Emergent BioSolutions Inc.
Form 10-K
March 10, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2007

OR

O 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 O No

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

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

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

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant as of June 29, 2007 was approximately $100,968,000 based on the price at which the common stock was last sold on that date as reported on the New York Stock Exchange.

As of February 29, 2008, the registrant had 29,750,237 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement for its 2008 annual meeting of stockholders scheduled to be held on May 21, 2008, 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, 2007, 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 2008 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® and *spi*-VEC are our trademarks. Each of the other trademarks, trade names or service marks appearing in this annual report on Form 10-K are the property of their respective owners.

EMERGENT BIOSOLUTIONS INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2007

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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, would and similar exp to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

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

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

You should read this annual report, including the documents that we have incorporated by reference herein and filed as exhibits hereto, completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

PART I

ITEM 1. BUSINESS

Overview

We are a profitable multinational biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics, consisting of vaccines and therapeutics that assist the body s immune system to prevent or treat disease. We manufacture and market BioThrax ®, also referred to as anthrax vaccine adsorbed, or AVA, the only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. We use internally generated cash flows from the sale of BioThrax to fund the development of a product pipeline that addresses a variety of infectious diseases and other medical conditions.

We develop immunobiotics for use against infectious diseases that have resulted in significant unmet or underserved public health needs and against biological agents that are potential weapons of bioterrorism and biowarfare. In addition to our licensed BioThrax product, we have product candidates in both advanced and earlier stages of development. Our advanced stage product candidates consist of an anthrax immune globulin therapeutic candidate, a typhoid vaccine candidate and a hepatitis B therapeutic vaccine candidate. Our earlier stage programs include botulinum vaccines, group B streptococcus vaccine and chlamydia vaccine candidates.

BioThrax is approved for pre-exposure prevention of anthrax infection by all routes of exposure, including inhalation. We are currently pursuing a label expansion for BioThrax as a post-exposure prophylaxis for anthrax infection in combination with antibiotic treatment, as well as a number of improvements for BioThrax, including an extension of expiry dating, a reduction in the number of required doses, and the addition of a second route of administration.

Revenues from product sales of BioThrax were $169.8 million in 2007, $148.0 million in 2006 and $127.3 million in 2005. The U.S. Department of Defense, or DoD, and the U.S. Department of Health and Human Services, or HHS, have been the principal customers for BioThrax. Since 1998, we have been a party to two procurement contracts for BioThrax with the DoD pursuant to which we have supplied over 10 million doses of BioThrax for immunization of military personnel, and the DoD has vaccinated more than 1.8 million military personnel with more than 7.1 million doses of BioThrax. We are not currently party to a procurement contract with the DoD. Since May 2005, we have supplied over 16 million doses of BioThrax to HHS for inclusion in the strategic national stockpile, or SNS. On September 25, 2007, we entered into a three-year agreement with HHS to supply 18.75 million doses of BioThrax to HHS for placement into the SNS, of which an additional 12.2 million doses remain to be delivered. We believe that in the future the DoD will procure additional doses of BioThrax directly from HHS to satisfy ongoing requirements for its active immunization program, and that these purchases may result in HHS procuring additional doses from us.

Our product candidates in advanced stages of development are:

Anthrax immune globulin therapeutic an intravenous therapeutic antibody product candidate for the treatment of post-symptomatic anthrax infection, which we are developing in part with funding from the National Institute of Allergy and Infectious Diseases of the National Institutes of Health, or NIAID, for which we expect to initiate a pivotal human trial and pivotal animal studies in 2008 and 2009;

Typhoid vaccine a single-dose, drinkable vaccine, for which we have completed a Phase I clinical program with trials in the United States, the United Kingdom and Vietnam, and are conducting a Phase II clinical program, which includes a recently completed clinical trial in Vietnam and planned clinical trials in the United States and in India; and

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

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

Group B streptococcus vaccine a multiple-dose, injectable vaccine for administration to women of childbearing age for protection of the fetus and newborn babies, for which we have successfully completed a Phase I clinical trial in the United Kingdom and are preparing to initiate a second Phase I clinical trial;

Next generation anthrax vaccine additional anthrax vaccine product candidates that would incorporate one or more advanced characteristics, such as a reduced number of doses, room temperature storage, novel adjuvants, recombinant subunits, an enhanced immune response, longer expiry dating, or a novel delivery method;

Botulinum vaccines two prophylactic vaccine product candidates to protect against illness caused by botulinum toxin which we are developing in collaboration with the United Kingdom Health Protection Agency, or HPA; and

Chlamydia vaccine an injectable vaccine for administration to adolescents designed to prevent illness caused by all clinically relevant strains of *Chlamydia trachomatis*.

We have established collaborations and funding arrangements for some of our product candidates. Our anthrax immune globulin therapeutic candidate is funded in part by NIAID under a development contract valued at up to $9.5 million that NIAID awarded us in the third quarter of 2007 to conduct animal efficacy studies and clinical trials, and under two grants valued at up to $3.8 million in the aggregate that NIAID awarded us in 2006 for non-clinical safety and efficacy studies and clinical trial planning for this product candidate. NIAID also has agreed to fund, manage and conduct a Phase I clinical trial of our group B streptococcus vaccine candidate. The Wellcome Trust provided funding for our Phase I and Phase II clinical trials of our typhoid vaccine candidate in Vietnam. In May 2006, we entered into a license and co-development agreement with Sanofi Pasteur, the vaccines business of Sanofi Aventis, under which we granted Sanofi Pasteur an exclusive, worldwide license

under our proprietary technology to develop and commercialize our Neisseria meningitis B vaccine candidate in exchange for payment to us of upfront and development fees, milestone payments and royalties.

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 worldwide leader in developing, manufacturing and commercializing immunobiotics. Key elements of our strategy to achieve this goal are:

Focus on core capabilities in product development and manufacturing. We focus our efforts on immunobiotic product development and manufacturing, which we believe are our core capabilities.

Acquire additional late-stage product candidates. 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, minimize product development and commercialization risks and may enable us to accelerate product development timelines. Specifically, we are primarily seeking to acquire one or more additional product candidates that are either in Phase III clinical trials or well positioned for entry into Phase III clinical trials in the near term. Additionally, we may announce from time to time the acquisition or license of early stage product candidates or the entry into collaborations to continue to refresh the earlier phases of our product development programs.

Mitigate costs in advancing selected pipeline products by seeking governmental and other third party grants and support. We seek non-dilutive funding arrangements with government agencies and non-governmental organizations, or NGOs, including clinical trial sponsorship, grants and development contracts, to advance the development of our product candidates. For example, the Centers for Disease Control and Prevention, or CDC, is independently conducting a clinical trial 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. In addition, NIAID has completed an independent animal efficacy study of BioThrax in combination with antibiotics as a post-exposure prophylaxis for anthrax infection. NIAID in collaboration with the BioMedical Advanced Research & Development Authority, or BARDA, of HHS also has awarded us funding for animal efficacy studies and clinical trials of our anthrax immune globulin therapeutic candidate. BARDA also has awarded funding of up to $11.5 million to support our post-exposure prophylaxis indication for BioThrax, of which $8.8 million was paid in the fourth quarter of 2007. The Wellcome Trust provided funding for our Phase I and Phase II clinical trials of our typhoid vaccine candidate in Vietnam. In addition, NIAID has agreed to fund, manage and conduct a Phase I clinical trial of our group B streptococcus vaccine candidate. We believe many of our product candidates may be of interest to governments and philanthropic organizations. We plan to continue to encourage government entities and NGO s to continue to conduct studies of, and provide financial support for the development of, our licensed product and product candidates.

Fund product development through internally-generated cashflows. We generate revenues and cash flows from sales of BioThrax. In turn, we use these cash flows to fund our development efforts, which we believe gives us an advantage over many of our competitors that rely primarily on external sources of funds. The revenues we derive from the sale of BioThrax help to insulate us from fluctuations in the capital markets and the uncertainties of development funding decisions by government agencies and NGO s. We are focused on increasing sales of BioThrax to the U.S. government, expanding the market for BioThrax to other customers and pursuing a label expansion and a number of improvements for BioThrax, including an extension of expiry dating, a reduction in the number of required doses and the addition of another route of administration. We seek to strike an appropriate balance between maintaining current profitability and continuing to invest in our product development pipeline, which we believe will maximize long term value.

Leverage internal manufacturing capabilities and infrastructure. Since 1998, we have manufactured BioThrax at our vaccine manufacturing facility Lansing, Michigan. The Lansing manufacturing facility is a multi-building vaccine production campus located on approximately 12.5 acres. To augment our existing manufacturing capabilities, we constructed a new 50,000 square foot manufacturing facility on our Lansing campus. We are currently conducting validation and qualification activities required for regulatory approval. We expect that this new facility will have the potential to reduce our manufacturing costs for BioThrax, while increasing dramatically our capacity to manufacture doses of BioThrax annually. This new facility will also allow us to manufacture other fermentation-based products, including production of our own vaccine candidates, as well as potentially allow us to provide contract manufacturing services for third parties.

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 2006 report issued by Frost & Sullivan, a market research organization, from 2002 to 2005, annual worldwide vaccine sales increased from $6.7 billion to $9.9 billion, a compound annual growth rate of approximately 14%. In this same report it is estimated that the worldwide sales of vaccines will grow at a compound annual rate of approximately 10.5% from 2005 through 2012. 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 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 NGO s may fund the cost of developing vaccines against these diseases. According to a 2006 report issued by Frost & Sullivan, public purchases of vaccines, including immunization programs and government stockpiles, account for approximately 90% of the total volume of worldwide vaccine sales. Alternatively, private market purchases of vaccines represent only 10% of total worldwide vaccine sales and yet account for approximately 60% of total worldwide vaccine revenues in 2005.

The market for biodefense countermeasures, including vaccines and therapeutics, has grown dramatically as a result of the increased awareness of the threat of global terror activity in the wake of the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. The U.S. government is the principal source of worldwide biodefense spending. Most U.S. government spending on biodefense programs results from development funding awarded by NIAID, BARDA and the DoD, and procurement of countermeasures by HHS, the 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 biological, chemical, radiological and nuclear attacks for the 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. The Pandemic and All-Hazards Preparedness Act, passed in 2006, established BARDA as the agency responsible for awarding procurement contracts for biomedical countermeasures and providing development funding for advanced research and development in the biodefense arena, and supplements the funding available under Project BioShield for radiological, nuclear, chemical and biological countermeasures, and provides funding for infectious disease pandemics. Funding for BARDA is created 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 procures biodefense countermeasures that it administers primarily through the Military Vaccine Agency, or MilVax. MilVax administers various vaccination programs for military personnel, including vaccines for common infectious diseases, such as influenza, and vaccines to protect against specific bioterrorism threats, such as anthrax and smallpox. The 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. We believe that in the future the DoD will procure additional doses of BioThrax directly from HHS to satisfy ongoing requirements for its active immunization program and that these purchases may result in HHS procuring additional doses from us.

In addition to the U.S. government, we believe that other potential additional 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;

NGO s and multinational companies, including the U.S. Postal Service and transportation and security companies; and

health care providers, including hospitals and clinics.

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

Scientific Background

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

A vaccine is normally given to a healthy person as a prophylaxis in order to generate an immune response that will protect against future infection and disease caused by a specific pathogen. Following vaccination, the immune system s memory of antigens presented by a vaccine allows for an immune response to be generated against a pathogen in order to provide protection against disease. A therapeutic vaccine is slightly different in that it acts to strengthen or modify the immune response in patients already infected with bacterial and viral pathogens in order to clear the pathogens from the infected host. Without treatment, such patients can be subject to recurring bouts of the disease.

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

Products

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

Immunobiotic Product or Product Candidate	Prophylactic or Therapeutic	Stage of Development
BioThrax (Anthrax Vaccine Adsorbed)	Pre-exposure prophylactic	FDA approved
	Post-exposure prophylactic*	Post-approval label expansion; animal efficacy and human safety and immunogenicity studies ongoing; BLA supplement planned
Next generation anthrax vaccine*	Pre-exposure prophylactic	Preclinical and Phase I
Anthrax immune globulin*	Therapeutic	Pivotal animal studies and pivotal human trial

		planned for 2008 and 2009
Typhoid vaccine	Prophylactic	Phase II
Hepatitis B therapeutic vaccine	Therapeutic	Phase II
Group B streptococcus vaccine	Prophylactic	Phase I
Botulinum vaccines*	Prophylactic	Preclinical
Chlamydia vaccine	Prophylactic	Preclinical
Neisseria meningitis B vaccine	Prophylactic	Preclinical; commercialization rights out-licensed to Sanofi Pasteur

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

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

BioThrax (Anthrax Vaccine Adsorbed)

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 and can survive without nutrients or air for extended periods. Anthrax infections occur if the spores enter the body through a cut, abrasion or open sore, or by ingestion or inhalation of the spores. Once inside the body, anthrax spores germinate into bacteria that then multiply. Anthrax bacteria secrete three proteins: protective antigen, lethal factor and edema factor, which individually are non-toxic but can become highly toxic if allowed to interact on the surface of human or animal cells.

