vaccine product candidate was related to immunogenicity studies. The decrease in spending for our hepatitis B therapeutic vaccine product candidate resulted from the cessation of new patient enrollment from our ongoing Phase II clinical trial in the United Kingdom and Serbia as a result of patient recruiting difficulties because we administer our product candidate as a monotherapy. The spending for our group B streptococcus vaccine product

candidate resulted from preparing for Phase I clinical trials for two of the protein components of the vaccine product candidate. We decided not to proceed with these trials and, as a result spending for our group B streptococcus vaccine product candidate will be significantly reduced in the future. The decrease in spending for our chlamydia vaccine product candidate, which is in preclinical development, was related to slowing development while seeking external funding.

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

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

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

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

Income Taxes

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

Net Loss Attributable to Noncontrolling Interest

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

Liquidity and Capital Resources

Sources of Liquidity

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

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

Cash Flows

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

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

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

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

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

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

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

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

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

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

Contractual Obligations

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

		Payments due by period					
(in thousands)	Total	2010	2011	2012	2013	2014	After 2014
Contractual obligations:							
Long-term indebtedness	$ 50,718	$ 5,791	$ 14,724	$ 2,331	$ 2,331	$ 25,541	$ -
Operating lease obligations	11,950	1,817					