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

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

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

The only FDA-approved product for pre-exposure prophylaxis of anthrax infection is BioThrax. The only FDA-approved products for post-exposure prophylaxis of anthrax infection are antibiotics, which are typically administered over a 60-day period. Antibiotics are effective against anthrax post-exposure by killing the anthrax bacteria before the bacteria can release anthrax toxins into the body. However, antibiotics are not effective against anthrax toxins once the toxins are present in the body. Nor are antibiotics effective against anthrax spores that are in the body and dormant following exposure. Anthrax spores may remain in the body for extended periods, which can potentially germinate into bacterium following the end of antibiotic treatment and lead to infection. Infection may also occur if patients do not adhere to the prolonged course of antibiotic treatment or are not able to remain on antibiotics for extended periods of time. In addition, antibiotics may not be effective against antibiotic resistant strains of anthrax. Because of these limitations, the CDC recommends administering BioThrax in combination with antibiotics under an investigation new drug application, or IND, with informed consent of the patient as a post-exposure prophylaxis for anthrax

infection as an emergency public health intervention.

Although BioThrax is not currently approved by the FDA for post-exposure prophylaxis, as discussed below, we are actively pursuing a label expansion for this indication. We are also developing an anthrax immune globulin therapeutic product candidate and we recently acquired a monoclonal anthrax antibody product candidate, both of which are deigned for post-exposure use. Several other companies also are developing post-exposure anthrax therapeutic products.

Our total revenues from BioThrax sales were $169.8 million in 2007, $148.0 million in 2006 and $127.3 million in 2005.

Description and benefits of BioThrax. BioThrax is the only FDA-approved vaccine for the prevention of anthrax infection. It is approved by the FDA as a pre-exposure prophylaxis for use in adults who are at high risk of exposure to anthrax spores. BioThrax is manufactured from a sterile culture filtrate, made from a non-virulent strain of *Bacillus anthracis,* and contains no dead or live bacteria. Based on its current product labeling, BioThrax is administered by subcutaneous injection in three initial doses followed by three additional doses, with an annual booster dose recommended thereafter. The three initial doses are given two weeks apart over a thirty-day period followed by three additional doses given at six, 12 and 18 months following the first vaccination. BioThrax includes aluminum hydroxide, or alum, as an adjuvant. BioThrax is not currently approved as a post-exposure prophylaxis. Following the October 2001 anthrax letter attacks, however, the CDC provided BioThrax under an IND protocol for administration on a voluntary basis to Capitol Hill employees and certain others who may have been exposed to anthrax.

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

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

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

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

BioThrax development activities. We are actively pursuing label expansions and improvements for BioThrax, including the following:

Extend expiry dating. The current FDA-approved expiry dating of BioThrax is three years. In December 2006, based on data generated from our ongoing stability studies, we submitted a supplement to our biologics license application, or BLA, for BioThrax to extend the expiry dating from three years to four years, which, if granted, would allow BioThrax to be stockpiled for a longer period of time. This application is still pending and we continue to discuss with FDA the requirements for approval of this supplement. We are unable to predict whether or when this application might be approved.

Add second route of administration. We have applied to the FDA using interim data from the CDC study to add a second route of administration of BioThrax to include intramuscular injection in addition to subcutaneous injection. We believe that intramuscular injection may result in fewer local reactions than subcutaneous injection. We may be required to wait for full study data to be submitted to the FDA before consideration of our application.

Reduce doses for pre-exposure prophylaxis. We have applied to the FDA to reduce the number of required doses of BioThrax for pre-exposure prophylaxis from six to five, with an annual booster dose thereafter. Our application is based on an analysis of interim data from an ongoing clinical trial being conducted by the CDC to evaluate whether as few as three doses of BioThrax, administered over six months, with booster doses up to three years apart, will confer an adequate immune response. The FDA has requested additional data, some of which may not be available until we receive final data from the CDC dose reduction trial, which we expect at the end of 2008. The FDA may not approve dose reduction based on interim data. If the final data from the CDC dose-reduction trial support a further reduction of doses, we plan to file an additional BLA supplement with FDA for approval of a three-dose regimen, with booster doses thereafter up to three years apart.

Expand label indication to include post-exposure prophylaxis. We plan to seek approval of BioThrax in combination with antibiotic therapy as a post-exposure prophylaxis for anthrax infection. In October 2007, we completed a human clinical trial of BioThrax for the post-exposure indication using the anticipated dosing schedule of three doses of BioThrax given two weeks apart. The purpose of this trial was to collect data that, in combination with data from our non-clinical studies, will be used to design our pivotal human clinical trial for this indication. We are currently conducting non-clinical studies for the post-exposure indication pursuant to the FDA animal rule. In these studies, we are evaluating the effect of a humanized dose of BioThrax in combination with antibiotics compared to antibiotics alone in rabbits exposed by inhalation to anthrax spores. We also plan to conduct one or more pivotal studies in non-human primates. The timing of such studies depends on the development of a non-human primate model by NIAID. 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 proportional to the effect of an undiluted dose in humans. This is referred to as a humanized dose. Only 44% of the rabbits treated with antibiotics alone survived, while 100% of the rabbits treated with either humanized doses or undiluted doses of BioThrax in combination with levofloxacin survived. In the trial, there were statistically significant increases in survival rates for rabbits treated with all dose amounts of BioThrax in combination with the antibiotic compared to rabbits treated with levofloxacin alone. These results were consistent with an earlier animal test conducted by the U.S. Army Medical Research Institute of Infectious Diseases, or USAMRIID, involving the administration of BioThrax in combination with an antibiotic to non-human primates infected with anthrax. We believe that the data from our rabbit and non-human primate 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 for anthrax infection. In September 2007, BARDA awarded us up to $11.5 million in development funding for this indication, $8.8 million of which was paid in the fourth quarter of 2007.

Next Generation Anthrax Vaccine

We have established a program to develop additional anthrax vaccine product candidates that would incorporate advanced characteristics, including one or more of the following: reduced number of doses, room temperature storage, enhanced immune response, longer expiry dating, or novel delivery method. We are evaluating candidates based on recombinant protective antigens, or rPA, of *Bacillus anthracis,* as well as a candidate based on *Bacillus anthracis* toxoid technology.

Our most advanced product candidate in this program is based on BioThrax combined with an adjuvant, known as VaxImmune ™ (CPG adjuvant), which we licensed from Coley Pharmaceuticals which was recently acquired by Pfizer, Inc. The DoD s Defense Advanced Research Projects Agency, or DARPA, previously funded a double-blind Phase I clinical trial of BioThrax plus VaxImmune vaccine candidate pursuant to a collaboration among DARPA, Pfizer and us. 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 VaxImmune alone. In this Phase I trial, the product candidate was administered in three doses by intramuscular injection at two week intervals. In this trial, the BioThrax VaxImmune combination vaccine candidate elicited an enhanced immune response. The immunogenicity results from this trial were statistically significant.

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

enable a product candidate to proceed to Phase II clinical development. Phase I clinical trials are required to establish the safety of a product candidate, not its immunogenicity, before Phase II clinical trials may begin.

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

Anthrax Immune Globulin

We are developing a human anthrax immune globulin therapeutic product as a treatment for patients who present with symptoms of anthrax disease. We expect that, if approved, this product would be prescribed as a single-dose intravenous infusion either as a monotherapy or in conjunction with an antibiotic. We are developing our anthrax immune globulin therapeutic product candidate using plasma produced by healthy donors who have been immunized with BioThrax. We have engaged Talecris Biotherapeutics, Inc. to fractionate, purify and fill our anthrax immune globulin therapeutic product candidate at its FDA-approved facilities. We have manufactured two full-scale lots of this product candidate under current good manufacturing practices, or cGMP, using a validated and approved process at Talecris. We plan to rely on the FDA s animal rule to support approval of our anthrax immune globulin therapeutic product candidate. We currently are conducting efficacy studies of this product candidate in infected rabbits, and we plan to conduct further efficacy studies in infected non-human primates in 2008 and 2009. In March 2007, we filed an IND for a Phase I clinical trial to evaluate the safety and pharmacokinetics of our anthrax immune globulin therapeutic candidate in healthy human volunteers. We expect to commence this trial in 2008. NIAID has provided us grant funding of up to $13.4 million for a combination of initiatives, including studies designed to assess the tolerability, pharmacokinetics and efficacy of this product candidate in infected rabbits, the development and validation of product assays, and a human clinical trial to evaluate safety and pharmacokinetics. We believe that favorable data from the animal efficacy studies and safety and pharmacokinetic data from the human clinical trial would be sufficient to support an application to the FDA for marketing approval of this product candidate.

Anthrax Monoclonal

In addition to our anthrax immune globulin product candidate, which is a polyclonal antibody therapeutic, we recently acquired a monoclonal antibody therapeutic from AVANIR Pharmaceuticals. This human monoclonal antibody product candidate is being developed as an intravenous treatment for patients who present with symptoms of anthrax disease and is being funded in part with a grant from NIAID to support efficacy testing in non-human primates and the establishment of cGMP manufacturing process.

We believe that anthrax therapeutics would be eligible to be procured by HHS under Project BioShield for inclusion in the SNS prior to receiving marketing approval, provided that the product candidate is deemed to be licensable**.**

Typhoid Vaccine

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

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

Description and development status. We are developing a live attenuated typhoid vaccine that contains deletions in two genes of the *Salmonella typhi* bacterium designed to eliminate virulence. We have designed our vaccine candidate to be administered in a single drinkable dose prior to travel to countries where typhoid is endemic. We believe that, if approved, the method of administration of our vaccine candidate would provide a competitive advantage compared to both currently approved typhoid vaccines. If we are unable to establish that our typhoid vaccine product candidate can induce a sufficient immune response after one drinkable dose, this competitive advantage will not be realized.

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

- An open-label, non-placebo controlled, pilot study conducted in the United Kingdom in nine healthy adult volunteers. The purpose of this study was to evaluate the safety and immunogenicity of our vaccine candidate. In this study, our vaccine candidate was immunogenic, eliciting both cell mediated and humoral immune responses, and well tolerated.
- A double-blind, placebo controlled, single dose escalating Phase I clinical trial conducted in the United States in 60 healthy adult volunteers. The purpose of this trial was to evaluate the safety, tolerability and immunogenicity of three dose levels of our vaccine candidate. In this trial, our vaccine candidate was immunogenic and well tolerated at all dose levels. The immunogenicity parameter for this trial was the proportion of trial participants with an immune response to the product candidate on day seven after dosing or day 28 after dosing. To be considered adequately immunogenic, 50% of the participants receiving a vaccine dose had to satisfy the primary immunogenicity endpoint. We performed analyses on both an intent to treat and a per protocol basis. Intent to treat analysis is based on the participants who receive a dose of vaccine. A per protocol analysis is based on the participants who complete a trial and substantially comply with the trial protocol. In both the intent to treat population and the per protocol population, 100% of the trial participants in the highest dose group and 56% of the participants in the lowest dose group had an immune response on day seven or day 28. The immune response rate for the highest dose group was statistically significantly greater than the immune response rate for the lowest dose group. The *P* value was 0.0068 in the intent to treat population and 0.0073 in the per protocol population.
- An open-label, non-placebo controlled, single dose Phase I clinical trial conducted in the United States in 32 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of two different presentations of the vaccine candidate, one using bottled water and another using tap water. We vaccinated 16 subjects with each presentation. Because one subject who received the tap water presentation of the vaccine candidate was excluded from the trial results due to a lack of post-baseline immunology data, the tap water presentation data reflected data from only 15 subjects. The immunogenicity parameter for this trial was the proportion of trial participants with an immune response to *Salmonella typhi* following administration of a single dose of the vaccine candidate. The immune response rate was 94% for the participants who received the bottled water presentation and 93% for the participants who received the tap water presentation. The response rate for both groups was statistically significantly higher than the assumed response rate of 50%. The *P* value was 0.0005 for the participants who received the bottled water presentation and 0.001 for the participants who received the tap water 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.

In these three clinical trials, our typhoid vaccine candidate demonstrated immunogenicity response levels following a single drinkable dose similar to those seen with multiple doses of the currently approved oral vaccine. As a result of these trials, we were able to establish the dose and regimen for our vaccine candidate with a formulation that we believe is appropriate for commercialization and intend to move the development program forward into Phase II safety and immunogenicity trials in the target populations that will be the focus of the Phase III efficacy trials to follow.

We have completed the following clinical trials of our typhoid vaccine candidate in endemic areas:

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

A single-blind randomized, placebo controlled, Phase II clinical trial of our vaccine candidate in Vietnam in 151 healthy children between the ages of 5 and 14 years. A total of 101 children received the vaccine candidate 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 the vaccine candidate 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 the vaccine candidate. In this trial, 93% of the children receiving a vaccine dose developed an immune response as measured by increases in *Salmonella typhi* LPS-specific IgG antibody levels, which is suggestive of systemic protective immunity, and 94% of the children receiving a vaccine dose developed an immune response as measured by increase in *Salmonella typhi* LPS-specific IgA antibody levels, which is suggestive of mucosal protective immunity. In the aggregate, 97% of the children receiving a vaccine dose developed an immune response, which was statistically significantly greater than the percentage of children receiving placebo who developed an immune response. The vaccine candidate was well tolerated by trial participants, with no serious adverse events reported.

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

Phase II clinical trial. We plan to conduct a randomized, double-blind, placebo-controlled, dose escalation Phase II clinical trial in the United States in healthy adults to evaluate the immunogenicity, safety and tolerability of our typhoid vaccine at a range of dose levels. Clinical trial supplies for this study were manufactured at a new manufacturing facility under scaled up conditions.

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 our vaccine candidate in the target population in preparation for our planned Phase III clinical study.

Disease surveillance study. We plan to conduct a disease surveillance study in India to confirm that a sufficient number of subjects will be included in the Phase III trial. The Wellcome Trust has provided funding for this surveillance study.

Phase III clinical trial. We plan to conduct a single-blind Phase III clinical trial in India, where typhoid is endemic. The purpose of this trial will be to evaluate the efficacy of our vaccine candidate in children who are likely to be exposed to the typhoid bacterium. We expect to undertake the primary analysis of the data from the trial after approximately one year, which, if the results are favorable, we plan to use to support the filing with the FDA of a BLA for marketing approval of our vaccine candidate. We plan to continue to monitor the incidence of typhoid in the trial participants for several years after vaccination.

Tolerability and immunogenicity study. Concurrently with our 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 our vaccine candidate to support marketing approval in the United Sates and Europe.

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

Hepatitis B Therapeutic Vaccine

Disease overview. Hepatitis B is a highly infectious virus transmitted from person to person by contact with blood and bodily fluids. Most hepatitis B infections in adults result in acute hepatitis, with the immune system eventually clearing the infection. However, in approximately

8% to 10% of infected adults and a much larger proportion of infected children, the immune system fails to clear the virus, resulting in immune tolerance of the virus and chronic infection. In addition, pregnant women suffering from hepatitis B can pass the infection on to their babies during childbirth. Babies born infected rarely clear the infection, with over 90% becoming chronically infected. According to the WHO, as many as 40% of people with chronic hepatitis B infection develop serious liver disease, including cirrhosis and liver cancer.

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

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

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

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

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

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

In February 2004, we completed an open-label, dose escalating Phase I clinical trial of our vaccine candidate in the United Kingdom in 30 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of two dose levels of our vaccine candidate. In this trial, we administered the two doses of vaccine over a period of approximately two months. The primary immunogenicity parameter for this trial was the proportion of trial participants with an immune response to the product candidate on day 28 after dosing or day 84 after dosing. In this trial, 50% of the participants in the low dose group and 40% of the participants in the high dose group demonstrated an immune response on day 28 or day 84. The results in the low dose group reflect a confidence interval of 19.0% to 81.0%. The results in the high dose group reflect a confidence interval of 18.5% to 61.5%. These confidence intervals indicate a 95% likelihood that the true value is within the range specified. The secondary immunogenicity endpoint for this trial was the proportion of participants who demonstrated the type of immune response known to be important in promoting clearance of the hepatitis B virus at any point during the trial. In this trial, 100% of the participants in the high dose group and 90% of the participants in the low dose group demonstrated such a response. We did not conduct a statistical analysis of the results from the secondary immunogenicity endpoint. The vaccine candidate was well tolerated by trial participants, with no serious adverse events

reported.

In the fourth quarter of 2006, we initiated a Phase II clinical trial of our vaccine candidate in trial participants chronically infected with the hepatitis B virus in the United Kingdom. The protocol provides for a placebo controlled, randomized, dose escalating study to be conducted in 45 chronic carriers of hepatitis B. We subsequently expanded this trial to Serbia to increase the rate of participant recruitment. If necessary, we may expand the trial to additional sites around the world to accelerate subject recruitment. The primary purpose of this trial is to evaluate the safety and tolerability of six monthly doses of our vaccine candidate.

The secondary purpose is to investigate whether the vaccine candidate can reduce the hepatitis B viral DNA load, a recognized surrogate endpoint for treatment of hepatitis B using current therapeutics. If the results of this Phase II clinical trial are favorable, we expect to submit an IND to the FDA to conduct one or more clinical trials of this vaccine candidate in the United States as may be appropriate to support approval of the product in the United States as well as in Europe. The FDA IND must become effective before we can conduct any clinical trials in the United States.

Group B Streptococcus Vaccine

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

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

Prevalence, market opportunity and current treatment. Concern about the number of group B streptococcus neonatal infections prompted the CDC to recommend routine screening of pregnant women for group B streptococcus bacteria and preventative antibiotic treatment at the time of labor for women found to be infected. In the absence of antibiotic treatment, the CDC estimates that the risk is one in 200 of delivering a baby with group B streptococcus infection. While the level of group B streptococcus disease decreased in the United States from 1.7 cases per 1,000 live births in 1993 to 0.4 cases per 1,000 live births in 2002, the CDC projects that there are approximately 2,750 neonatal infections each year in the United States. In a study of 338 of these cases of neonatal infections, the death rate was approximately 6%. The NIH has identified prevention of group B streptococcus infection in newborns as a major vaccine objective. We expect the target market for our vaccine candidate to be women of childbearing age.

Approximately 10% to 30% of women are found to be carrying the bacterium as a normal component of the vaginal microflora. The existing method of prevention of group B streptococcus infection in neonates is the targeted administration of intravenous antibiotics to women during labor. However, this approach is invasive and only partially effective. In addition, antibiotics create the risk of possible adverse reactions and may lead to the development of antibiotic resistant strains of the bacteria. Direct vaccination of newborns is not effective because their immune systems are too immature to respond effectively to the vaccine. Antibiotics are used to treat babies after infection.

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

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

We have identified several novel surface associated proteins and are working on the development of two of these proteins as components of our vaccine candidate. We believe that a combination of proteins will be required to provide effective protection. We have conducted preclinical studies in which we evaluated the safety and immunogenicity of these proteins. Based on the results of these preclinical studies, we have initiated a clinical development program. We have completed an open-label, dose escalating Phase I clinical trial of the first protein component of our vaccine candidate in the United Kingdom in 47 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of this protein as an individual recombinant protein. The protein was administered with alum as an adjuvant and tested at four different dose levels. Subjects received two doses of vaccine given 28 days apart.

In this trial, the protein was immunogenic at all dose levels tested. We performed analyses on both intent to treat and a per protocol basis. In both the intent to treat population and the per protocol population, the immune response rate was 83% at the lowest dose tested and 100% at the highest dose tested. The response rate for both the highest dose group and the lowest dose group was statistically significantly higher than the assumed response rate of 50%. For the lowest dose group, the *P* value was 0.0386 in both the intent to treat population and the per protocol population. For the highest dose group, the *P* value was 0.0039 in the intent to treat population and 0.0078 in the per protocol population. The vaccine candidate was well tolerated by trial participants at all dose levels tested, with no serious adverse event s reported. None of the subjects withdrew due to an adverse event.

In the fourth quarter of 2006, we entered in to a clinical trial agreement with NIAID under which NIAID has agreed to fund, manage and conduct a Phase I clinical trial of our group B streptococcus vaccine product candidate. In the proposed study, NIAID would test the same recombinant subunit antigen we evaluated in our Phase I trial in the United Kingdom alone and in combination with a second recombinant subunit antigen. The second recombinant subunit antigen would also be tested separately. The trial is to be conducted at a NIAID clinical research site, with NIAID serving as the IND sponsor. An IND must become effective before the clinical trial may begin.

Botulinum Vaccines

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

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

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

Description and development status. We are developing two vaccine candidates to protect against illness caused by botulinum toxin. The first is a recombinant protein subunit trivalent botulinum vaccine for protection against botulinum serotypes A, B and E in collaboration with HPA. We hold an exclusive license from HPA to the recombinant technology that we are using in the development of our vaccine candidate. HPA is also providing us with process development and toxicology expertise, access to its facilities and specialized manufacturing capabilities. We are designing this vaccine candidate to be administered by intramuscular injection with an alum adjuvant in a three-dose regimen. Our recombinant vaccine candidate is based on a fragment of the botulinum toxin that we have selected as an antigen because we believe it to be non-toxic and immunogenic.

We are producing this recombinant antigen in an *E. coli* expression system. We believe that our technology will allow us to develop a stable product with possible cross-protection against a range of toxin subtypes and ease of formulation into a multivalent vaccine. We have established a small scale production process for botulinum serotypes A, B, and E and have conducted proof-of-concept studies of this vaccine candidate in mice for all three of these serotypes. In these studies, the vaccine elicited antibodies and provided protection against challenge with the botulinum toxin. We anticipate that the manufacture of our recombinant vaccine in a cGMP facility will not require the high level of containment that is required for the production of conventional, non-recombinant toxoid vaccines that involve cultivation of the disease-causing organism.

Our second vaccine candidate is also a trivalent botulinum toxoid vaccine using a combination of botulinum serotypes A, B and E. Initially our candidate was developed using botulinum serotype B derived from the starting material from a pentavalent botulinum toxoid vaccine developed by the Michigan Department of Public Health and serotype A from HPA. We are designing this vaccine to be administered by injection with an alum adjuvant. We anticipate that several doses will be needed to elicit a strong immune response. We are performing development activities at existing HPA facilities, which we expect may expedite production of clinical material for the vaccine. HPA is also providing us with process development and specialized manufacturing capabilities for the vaccine. We have completed a proof-of-concept study of this vaccine candidate in mice, which confirmed the suitability of the vaccine for further development. Should we recieve U.S. government funding, we plan to file an IND to initiate a Phase I clinical trial to evaluate the safety of this vaccine candidate in healthy volunteers. Our regulatory plan also includes reliance on safety and immunogenicity data from the pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan, including the results of a Phase II safety and immunogenicity clinical trial conducted by the DoD from July 1998 to May 2000, animal efficacy data and use of the pentavalent vaccine by the CDC in immunizing at risk laboratory personnel.

In addition to our botulinum vaccine programs, we are developing a human botulinum immune globulin candidate in collaboration with HPA as an intravenous therapeutic for symptomatic botulinum exposure. We believe that botulinum immune globulin has the potential to provide immediate protection from the effects of botulinum toxin.

We plan to rely on the FDA animal rule in connection with the development of our botulinum-related product candidates. We have applied for U.S. government funding to support the further development of our botulinum-related product candidates. We will continue to assess, and may alter, our future development plans for these products based on the U.S. government s interest in providing development funding for, and procuring, botulinum countermeasures.

Chlamydia Vaccine

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

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

Description and development status. We are developing a recombinant protein subunit chlamydia vaccine for all clinically relevant strains of *Chlamydia trachomatis,* including strains that cause ocular disease. We are designing our vaccine candidate to be administered by injection with a novel adjuvant in a three-dose regimen. We are currently evaluating in-license opportunities for the adjuvant. We have cloned our vaccine candidate and produced it in *E. coli.* In studies in mice, our vaccine candidate protected against both upper reproductive tract disease and lower reproductive tract infection induced by *Chlamydia trachomatis.* In addition, the fertility of mice immunized with our vaccine candidate was equivalent to that observed in healthy animals.

Meningitis B Vaccine

Disease overview. Meningococcal disease is a life threatening condition caused by infection with the bacterium *Neisseria meningitidis. Neisseria meningitidis* is classified into 12 groups based on differences in the surface coating of the bacterium that elicit distinct immune responses. According to the WHO, group B is the most common cause of endemic meningitis in industrialized countries, accounting for 30% to 40% of cases in North America and 30% to 80% of cases in Europe.

Meningococcal disease has a fatality rate of approximately 10%. The infection can develop very rapidly and cause death within 24 hours of the symptoms first becoming apparent. Children from six months to two years of age are at the highest risk of group B meningococcal infection, with teenagers also at enhanced risk.

Prevalence, market opportunity and current treatment. The WHO estimates that approximately 1.2 million cases of bacterial meningitis occur annually worldwide, resulting in approximately 135,000 deaths. The WHO estimates that approximately 500,000 of these cases and 50,000 of these deaths are caused by the bacterium *Neisseria meningitidis.* In the United States, 2,333 cases of meningococcal disease were reported in 2001, with approximately one-third due to group B. In 2003, 1,756 cases of meningococcal disease were reported in the United States. Currently, there is no meningitis vaccine on the market that is protective against group B meningococcal infection. Current meningitis B treatments include antibiotics and clinical support. The rapid progression of the infection means that antibiotic therapy can be ineffective in preventing serious morbidity and mortality.

Description and development status. We are developing a recombinant protein subunit meningitis B vaccine for babies, children and adolescents. We are designing our vaccine candidate to be administered by injection with an alum adjuvant in a two-dose regimen for children under age five and a single-dose regimen for children over age five. We do not expect that a booster dose will be required. We anticipate that the vaccine will consist of two or three protein antigens. We are currently evaluating a pool of more than 40 protein candidates in a number of preclinical studies. We are producing recombinant proteins in *E. coli.* We have entered into a collaboration agreement with Sanofi Pasteur for this vaccine candidate.

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

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

Under the agreement, Sanofi Pasteur paid us an initial fee of 3 million. In addition, Sanofi Pasteur has agreed to pay all expenses incurred by us under the development program, and we have received approximately 7.4 million since the inception of this arrangement. We are also eligible to receive payments of up to a maximum of 73 million upon the achievement of specified research, development and commercialization milestones. Sanofi Pasteur has agreed to pay royalties to us based on net sales by Sanofi Pasteur, its affiliates and sublicensees of licensed products from the collaboration, including specified minimum royalties with respect to sales of any combination product. In addition, Sanofi Pasteur has agreed to pay us a portion of specified sublicense income received by Sanofi Pasteur or its affiliates.

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

Manufacturing

We conduct our primary vaccine manufacturing operations at a multi-building campus on approximately 12.5 acres in Lansing, Michigan. To augment our existing manufacturing capabilities, we have constructed a new 50,000 square foot manufacturing facility on our Lansing campus. We substantially completed construction of this facility in 2006, and are currently conducting validation and qualification activities required for regulatory approval. This new facility is a large scale manufacturing plant that we can use to produce multiple fermentation based vaccine products, subject to complying with appropriate change-over procedures.

We also own two buildings in Frederick, Maryland that are available to support our future manufacturing requirements. We are also performing initial engineering designs and preliminary utility build out of one of these buildings. We may elect to lease all or a substantial portion of, or sell, one of these facilities to third parties.

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

Hollister-Stier Laboratories LLC performs the contract filling operation for BioThrax vials at its FDA-approved facility located in Spokane, Washington. Hollister-Stier has agreed to meet all of our firm purchase orders for contract filling of BioThrax based on a good faith annual estimate that we provide prior to each calendar year. In addition, Hollister-Stier has agreed to accommodate fill requests in excess of our annual estimate, subject to its available production capacity. Our contract with Hollister-Stier expires December 31, 2010.

Talecris Biotherapeutics 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 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. Talecris has agreed to perform plasma fractionation and purification and contract filling for the manufacture of our anthrax immune globulin therapeutic candidate for preclinical or animal studies, for clinical use or for non-clinical testing required for clinical trials and for commercial sale. We have agreed to pay Talecris royalties on net sales on a country-by-country basis for commercial product manufactured by Talecris under the contract. Our contract with Talecris expires December 31, 2013 or five years following initiation of commercial manufacturing. We have the option to extend the term for an additional five-year period upon notice to Talecris at least 12 months prior to the expiration of the initial term. After three years following initiation of commercial manufacturing, either party may terminate the contract upon two years advance notice. We have the right to terminate the contract, under specified circumstances, if we discontinue our production of anthrax immune globulin source plasma or the development of our anthrax immune globulin therapeutic candidate.

We used a contract manufacturer for the supply of our typhoid vaccine candidate for the Phase I and Phase II trials in Vietnam. We may use a different contract manufacturer for the supply of this vaccine candidate for the Phase II study in India, for the Phase III clinical supply, and for commercial manufacturing. We also plan to use a contract manufacturer for the clinical and commercial supplies of our group B streptococcus vaccine 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 immunobiotic products and the scale-up process necessary to manufacture quantities of immunobiotics sufficient for commercial launch are complex. If we are unable to secure a relationship with third party contract manufacturers that can provide sufficient supplies for the commercial launch of our product candidates, our ability to capture market share may be adversely affected.

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

Marketing and Sales

We currently market and sell BioThrax directly to the 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 of any other biodefense product candidates that we successfully develop. We plan to expand our sales and marketing organization as we broaden our sales activities of biodefense products 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 Singapore and Munich, Germany, and a joint venture in Malaysia, to target sales of biodefense products to foreign governments. We have augmented our international efforts by engaging third party marketing representatives to identify potential opportunities to sell BioThrax in the Middle East, India, Australia, and several countries in Southeast Asia and Europe.

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 generally expect to retain commercial rights for our product candidates that we successfully develop in situations in which we believe it is possible to access the market through a focused, specialized sales force. In particular, we believe that such a sales force could address commercial markets that overlap with markets for our biodefense products, such as the market for typhoid vaccines and other vaccines for travelers to developing countries. 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 to access particular markets.

We have entered into an agreement with Ninebio Sdn. Bhd. to form a joint venture in Malaysia that will focus on creating critical biologics infrastructure and supplying biodefense countermeasures, including BioThrax and other medical and complementary products and services to the Government of Malaysia. It is anticipated that the joint venture will also supply such products and services to certain member countries of the Organisation of the Islamic Conference and other countries within Asia. 9Bio is a Malaysian Government owned company and one of the National Institutes of Health under the Ministry of Health. The Government of Malaysia, through 9Bio, has selected us as one of its principal partners to assist, as a contract service provider, in building vaccine development and manufacturing infrastructure. The joint venture will be majority owned by us.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience, and resources provide us with competitive advantages, we face potential competition from many different sources, including commercial pharmaceutical and biotechnology companies, academic institutions, government agencies and private and public research institutions. GlaxoSmithKline, Sanofi-Aventis, Wyeth, Merck and Novartis generated over 80% of total worldwide vaccine revenues in 2005. The concentration of the industry reflects a number of factors, including:

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

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

Many of our competitors, including those named above, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring products, product candidates and technologies complementary to, or necessary for, our programs. Smaller or more narrowly focused companies, including Cangene, Human Genome Sciences, Acambis, Avant Immunotherapeutics, Dor BioPharma, Dynport Vaccine Company LLC, Elusys, Bavarian Nordic, Pharmathene and Avecia, 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.

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

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

Specifically, the competition for BioThrax and our product candidates includes the following:

BioThrax. Although BioThrax is the only product approved by the FDA for human use for the prevention of anthrax infection, we face significant potential competition for the supply of this vaccine to the U.S. government. Various agencies of the U.S. government are providing funding to our competitors for development of an anthrax vaccine based on recombinant protective antigen. Avecia is currently developing a recombinant protective antigen based anthrax vaccine. HHS has issued an RFP for grants to develop and procure a recombinant protective antigen based anthrax vaccine which could reduce demand for BioThrax. In addition, HPA manufactures an anthrax vaccine for use by the government of the United Kingdom. Other countries as well may have anthrax vaccines for use by or in development for their own internal purposes.

Anthrax immune globulin and monoclonal therapeutic. Cangene is currently developing an anthrax immune globulin 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 for 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 contracts to Human Genome Sciences and Cangene in 2005 to supply their anthrax therapeutics for evaluation of efficacy as a post-exposure therapeutic for anthrax infection.

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

Typhoid vaccine. One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the United States and Europe. In addition, combination vaccines are available for the prevention of hepatitis A and typhoid infections. Antibiotics typically are used to treat typhoid after infection. Avant Immunotherapeutics Inc. has announced it has an oral, single dose, live attenuated typhoid vaccine candidate in Phase II clinical development with funding from NIAID.

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

Group B streptococcus vaccine. The existing method of prevention of group B streptococcus infection in neonates is the targeted administration of intravenous antibiotics to women during labor. A number of competitors have passive immune vaccines in preclinical development.

Chlamydia vaccine. There is no vaccine currently on the market for chlamydia. Although we are not aware of any competing chlamydia vaccine candidate in clinical development, competitors may have chlamydia vaccine candidates in preclinical development. Screening tests and targeted antibiotic treatments have been effective at containing chlamydia in the United States and Europe, which may have the effect of decreasing demand for a vaccine.

Meningitis B vaccine. Currently, there is no meningitis vaccine on the market that is protective against group B meningococcal infection. Novartis markets a meningitis B vaccine in New Zealand to people under the age of 20 and is also developing a broad coverage protein subunit vaccine candidate. Current meningitis B treatment strategies include antibiotics and clinical support.

Intellectual Property and Licenses

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

technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of February 22, 2008, we owned or licensed exclusively a total of 14 U.S. patents and 27 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 of great importance the patent rights that we own or exclusively licensed from HPA relating to our recombinant bivalent botulinum vaccine candidate and our botulinum toxoid vaccine.

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

Typhoid vaccine. We hold three U.S. patents relating to our typhoid vaccine candidate. These patents have claims to the composition of matter of the vaccine candidate and methods of use of live attenuated *Salmonella typhi* bacteria as vaccines for the treatment and prevention of typhoid and for the delivery of vaccine antigens. In addition, we have three pending U.S. patent applications with claims to additional compositions and methods of therapy that are generally related to our typhoid vaccine candidate. Our issued U.S. patents expire, and, if issued, our U.S. patent applications would expire, between 2015 and 2020. We hold 46 foreign counterparts to our issued U.S. patents relating to our typhoid vaccine candidate, including counterparts under the European Patent Convention and in Japan, that expire, and 15 foreign patent applications that, if issued, would expire, between 2015 and 2020. Additional patents relating to our typhoid vaccine and delivery of vaccine antigens are discussed below under STM technology.

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

Group B streptococcus vaccine. We hold three U.S. patents relating to our group B streptococcus vaccine candidate with claims to the composition of matter of the vaccine candidate and methods of use for the prevention or treatment of infection caused by *Streptococcus agalactiae.* In addition, we have seven pending U.S. patent applications with claims to additional compositions and methods of therapy relating to our group B streptococcus vaccine candidate. Our issued U.S. patents expire, and, if issued, our U.S. patent applications would expire, between 2019 and 2027. We hold 82 foreign counterpart patents relating to our group B streptococcus vaccine candidate, including counterparts under the European Patent Convention and in Japan, that expire, and 34 foreign patent applications that, if issued, would expire, in 2019.

STM technology. We own three U.S. patents with claims to methods for the identification of virulence genes using our signature tagged mutagenesis, or STM, technology, which we used to identify and develop the gene mutations that form the basis of our typhoid vaccine and hepatitis B therapeutic vaccine candidates. We also own 16 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 16 foreign patent applications that, if issued would expire in 2015. Our rights under these patents are licensed on a limited non-exclusive basis to third parties to practice the STM method with respect to specific microorganisms, not including *Salmonella typh*i or hepatitis virus.

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

commercialization, thereby reducing any advantage of the patent.

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

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

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

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

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

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

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

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

MVA platform technology. In July 2006, in connection with our acquisition of ViVacs GmbH, or Vivacs, a German limited liability company, we acquired a license agreement with StMUGV that provides us the non-exclusive, worldwide right to develop and produce viruses and viral products, including recombinant viral vectors, using the modified vaccinia Ankara virus, or MVA. Under the license agreement, we are required to pay StMUGV a percentage of the net revenue or license fees, that we receive from products developed using MVA that are used for research or other purposes and a percentage of the license fees that we receive from products developed using MVA that are licensed as starting material for the production of a smallpox vaccine.

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

Government Regulation

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

U.S. Government Regulation

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

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

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

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

Preclinical Studies and the IND

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

Clinical Trials

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

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

Clinical trials must be conducted in compliance with good clinical practice, or GCP, requirements. In addition, federal law now requires the listing, on a publicly-available website, of registry and results information for most clinical trials that we conduct. The federal requirements for submission of results information will be phased-in over the next three years. Some states have similar 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, approval of such products can be based on clinical data from trials in healthy subjects that demonstrate adequate safety and immunogenicity and efficacy data from adequate and well controlled animal studies. Among other requirements, the animal studies must establish that the biological product is reasonably likely to produce clinical benefits in humans. Because the FDA must agree that data derived from animal studies may be extrapolated to establish safety and effectiveness in humans, these studies add complexity and uncertainty to the testing and approval process. In addition, products approved under the animal rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

Marketing Approval

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

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

The FDA may deny an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if additional clinical data is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. If the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that contraindications, warning statements or precautions be included in the product labeling, require that additional studies be conducted following approval as a

condition of the approval, impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan or risk evaluation and mitigation strategy, or otherwise limit the scope of any approval or limit labeling. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized. The FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Fast Track Designation

In February 2007, the FDA granted Fast Track designation for BioThrax as a post-exposure prophylaxis for anthrax infection. The FDA s Fast Track programs, one of which is Fast Track designation, are designed to facilitate the development and review of new drugs and biologics that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for the conditions. Fast Track designation applies to a combination of the product and the specific indication for which it is being studied. Thus, it is the development program for a specific drug or biologic for a specific indication that receives Fast Track designation. The sponsor of a product designated as being in a Fast Track drug development program may engage in early communication with the FDA, including timely meetings and early feedback on clinical trials. Products in Fast Track drug development programs also may receive priority review or accelerated approval and sponsors may be able to submit portions of an application before the complete application is submitted. The FDA may notify a sponsor that its program is no longer classified as a Fast Track development program if the Fast Track designation is no longer supported by emerging data or the designated drug development program is no longer being pursued.

Ongoing Regulation

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

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

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

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

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

restrictions on the marketing or manufacturing of a product;

warning letters;

withdrawal of the product from the market;

refusal to approve pending applications or supplements to approved applications;

voluntary or mandatory product recall;

fines or disgorgement of profits or revenue;

suspension or withdrawal of regulatory approvals;

refusal to permit the import or export of products;

product seizure; and

injunctions or the imposition of civil or criminal penalties.

BioThrax Lot Release and FDA Review

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

Regulation of Immune Globulin Products

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

Legislation and Regulation Related to Bioterrorism Counteragents and Pandemic Preparedness

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

Project BioShield

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

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

the agent for which the countermeasure is designed can cause serious or life-threatening disease;

the product may reasonably be believed to be effective in detecting, diagnosing, treating or preventing the disease;

the known and potential benefits of the product outweigh its known and potential risks; and

there is no adequate alternative to the product that is approved and available.

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

Safety Act

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

Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act, or PREP Act, enacted by Congress in 2005 provides immunity for manufacturers from all claims under state or federal law for loss arising out of the administration or use of a covered countermeasure. However, injured persons may still bring a suit for willful misconduct against the manufacturer under some circumstances. Covered countermeasures include security countermeasures and qualified pandemic or epidemic products, including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or credible risk of a future public health emergency. On February 1, 2007, the Secretary of HHS issued the first declaration under the PREP Act to protect countermeasures from liability that are necessary to prepare the nation for an avian influenza pandemic. We have applied for a PREP Act declaration for BioThrax in connection with our September 2007 BioThrax procurement contract with HHS. To date, the Secretary has not issued the declaration for BioThrax or for any of our product candidates.We cannot predict whether the PREP Act will provide protections for our products or product candidates in the future, whether Congress will fund the relevant compensation programs or if the necessary prerequisites for immunity would be triggered with respect to our product or product candidates.

Foreign Regulation

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

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

The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is currently mandatory for products developed by means of a biotechnological process, including recombinant DNA technology, the controlled expression of genes coding for biologically active proteins and monoclonal antibody methods, and new chemical

entities for the treatment of acquired immune deficiency syndrome, cancer and neurodegenerative disorder or diabetes. Beginning in May 2008, the centralized procedure will be mandatory for products for the treatment of auto-immune diseases and other immune dysfunctions and viral diseases. The centralized process is optional for medicines that constitute a significant therapeutic, scientific or technical innovation or for which a centralized process is in the interest of patients.

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

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

Orphan Drugs

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

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

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

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

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

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

Reimbursement and Pricing Controls

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

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

Under the Medicaid program (a joint federal/state program that provides medical coverage to certain low income families and individuals), pharmaceutical manufacturers must pay prescribed rebates on specified drugs and biologics to enable them to be eligible for reimbursement. Vaccines are generally exempt from these rebate requirements and generally are not provided through Medicaid. Medicare (the federal program that provides medical coverage for the elderly and disabled) generally reimburses for physician-administered drugs and biologics on the basis of the product s average sales price, although the vaccines that are reimbursed under Part B (Influenza, Pneumococcal and Hepatitis B) are reimbursed based on average wholesale price. Outpatient drugs and other vaccines may be reimbursed under Medicare Part D. Part D is administered through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. Various states have adopted further mechanisms that seek to control drug and biologic prices, including by disfavoring higher priced products and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products.

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

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

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

Regulations Regarding Government Contracting

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

Vaccine Injury Compensation Program

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

Hazardous Materials and Select Agents

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

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

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

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

Other Regulations

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

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

Personnel

As of December 31, 2007, we had 560 employees, including 170 employees engaged in product development, 244 employees engaged in manufacturing, 10 employees engaged in sales and marketing and 136 employees engaged in general and administrative activities. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

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 by applicable law, the rules of the SEC or the New York Stock Exchange listing standards regarding any amendment to, or waive of, our code of business conduct and ethics. The information contained on, or that can be accessed through, our website is not a part of or incorporated by reference in this annual report on Form 10-K.

ITEM 1A. RISK FACTORS

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

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

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales of BioThrax, our FDA-approved anthrax vaccine and only marketed product. In 2006 and 2007, we derived substantially all of our revenue from our BioThrax contracts with the DoD and HHS. In October 2007, the White House issued a Presidential Directive that outlines the U.S. government s objective to enhance coordination and cooperation among federal agencies with respect to countermeasure procurement and stockpile management. Also in October 2007, the U.S. Government Accountability Office, or GAO, issued a report that was critical of HHS for lacking an effective strategy to minimize waste in the SNS, citing concerns of large amounts of BioThrax that will become unusable each year due to shelf life expiration. We believe that the DoD has a continued commitment to procure BioThrax for its active immunization program, but that in the future the DoD will likely procure additional doses of BioThrax to satisfy ongoing requirements for its active immunization program directly from HHS and not from us. It is possible that these purchases by DoD from HHS will not result in any additional purchases by HHS from us. Our existing and prior contracts with the DoD and HHS do not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government. HHS has issued an RFP for grants to develop and procure a recombinant protective antigen based anthrax vaccine. If we apply for the grant, we may not win the award. The development of our recombinant protective antigen product candidate could be harmed. Additionally, procurement by HHS of a recombinant protective antigen based anthrax vaccine could reduce demand for BioThrax. The success of our business and our operating results for the foreseeable future are substantially dependent on the price per dose, the number of doses and the timing of deliveries for BioThrax sales to the U.S. government.

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

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

- the need to devote substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded; and
- the expenses that we might incur and the delays that we might suffer if our competitors protest or challenge contract awards made to us pursuant to competitive bidding, and the risk that any such protest or challenge could result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract.

The U.S. government may choose to award future contracts for the supply of anthrax vaccines and other biodefense product candidates that we are developing to our competitors instead of to us. If we are unable to win particular contracts, we may not be able to operate in the market for products that are provided under those contracts for a number of years. For example, if any other company is successful in developing a next generation anthrax vaccine, U.S. government customers may purchase only the next generation vaccine and not BioThrax. If we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition, and operating results could be materially adversely affected.

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

Our principal customer for BioThrax 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. 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 additional regulations and obligations under our U.S. government contracts.

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

procurement integrity;

export control;

government security regulations;

employment practices;

protection of the environment;

accuracy of records and the recording of costs; and

foreign corrupt practices.

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

On September 25, 2007, we entered into an agreement with HHS to supply 18.75 million doses of BioThrax to HHS for placement into the SNS for a firm fixed price of $400 million. If we receive FDA approval of an application to extend the expiry dating of BioThrax from three years to four years, HHS has agreed to adjust the price per dose under the agreement, with an aggregate value of such price increase of approximately $34 million. The regulatory approval process is complex and uncertain, and there is no guarantee that we will receive approval of four-year expiry dating. If we do not receive FDA approval of four-year expiry dating during the term of the agreement, we will not be entitled to receive the $34 million related to the increased price per dose.

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

Our existing and prior contracts for the supply of BioThrax with the DoD and HHS have been fixed price contracts. We expect that our future contracts with the U.S. government for BioThrax as well as 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. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of a fixed price contract or cause a loss.

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

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

terminate existing contracts, in whole or in part, for any reason or no reason;

unilaterally reduce or modify contracts or subcontracts;

cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;

decline to exercise an option to renew a contract;

exercise an option to purchase only the minimum amount specified in a contract;

decline to exercise an option to purchase the maximum amount specified in a contract;

claim rights 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 contract for BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the government s convenience. Under general principles of government contracting law, if the government terminates a contract for convenience, the terminated company may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. One or more of our government contracts could be terminated under these circumstances. Some government contracts grant the government the right to use, for or on behalf of the U.S. government, any technologies developed by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the government.

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

The results of ongoing or future legal proceedings could reduce demand for BioThrax by the U.S. government. For example, in 2003, a group of unnamed military personnel filed a lawsuit seeking to enjoin the DoD from administering BioThrax on a mandatory basis without informed consent of the recipient or a Presidential waiver, and, in 2004, a federal court issued the requested injunction. 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 military personnel and emergency DoD civilian 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 court in which that case was pending dismissed the action, concluding that FDA did not make a clear error of judgment in reaffirming the safety and efficacy of BioThrax.

Although we are not a party to the lawsuits challenging the DoD s mandatory use of the vaccine, if a court were to again enjoin the DoD's use of BioThrax on a mandatory basis, the amount of future purchases of BioThrax by the U.S. government could be affected. Furthermore, contractual indemnification provisions and statutory liability protections may not fully protect us from all related liabilities, and statutory liability protections could be revoked or amended to reduce the scope of liability protection. In addition, lawsuits brought directly against us by third parties, even if not successful, require us to spend time and money defending the related litigation.

Risks Related to Our Financial Position and Need for Additional Financing

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

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

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

As of December 31, 2007, we had $57.9 million principal amount of debt outstanding and remaining borrowing availability of $3.2 million under our revolving line of credit. We may seek to raise substantial external debt financing to provide additional financial flexibility. Our leverage could have significant adverse consequences, including:

requiring us to dedicate a substantial portion of any cash flow from operations to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
increasing the amount of interest that we have to pay on debt with variable interest rates if market rates of interest increase;

increasing our vulnerability to general adverse economic and industry conditions;

limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and

placing us at a competitive disadvantage compared to our competitors that have less debt.

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

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

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

As of December 31, 2007, we had $105.7 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 timing of, and the costs involved in, completion of validation and qualification activities related to our new manufacturing facility in Lansing, Michigan and the build out of our manufacturing facilities in Frederick, Maryland;
the scope, progress, results and costs of our preclinical and clinical development activities;

the costs, timing and outcome of regulatory review of our product candidates;

the number of, and development requirements for, other product candidates that we may pursue;

the costs of commercialization activities, including product marketing, sales and distribution;

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
the extent to which we acquire or invest in businesses, products and technologies;

our ability to obtain development funding from government entities and non-government and philanthropic organizations; and

our ability to establish and maintain collaborations, such as our collaboration with Sanofi Pasteur.

Our committed external sources of funds consist of the remaining borrowing availability under our revolving line of credit with Fifth Third Bank, development funding under our collaboration agreement with Sanofi Pasteur, funding from NIAID and BARDA, including for studies related to our anthrax immune globulin therapeutic product candidate. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate

collaboration and licensing arrangements, which we may not be able to obtain when needed or on attractive terms, which would force us to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

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

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

Risks Related to Manufacturing and Manufacturing Facilities

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

We are spending significant amounts for the validation and qualification activities for our new 50,000 square foot manufacturing facility on our Lansing, Michigan campus, which has been designed and constructed to enable us to manufacture BioThrax on a large scale for our existing and potential future customers. This new facility is a large scale manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures.

We also own two buildings in Frederick, Maryland that are available to address our future manufacturing requirements and have initiated initial engineering design and preliminary utility build out for these facilities. The completion of the Lansing facility and, if we proceed, the build out of the Frederick facilities, will involve substantial expenditures and likely require external sources of funds. Any delays in the validation and qualification activities may adversely affect our ability to manufacture our commercial product candidates for clinical trials or commercial sale.

We anticipate that we will initiate large scale manufacturing of BioThrax at the new Lansing facility in 2008. Our plans assume that the FDA will not require us to complete a human bridging trial demonstrating that BioThrax manufactured at our new facility is bioequivalent to BioThrax manufactured at our existing facility. We currently expect to rely on non-clinical studies for these purposes. However, the FDA has not approved our plan to rely on non-clinical studies without conducting a human bridging trial and may not do so. If the FDA requires us to conduct a human bridging trial, the initiation of large scale manufacturing of BioThrax at our new Lansing facility will be delayed and we will incur additional unanticipated costs.

Constructing and preparing a facility for commercial vaccine manufacturing is a significant project. For example, constructing the new Lansing facility with increased manufacturing capacity requires that we scale-up both fermentation and downstream processing compared to the levels employed at our existing production facility. These projects may result in unanticipated delays and cost more than expected due to a number of factors, including regulatory requirements. The FDA must approve our new manufacturing facilities before they can be used to commercially manufacture our products. For example, we are required to show that the product we manufacture in our new Lansing facility is comparable to BioThrax manufactured at our existing facility, which, as discussed above, may require additional clinical studies.

The costs and time required to comply with the FDA s current Good Manufacturing Practice, or cGMP, regulations, or similar regulatory requirements for sales of our products outside the United States, may be significant. If validation and qualification activities of our new facility in Lansing are delayed, we may not be able to manufacture sufficient quantities of BioThrax to allow us to increase sales of BioThrax to the U.S. government and other customers, which would limit our opportunities for growth. Cost overruns associated with constructing either our Lansing or Frederick facilities could require us to raise additional funds from external sources. We may not be able to do so on favorable terms or at all.

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

BioThrax and all our product candidates are biologics. Manufacturing biologic products, especially in large quantities, is complex. The products must be made consistently and in 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 obtaining materials, filling, labeling, packaging, storage and shipping and quality control and testing, some of which we experience from time to time, may result in lot failures, delay in the release of lots, product recalls or spoilage. We will not be able to sell any lots that fail to satisfy release testing specifications.

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

In addition, BioThrax must be maintained at a prescribed temperature range during shipping, and variations from that temperature range could result in loss of product and could adversely affect profitability. Delays, lot failures, and shipping deviations or spoilage 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 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.

In addition, providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. For example, the U.S. government has designated our Lansing facility as a facility requiring additional security to protect against potential terrorist threats to the facility. Any disruption that impedes our ability to manufacture and ship BioThrax in a timely manner could reduce our revenues and materially harm our business, financial condition and operating results. We do not carry business interruption insurance.

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

We have outsourced the operation for filling BioThrax into vials to a single company, Hollister-Stier Laboratories LLC. Our contract with Hollister-Stier expires on December 31, 2010. We have not established internal redundancy for our filling functions and currently have no substitute provider that can handle our filling needs. If Hollister-Stier is unable to perform filling services for us, we would need to identify and engage an alternative filling company or develop our own filling capabilities. Any new contract filling company or filling capabilities that we acquire or develop will need to obtain FDA approval for filling BioThrax at its facilities. Identifying and engaging a new contract filling company or developing our own filling capabilities and obtaining FDA approval could involve significant cost and delay. As a result, we might not be able to deliver BioThrax orders on a timely basis and our revenues could decrease.

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

The timing and amount of customer demand is difficult to predict. We may not be able to scale-up our production quickly enough to fill any new customer orders on a timely basis. This could cause us to lose new business and possibly existing business. For example, we may not be able to scale-up manufacturing processes for our product candidates to allow production of commercial quantities at a reasonable cost or at all.

Furthermore, if we overestimate customer demand, or choose to commercialize products for which the market is smaller than we anticipate, we could incur significant unrecoverable costs from creating excess capacity. In addition, if we do not successfully develop and commercialize any of our product candidates, we may never require the production capacity that we expect to have available.

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

We currently rely on third parties to manufacture the supplies of our immunobiotic product candidates that we require for preclinical and clinical development, including our immune globulin therapeutic product candidates, typhoid vaccine, hepatitis B therapeutic vaccine, and group B streptococcus vaccine candidates. Any significant delay in obtaining adequate supplies of our product candidates could adversely affect our ability to develop or commercialize these product candidates. Although we recently commissioned a new pilot plant manufacturing facility on our Lansing campus for production of preclinical and clinical supplies of our product candidates, we expect that we will continue to use third parties for these purposes.

In addition, we expect that we will rely on third parties for a portion of the manufacturing process for commercial supplies of product candidates that we successfully develop, including fermentation for some of our vaccine product candidates, plasma fractionation and purification for our immune globulin therapeutic product candidates and contract fill and finish operations. If our contract manufacturers are unable to scale-up production to generate enough materials for commercial launch, the success of those products may be jeopardized. 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 may require review from the FDA and satisfaction of comparable foreign requirements. This review may be costly and time consuming. There are a limited number of manufacturers that operate under the FDA s cGMP requirements and that are both capable of manufacturing for us and willing to do so. Our only current long-term manufacturing agreements are our agreement with Talecris Biotherapeutics, Inc., for fractionation and purification of plasma for our anthrax immune globulin therapeutic candidate, and our collaboration with HPA, under which HPA provides specialized manufacturing capabilities for our recombinant bivalent botulinum vaccine candidate and the bivalent botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin therapeutic candidate.

We currently rely on third parties for regulatory compliance and quality assurance with respect to the supplies of our product candidates that they produce for us. We also will rely for these purposes on any third party that we use for production of commercial supplies of product candidates that we successfully develop. Manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP regulations and other governmental regulations and corresponding foreign standards.

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

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

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

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

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

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

We also are subject to export control regulations governing the export of BioThrax and technology and materials used to develop and manufacture BioThrax and our product candidates. If we fail to comply with environmental, occupational health and safety, biosafety and export control laws, we could be held liable for fines, penalties and damages that result, and any such liability could exceed our assets and resources. In addition, we could be required to cease immediately all use of a select agent or toxin, and we could be prohibited from exporting our products, technology and materials. Our general liability and excess insurance policies provide for coverage up to annual aggregate limits of $12 million, with coverage of $1 million per occurrence and $2 million in the aggregate for general liability and $10 million per occurrence and in the aggregate for excess liability.

The general liability policy currently has a $15,000 per occurrence deductible. Both policies exclude coverage for liabilities relating to the release of pollutants. We do not currently hold insurance policies expressly providing for coverage relating to our use of hazardous materials other than storage tank liability insurance for our Lansing facility with a $1 million annual aggregate limit and a $10,000 per claim deductible. The insurance that we currently hold may not be adequate to cover all liabilities relating to accidental contamination or injury as a result of pollution conditions or other extraordinary or unanticipated events.

Risks Related to Product Development

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

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

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

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

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

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

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

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

In addition, because some of our current and future vaccine candidates contain live attenuated viruses, our testing of these vaccine candidates is subject to additional risk. For example, there have been reports of serious adverse events following administration of live vaccine products in clinical trials conducted by other vaccine developers. Also, for some of our current and future vaccine candidates, we expect to conduct clinical trials in chronic carriers of the disease that our product candidate seeks to prevent. There have been reports of disease flares in chronic carriers following administration of live vaccine products.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if 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.

In addition, our development plan for BioThrax as a post-exposure prophylaxis for anthrax infection provides for a non-human primate efficacy study. However, the timing of our non-human primate efficacy study depends upon the successful development of a non-human primate model by NIAID. If NIAID does not successfully develop a non-human primate model, our development plans for BioThrax as a post-exposure prophylaxis for anthrax infection will be delayed, possibly significantly.

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

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

Risks Related to Commercialization

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

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

The market for sales of BioThrax to customers other than the U.S. government is new and undeveloped, and we may not be successful in generating meaningful sales of BioThrax to these potential customers. To date, we have made only modest sales to these customers. In particular, we have supplied small amounts of BioThrax directly to several foreign governments. In 2007, 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 and the terms of our U.S. government contracts may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of BioThrax, the U.S. government may decide, particularly in the current environment of elevated concerns about global terrorism, to increase the scope of export prohibitions. These controls could limit our sales of BioThrax to foreign governments and other foreign customers. 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. If the DoD required delivery of these additional doses, it could affect our production schedule and deplete BioThrax supplies that would otherwise be available for commercial sales. In addition, the DoD could either sell BioThrax directly to foreign governments at a lower price than we may offer or donate BioThrax to foreign governments under the DoD s Foreign Military Sales program.

Our ability to meet any potential increased demand that develops for sales of BioThrax to customers other than the U.S. government depends on our available production capacity. We use substantially all of our current production capacity at our facility in Lansing to manufacture BioThrax for sale to U.S. government customers. Our plan is to initiate large scale manufacturing of BioThrax at our new manufacturing facility in 2008. If validation and qualification activates for our new facility in Lansing are delayed, we may not be able to manufacture sufficient quantities of BioThrax to allow us to increase sales of BioThrax to customers other than the U.S. government which would limit our opportunities for growth.

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

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

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

In another report, issued in October 2007, the GAO questioned whether both HHS and the DoD should purchase BioThrax directly from us and suggested that the DoD acquire BioThrax from the SNS rather than from us. We believe that the DoD will procure BioThrax from the SNS rather than entering into separate procurement contracts with us. Such determination could result in a lower volume of overall BioThrax sales to the U.S. government.

The use of vaccines carries a risk of adverse health effects. The adverse reactions that have been associated with the administration of BioThrax are similar to those observed following the administration of other adult vaccines and include local reactions, such as redness, swelling and limitation of motion in the inoculated arm, and systemic reactions, such as headache, fever, chills, nausea and general body aches. In addition, some serious adverse events have been reported to the vaccine adverse event reporting system database maintained by the CDC and the FDA

with respect to BioThrax. The report of any such adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event. These serious adverse events, including diabetes, heart attacks, autoimmune diseases, including Guillian Barre syndrome, lupus and multiple sclerosis, lymphoma and death, have not been causally linked to the administration of BioThrax.

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

- the prevalence and severity of any side effects;
- the efficacy and potential advantages over alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- 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 2004, members of the military and various activist groups who opposed mandatory inoculation with BioThrax petitioned the FDA and a federal court to revoke the license for BioThrax and to terminate the DoD program for the mandatory administration of BioThrax to military personnel. Although the DoD prevailed in the challenge to its mandatory vaccination program, the actions of these groups created negative publicity about BioThrax. Lawsuits or publicity campaigns could limit the demand for BioThrax and our biodefense product candidates and harm our future business.

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

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

We may not be able to attract, hire, train and retain qualified sales and marketing personnel to build a significant or effective marketing and sales force for sales of biodefense product candidates to customers other than the U.S. government or for sales of our commercial product candidates.

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

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

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

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

Any immunobiotic product candidate that we successfully develop and commercialize is likely to compete with currently marketed products, such as vaccines and therapeutics, including antibiotics, and with other product candidates that are in development for the same indications. In many cases, the currently marketed products have well known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. In addition, we are aware of product candidates of third parties that are in development, which, if approved, would compete against product candidates for which we 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 immunobiotic product candidates. For example, HHS has awarded a SNS supply contract to a competitor of ours for an anthrax immune globulin 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 a SNS supply contract to another competitor of ours for a monoclonal antibody to anthrax as a post-exposure therapeutic for anthrax infection. Several companies have botulinum vaccines in early clinical or preclinical development. One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the United States and Europe. Numerous companies have vaccine candidates in development that would compete with any of our commercial immunobiotic product candidates for which we obtain marketing approval.

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

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

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

The Public Readiness and Emergency Preparedness Act, or PREP Act, which was signed into law in December 2005, creates general immunity for manufacturers of biodefense countermeasures, including security countermeasures, when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is meant to provide general immunity from all claims under state or federal law for loss arising out of the administration or use of a covered countermeasure. Manufacturers are not entitled to this protection in cases of willful misconduct. Upon a declaration by the Secretary, a compensation fund is created to provide timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure. The covered injuries to which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer only after they have exhausted their remedies under the compensation program. However, a willful misconduct action could be brought against us if any individuals exhausted their remedies under the compensation program and thereby expose us to liability.

Our September 2007 contract with HHS provides that BioThrax in the SNS will not be administered in humans until the Secretary of HHS issues a PREP Act declaration applicable to BioThrax. We do not know, however, whether the PREP Act would provide adequate coverage or survive anticipated legal challenges to its validity.

In August 2006, the Department of Homeland Security approved our application under the Safety Act enacted by the U.S. Congress in 2002 for liability protection for sales of BioThrax. The Safety Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. In addition, the Safety Act provides a process by which an anti-terrorism technology may be certified as an approved product by the Department of Homeland Security and therefore entitled to a rebuttable presumption that the government contractor defense applies to sales of the product.

The government contractor defense, under specified circumstances, extends the sovereign immunity of the United States to government contractors who manufacture a product for the government. Specifically, for the government contractor defense to apply, the government must approve reasonably precise specifications, the product must conform to those specifications and the supplier must warn the government about known dangers arising from the use of the product. Although we are entitled to the benefits of the Safety Act, it may not provide adequate protection from any claims made against us.

In addition, although our prior contracts with DoD and HHS provided that the U.S. government would indemnify us for any damages resulting from product liability claims, our current contract with HHS does not contain such indemnification, and we cannot be certain that we will be able to negotiate similar indemnification provisions in future contracts or that the U.S. government will honor its indemnification obligations. For example, although we have notified the DoD of the lawsuits filed against us by current and former members of the U.S. military claiming damages as the result of personal injuries allegedly suffered from vaccination with BioThrax, the DoD has not yet acted on our claim for indemnification pending resolution of our claims under our product liability insurance. Members of Congress have proposed and may in the future propose legislation that reduces or eliminates the statutory liability protections for manufacturers of biodefense countermeasures

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

We face an inherent risk of product liability exposure related to the sale of BioThrax and any other products that we successfully develop and the testing of our product candidates in clinical trials. For example, we currently are a defendant in two federal lawsuits filed on behalf of two individuals 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.

The plaintiff in one of the actions has alleged that the vaccine caused erosive rheumatoid arthritis and has requested damages in excess of $1 million. The plaintiff in the other suit has 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 has requested damages in excess of $10 million.

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

If we cannot successfully defend ourselves against 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, liability claims may result in:

decreased demand for any product candidates or products that we may develop;

injury to our reputation;

withdrawal of clinical trial participants;

withdrawal of a product from the market;

costs to defend the related litigation;

substantial monetary awards to trial participants or patients;

loss of revenue; and

the inability to commercialize any products that we may develop.

We currently have product liability insurance for coverage up to a $10 million annual aggregate limit with a deductible of $75,000 per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Product liability insurance is difficult to obtain and increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. For example, from 2002 through February 2006, we were unable to obtain product liability insurance for sales of BioThrax on commercially reasonable terms. We do not believe that the amount of insurance we have been able to obtain for BioThrax is sufficient to manage the risk associated with the potential large scale deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on contractual indemnification provisions and statutory protections to limit 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 United States and in other markets. Reimbursement by a third party payor may depend upon a number of factors, including the third party payor s determination that use of a product is:

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost-effective; and

neither experimental nor investigational.

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

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

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

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

which we expect will attempt to negotiate price concessions from pharmaceutical manufacturers.

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

The scope of coverage and payment policies varies among third party private payors, including indemnity insurers, employer group health insurance programs and managed care plans. These third party carriers may base their coverage and reimbursement on the coverage and reimbursement rate paid by carriers for Medicare beneficiaries. Furthermore, many such payors are investigating or implementing methods for reducing health care costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by health care providers. If third party payors do not provide adequate coverage or reimbursement for any products we may develop, it could have a negative effect on 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 United States, which may include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could decrease the price we receive for any approved products which, in turn, could adversely affect our operating results and our overall financial condition.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to 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, chief executive officer and chairman of our Board of Directors and Daniel J. Abdun-Nabi, president and chief operating officer to be key to our BioThrax operations and our efforts to develop and commercialize our product candidates. Both of these key employees are at will employees and can terminate their employment at any time. We do not maintain key person insurance on any of our employees.

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

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

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

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

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

may be subject to civil and criminal penalties and administrative sanctions, including:

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

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

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

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

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

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

We rely on property and equipment owned by the DoD in the manufacturing process for BioThrax.

We have the right to use certain property and equipment owned by the DoD, referred to as government furnished equipment, or GFE, at our Lansing, Michigan site in the manufacture of BioThrax. We pay the DoD a small usage fee for the GFE based on the number of doses of BioThrax that we produce for sale to customers other than the U.S. government. We have the option to purchase all or part of existing GFE from the DoD on terms to be negotiated with the DoD. If the DoD 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 DoD 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 the FDA to establish the product candidate s safety and efficacy. Our future products may not be effective, may be only moderately effective or may prove to have significant side effects,

toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

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

We intend to pursue FDA approval of BioThrax as a post-exposure prophylaxis, our immune globulin therapeutic candidates, our recombinant bivalent botulinum vaccine candidate, and a next generation anthrax vaccine under the FDA animal rule, as described above. We cannot guarantee that FDA will permit us to proceed with any of our products or product candidates under the animal rule. Even if we are able to proceed pursuant to the animal rule, FDA may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products.

We have applied to the FDA to reduce the number of required doses of BioThrax for pre-exposure prophylaxis from six to five, with an annual booster dose thereafter. Our application is based on an interim analysis of data from an ongoing clinical trial being conducted by the CDC to evaluate whether as few as three doses of BioThrax, administered over six months, with booster doses up to three years apart, will confer adequate immune response. In April 2006, the FDA issued a complete response letter to our application, requesting clarification and requiring additional analysis of the data that we submitted. The data analysis is complete, and we have submitted an amendment to our application. If the FDA does not find our response to be adequate, we might be required to conduct additional independent testing to continue to pursue the development of this reduced dosing regimen. Responding to the FDA s complete response letter will delay potential approval of our application. If we are unable ultimately to respond satisfactorily to the FDA, our application will not be approved.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in 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 immunobiotic product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies, including through inspections of our facilities. As an approved product, BioThrax is subject to these requirements and ongoing review.

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

After we acquired BioThrax and related vaccine manufacturing facilities in Lansing in 1998 from the Michigan Biologic Products Institute, we spent significant amounts of time and money renovating those facilities before the FDA approved a supplement to our manufacturing facility license in December 2001. The State of Michigan had initiated renovations after the FDA issued a notice of intent to revoke the FDA license to manufacture BioThrax in 1997. The notice of intent to revoke cited significant deviations by the Michigan Biologic Products Institute from cGMP requirements, including quality control failures. In March 2007, the FDA notified us that our manufacturing facility license is no longer subject to the notice of intent to revoke.

After approving the renovated Lansing facilities in December 2001, the FDA conducted routine, biannual inspections of the Lansing facilities in September 2002, May 2004 and May 2006. Following each of these inspections, the FDA issued inspectional observations on Form FDA 483. We responded to the FDA regarding the inspectional observations relating to each inspection and, where necessary, implemented corrective action. In December 2005, the FDA stated in its final order on BioThrax that at that time we were in 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. We have filed with the FDA our responses to all inspectional observations relating to the May 2006 inspection. The FDA has acknowledged receipt of our responses and has advised us that it has concluded that the May 2006 inspection is closed. FDA did not inspect the Lansing facilities in 2006. However, pursuant to its standard procedures, we expect that the FDA will review and assess our corrective actions at its next inspection. If in connection with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, the FDA may undertake enforcement action against us.

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

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

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

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

The Fast Track designation for BioThrax as a post-exposure prophylaxis for anthrax infection may not actually lead to a faster development or regulatory review or approval process.

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

For each of our product candidates, we plan to evaluate the merits of retaining commercialization rights for ourselves or entering into collaboration arrangements with leading pharmaceutical or biotechnology companies or non-governmental organizations, such as our collaboration agreement with Sanofi Pasteur for our meningitis B vaccine candidate. We expect that we will selectively pursue collaboration arrangements in situations in which the collaborator has particular expertise or resources for the development or commercialization of our products and product candidates or 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. The terms of any collaborations or other arrangements that we establish may not be favorable to us.

Any collaboration that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. It is likely that our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations. In particular, the successful development of our meningitis B vaccine candidate will initially depend on the success of our research collaboration with Sanofi Pasteur and whether Sanofi Pasteur selects one or more viable candidates pursuant to the collaboration for development of a product.

Thereafter, Sanofi Pasteur will have significant discretion in the development and commercialization of any such candidate. Sanofi Pasteur may choose not to pursue further development and commercialization of any candidate that it selects based on many factors outside our control. Sanofi Pasteur has the ability to suspend development of a candidate under the collaboration in various circumstances. The risks that we are subject to in our current collaborations, and anticipate being subject to in future collaborations, include the following:

- our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach by us;
- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we 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 decide not to continue to work with us in the development of our product candidates.

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

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

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

Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates. In addition, we encourage government entities and non-government organizations to conduct studies of, and pursue other development efforts for, our product candidates. For example, the CDC is currently conducting an independent clinical trial to evaluate the administration of BioThrax in a regimen of fewer doses. We participate in monthly meetings with the trial investigators and in the annual review meeting for this trial and provide input to the CDC for responses to FDA questions and requests for additional information.

We expect to rely on data from these development efforts in seeking marketing approval for our product candidates. For example, our BLA supplement for a label expansion of BioThrax for a regimen of fewer doses is based on the interim trial report provided to us by the CDC from its ongoing clinical trial. We currently are awaiting the final data from the CDC trial. These government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. In addition, government entities depend on annual Congressional appropriations to fund these development efforts. In prior years, there has been some uncertainty whether Congress would choose to fund the CDC trial. Although the trial has been funded to date, Congress may not continue to fund the trial.

Risks Related to Our Intellectual Property

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

Our success, particularly with respect to our commercial business, will depend in large part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology and products. The patent situation in the field of immunobiotics and other pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions.

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

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

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend our intellectual property rights and, although we 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. Under our collaboration agreement with Sanofi Pasteur for our meningitis B vaccine candidate, we have the right to prosecute and maintain our patent rights under the collaboration agreement.

Sanofi Pasteur is responsible for prosecuting and maintaining joint patent rights under the collaboration agreement, although we have the right to support the continued prosecution or maintenance of the joint patent rights if Sanofi Pasteur fails to do so. In addition, Sanofi Pasteur has the first right to pursue claims against third parties for infringement of the patent rights under the collaboration agreement and assume the defense of any infringement claims that may arise, although we have the right to pursue infringement claims against third parties and assume the defense of infringement claims if Sanofi Pasteur fails to do so.

Under our licenses with HPA relating to our recombinant bivalent botulinum vaccine candidate and the botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin therapeutic candidate, HPA is responsible for prosecuting and maintaining patent rights, although we have the right to support the continued prosecution or maintenance of the patent rights if HPA fails to do so. In addition, we have the first right to pursue claims against third parties for infringement of the patent rights and assume the defense of any infringement claims that may arise.

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

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

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

We are a party to a number of license agreements. We consider our licenses with HPA relating to our recombinant bivalent botulinum vaccine candidate and the botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin therapeutic candidate to be material to our business. Under these license agreements, we obtained the exclusive, worldwide right to develop, manufacture and commercialize pharmaceutical products that consist of botulinum toxoid components or recombinant botulinum toxin components for the prevention or treatment of illness in humans caused by exposure to the botulinum toxin, subject to HPA s non-exclusive right to make, use or sell recombinant botulinum products to meet public health requirements in the United Kingdom.

We expect to enter into additional licenses in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

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

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

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

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

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents and other intellectual property rights of third parties under which we do not hold licenses or other rights. Third

parties may own or control these patents and intellectual property rights in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement or other similar suit were brought against us or our collaborators, we or they could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement or other similar claims, or to avoid potential claims, we or our collaborators may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be 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. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology and pharmaceutical industries. For example, we monitored litigation between Bavarian Nordic and Acambis relating to the manufacture of the modified vaccinia Ankara virus, or MVA, as a smallpox vaccine for biodefense use by the U.S. government. This litigation was terminated by a settlement and consent order filed by the parties with the U.S. International Trade Commission, or ITC, in August 2007 and subsequently published in the U.S. Federal Register. According to the published terms of the consent order, Acambis agreed not to import or sell within the United States its ACAM3000 vaccine product, and further agreed not to challenge the validity or enforceability of certain Bavarian Nordic patents. In addition, the consent order vacated the initial determination of the ITC that Bavarian Nordics patents were invalid, but if valid would have been infringed by importation or sale of ACAM3000 in the United States.

We have licensed from the Bavarian State Ministry of the Environment, Public Health and Consumer Protection, or StUMGV, rights to materials and technology related to MVA. Our MVA platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based on these rights. We are aware of litigation brought by Bavarian Nordic against StUMGV in which Bavarian Nordic is seeking information concerning StUMGV s ownership rights to the MVA in its possession. Our ability to use our MVA platform technology could be negatively affected by patent infringement litigation or other legal actions brought by Bavarian Nordic or other parties challenging our rights to use MVA materials or technology.

For example, we have filed an opposition in the European Patent Office against Bavarian Nordic s patent covering certain aspects of the MVA technology. We may also become a party to trademark invalidation and interference proceedings in foreign trademark offices. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Risks Related to Our Acquisition Strategy

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

We have pursued an acquisition strategy since our inception to build our business of developing, manufacturing and commercializing immunobiotics. We commenced operations in September 1998 through an acquisition of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing and vaccine development and production know-how from the Michigan Biologic Products Institute. We acquired our pipeline of commercial vaccine candidates through our acquisition of ViVacs in 2006 and Microscience in 2005 and our acquisition of substantially all of the assets of Antex in 2003.

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

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

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

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

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

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

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

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

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

Risks Related to 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 and voting arrangements among our significant stockholders. As of February 29, 2008, Mr. El-Hibri was the beneficial owner of a majority of our outstanding common stock. Because Mr. El-Hibri has the ability to control the election of the members of our board, and because of his substantial control of our capital stock, Mr. El-Hibri will likely have the ability to delay or prevent a change of control of 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 change 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;
- following November 20, 2008, advance notice requirements for stockholder nominations for election of directors and other proposals;
- the inability of stockholders to act by written consent;
- the inability of stockholders to call special meetings; and
- the ability of our Board of Directors to designate the terms of and issue new series of preferred stock without stockholder approval.

Until November 20, 2008, the affirmative vote of holders of our capital stock representing a majority of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. Following November 20, 2008, the affirmative vote of holders of our capital stock representing at least 75% of the voting power of all outstanding stock entitled to vote is required to amend or repeal the above provisions of our certificate of incorporation. Until November 20, 2008, the affirmative vote of either at least 75% of the directors then in office or holders of our capital stock representing a majority of the voting power of all outstanding stock entitled to vote is required to amend or repeal our by-laws.

Following November 20, 2008, 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.

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

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through February 29, 2008, our common stock has traded as high as $17.75 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 United States and foreign countries;

developments or disputes concerning patents or other proprietary rights;

the recruitment or departure of key personnel;

variations in our financial results or those of companies that are perceived to be similar to us;

market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts reports or recommendations;
general economic, industry and market conditions; and

the other factors described in this Risk Factors section.

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 21.2 million shares of our common stock outstanding as of February 29, 2008 have the right to require us to register these shares of common stock under specified circumstances.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

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

Location	Use	Segment	Approximate square feet	Owned/leased
Lansing, Michigan	Manufacturing operations facilities, office space and laboratory space	Biodefense	214,000	Owned
Frederick, Maryland	Future manufacturing facilities and office and laboratory space	Biodefense/Commercial	290,000	Owned
Gaithersburg, Maryland	Office and laboratory space	Biodefense/ Commercial	36,000	Leases expire 2008

Rockville, Maryland	Office space	Biodefense/Commercial	23,000	Lease expires 2016
Wokingham, England	Office and laboratory space	Commercial	29,000	Leases expire 2016

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

We operate vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan. To augment our existing manufacturing capabilities, we have constructed a new 50,000 square foot manufacturing facility on our Lansing campus. We substantially completed construction of this facility in 2006, and are currently conducting validation and qualification activities required for regulatory approval. This new facility is a large scale manufacturing plant that we can use to produce multiple fermentation based vaccine products, subject to complying with appropriate change-over procedures. We expect the facility to cost approximately $75 million when complete, including approximately $55 million for the building and associated capital equipment, with the balance related to validation and qualification activities required for regulatory approval and initiation of manufacturing. We have incurred costs of approximately $63 million for these purposes through December 2007.

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

We are in the preliminary phase of establishing plans to build out this site for product development and a portion of our potential future product manufacturing requirements. Our preliminary plans contemplate that the site would be designed to provide laboratory space, product development and pilot plant production capabilities, full scale commercial manufacturing operations, warehouse and storage facilities, fill and finish operations and administrative office space. We expect that we will complete the build out of this site in several stages. Our preliminary plans contemplate a build out of one of the two buildings on this site to accommodate laboratory space, product development, pilot plant initial product launch capabilities and administrative office space during 2008 or 2009. These plans also contemplate that we will build out commercial manufacturing operations two to three years after establishing initial product launch capabilities. We have incurred costs of approximately $4 million through December 2007 related to initial engineering design and preliminary utility build out of these facilities. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that would be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project. We may elect to lease all or a substantial portion of, or sell, one of these facilities to third parties.

Other. We lease two separate product development facilities. Our facility in Gaithersburg, Maryland of approximately 36,000 square feet contains a combination of laboratory and office space. 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 Rockville, Maryland contains approximately 23,000 square feet of office space, including our executive offices.

ITEM 3. LEGAL PROCEEDINGS

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 dangers 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.

The second lawsuit was dismissed with prejudice in September 2007. The third lawsuit was dismissed with prejudice in January 2008. In the one remaining lawsuit, we moved to dismiss for lack of personal jurisdiction, or in the alternative, to transfer the lawsuit to federal court in Michigan. In October 2006, that lawsuit was dismissed for lack of personal jurisdiction. The plaintiff appealed the dismissal to the U.S. Court of Appeals for the Ninth Circuit, and that appeal remains pending. If the appellate court reverses the dismissal, we intend to rely on defenses similar to those on which we prevailed in the cases that were filed between 2001 and 2003. We believe that we are entitled to indemnification under our contract with the DoD for legal fees and any damages that may result from the pending claim.

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

MilVax litigation. In 2003, six unidentified plaintiffs filed suit in the U.S. District Court for the District of Columbia against the U.S. government seeking to enjoin the Anthrax Vaccine Immunization Program administered under MilVax under which all military personnel were required to be vaccinated with BioThrax. In October 2004, the District Court enjoined the DoD from administering BioThrax to military personnel on a mandatory basis without their informed consent or a Presidential waiver. This ruling was based in part on the District Court s finding that the FDA, as part of its review of all biological products approved prior to 1972, had not properly issued a final order determining that BioThrax is safe and effective and not misbranded. In December 2005, the FDA issued a final order determining that BioThrax is safe and effective and not misbranded. In February 2006, the U.S. Court of Appeals for the District of Columbia, on appeal of the injunction by the government, ruled that the injunction had dissolved by its own terms as a result of the FDA s final order. The matter remains pending in the District Court, where subsequent proceedings have focused on whether the plaintiffs are entitled to recover attorneys fees from the government.

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

Other. We are, and may in the future become, subject to other legal proceedings, claims and litigation arising in the ordinary course of our business in connection with the manufacture, distribution and use of our products and product candidates. For example, Emergent BioDefense Operations is a defendant, along with many other vaccine manufacturers, in a series of lawsuits that have been filed in various state and federal courts in the United States alleging that thimerosal, a mercury-containing preservative used in the manufacture of some vaccines, caused personal injuries, including brain damage, central nervous system damage and autism. No specific dollar amount of damages has been claimed. Emergent BioDefense Operations Inc. or Emergent BioDefense Operations, is currently a named defendant in 40 lawsuits pending in two jurisdictions: three in California and 37 in Illinois. The products at issue in these lawsuits are pediatric vaccines. Because we are not currently and have not historically been in the business of manufacturing or selling pediatric vaccines, we do not believe that we manufactured the pediatric vaccines at issue in the lawsuits.

Under a contractual obligation to the State of Michigan, we manufactured one batch of vaccine suitable for pediatric use. However, the contract required the State to use the vaccine solely for Michigan public health purposes. We no longer manufacture any products that contain thimerosal. We have submitted a request for coverage of the defense and indemnity costs incurred as a result of these thimerosal claims to our insurance carriers. The insurance carrier that issued our general liability policies during the relevant years is disputing coverage.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

PART II

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

Market Information and Holders

Our common stock has traded on the New York Stock Exchange under the symbol EBS since November 15, 2006. Prior to that time, there was no public market for our common stock. The following table sets forth the high and low sales prices per share of our common stock during each quarter of the year ended December 31, 2007 and for the period from November 15, 2006 to December 31, 2006:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year Ended December 31, 2007				
High	$ 17.75	$ 14.85	$ 12.67	$ 10.70
Low	$ 10.50	$ 8.33	$ 7.67	$ 4.40
Year Ended December 31, 2006				
High	n/a	n/a	n/a	$ 12.72
Low	n/a	n/a	n/a	$ 9.75

As of February 29, 2008, the closing price per share of our common stock on the New York Stock Exchange was $7.47 and we had 48 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 currently intend to retain all of our future earnings to finance the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

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

Through December 31, 2007, we have used approximately $12.2 million of the net proceeds from the offering to fund development of our product candidates, comprised of approximately $1.6 million for label expansions and improvements for BioThrax, approximately $1.2 million for a next generation anthrax vaccine candidate, approximately $2.5 million for our anthrax immune globulin therapeutic candidate, approximately $3.3 million for our typhoid vaccine candidate and approximately $3.6 million for our hepatitis B therapeutic vaccine candidate. Through December 31, 2007, we have used approximately $19.9 million of the net proceeds from the offering to fund a portion of the construction, installation, validation and qualification activities costs for our new manufacturing facility in Lansing. We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10 percent or more of our common stock or to any affiliate of ours. We have invested the balance of the net proceeds from the offering in short-term, investment grade, interest-bearing instruments. There has been no material change in our planned use of the balance of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

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

We have derived the consolidated statement of operations data for the years ended December 31, 2007, 2006 and 2005 and the consolidated balance sheet data as of December 31, 2007 and 2006 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, 2004 and 2003 and the consolidated balance sheet data as of December 31, 2005, 2004 and 2003 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)	**2007**	**2006**	**2005**	**2004**	**2003**
Statements of operations data:					
Revenues:					
Product sales	$ 169,799	$ 147,995	$ 127,271	$ 81,014	$ 55,536
Contracts and grants	13,116	4,737	3,417	2,480	233
Total revenues	182,915	152,732	130,688	83,494	55,769
Operating expenses (income):					
Cost of product sales	40,309	24,125	31,603	30,102	22,342
Research and development	53,958	45,501	18,381	10,117	6,327
Selling, general & administrative	55,555	44,601	42,793	30,323	19,547
Purchased in-process research and development	-	477	26,575	-	1,824
Settlement of State of Michigan Obligation	-	-	-	(3,819)	-
Litigation settlement	-	-	(10,000)	-	-
Total operating expenses	149,822	114,704	109,352	66,723	50,040
Income from operations	33,093	38,028	21,336	16,771	5,729
Other income (expense):					
Interest income	2,809	846	485	65	100
Interest expense	(71)	(1,152)	(767)	(241)	(293)
Other income (expense), net	156	293	55	6	168
Total other income (expense)	2,894	(13)	(227)	(170)	(25)
Income before provision for income taxes	35,987	38,015	21,109	16,601	5,704
Provision for income taxes	13,051	15,222	5,325	5,129	1,250
Net income	$ 22,936	$ 22,793	$ 15,784	$ 11,472	$ 4,454
Earnings per share basic	$ 0.79	$ 0.99	$ 0.77	$ 0.61	$ 0.24
Earnings per share diluted	$ 0.77	$ 0.93	$ 0.69	$ 0.56	$ 0.22
Weighted average number of shares basic	28,995,667	23,039,794	20,533,471	18,919,850	18,904,992
Weighted average number of shares diluted	29,663,127	24,567,302	22,751,733	20,439,252	20,316,752

	As of December 31,				
(in thousands)	**2007**	**2006**	**2005**	**2004**	**2003**
Balance Sheet Data:					
Cash and cash equivalents	$ 105,730	$ 76,418	$ 36,294	$ 6,821	$ 7,119
Working capital	88,649	82,990	29,023	7,509	(3,147)
Total assets	273,508	238,255	100,332	69,056	37,127
Total long-term liabilities	46,688	35,436	10,502	11,921	1,228
Total stockholders equity	171,159	138,472	59,737	22,949	8,448

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

We are a profitable multinational biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics, consisting of vaccines and therapeutics that assist the body s immune system to prevent or treat disease. We manufacture and market BioThrax®, the only vaccine approved by the U.S. Food and Drug Administration, for the prevention of anthrax infection. We use internally generated cash flows from the sale of BioThrax to fund the development of a product pipeline that addresses a variety of infectious diseases and other medical conditions. We develop immunobiotics for use against infectious diseases that have resulted in significant unmet or underserved public health needs and against biological agents that are potential weapons of bioterrorism and biowarfare. We operate in two business segments, biodefense and commercial.

Our biodefense business focuses on immunobiotics for use against biological agents that are potential weapons of bioterrorism and biowarfare. Our product candidates targeted to the biodefense market are anthrax immune globulin therapeutic, next generation anthrax vaccine and botulinum vaccines and botulinum immune globulin therapeutic. Our commercial business focuses on immunobiotics for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. Our product candidates targeted to the commercial market are typhoid vaccine, hepatitis B therapeutic, group B streptococcus and chlamydia vaccines. We expect to continue to seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties.

Our biodefense business has generated net income for each of the last three fiscal years. Our commercial business has generated revenue through development grant funding and an upfront license fee and additional payments for development work under a collaboration agreement with Sanofi Pasteur. None of our commercial product candidates have received marketing approval and therefore, have not generated any product sales revenues. As a result, our commercial business has incurred a net loss for each of the last three fiscal years.

Product Sales

We have derived substantially all of our revenues from BioThrax sales to the DoD and HHS, and expect for the foreseeable future to continue to derive substantially all of our revenues from the sales of BioThrax to HHS. Our total revenues from BioThrax sales were $169.8 million in 2007, $148.0 million in 2006 and $127.3 million in 2005. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers and pursuing label expansions and improvements for BioThrax.

In addition to BioThrax, our advanced product portfolio includes an anthrax immune globulin therapeutic candidate for biodefense indications and a typhoid vaccine and hepatitis B therapeutic vaccine for commercial infectious disease indications. We are developing our anthrax immune globulin therapeutic in part with funding from NIAID. The Wellcome Trust provided funding for the Phase I and Phase II clinical trials of our typhoid vaccine candidate. We typically advance development of our biodefense product candidates only with external funding, and may slow down or put development programs on hold during periods that are not covered by funding.

Our early stage product portfolio includes a next generation anthrax vaccine and botulinum vaccine and immune globulin therapeutic candidates for biodefense indications and group B streptococcus and chlamydia vaccine candidates for commercial infectious disease indications. We have entered into collaboration agreements with the HPA for the development of a recombinant botulinum vaccine candidate and a botulinum immune globulin candidate. The NIAID is conducting and funding the Phase I clinical trial of our group B streptococcus vaccine candidate.

We are actively pursuing additional government sponsored development grants as well as encouraging both governmental and non-governmental agencies and philanthropic organizations to provide development funding, or to conduct clinical studies of these products. For example, the Wellcome Trust provided funding for the Phase I and Phase II clinical trials of our typhoid vaccine candidate. In addition, the NIAID is conducting and funding one of the Phase I clinical trials of our group B streptococcus vaccine candidate.

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 new 50,000 square foot manufacturing facility on our Lansing campus. We expect the facility to cost approximately $75 million when complete, including approximately $55 million for the building and associated capital equipment, with the balance related to validation and qualification activities required for regulatory approval and initiation of manufacturing. We have incurred costs of approximately $63 million for these purposes through December 2007. We substantially completed construction of this facility in 2006, and are conducting validation and qualification activities required for regulatory approval. This new facility is a large scale manufacturing plant that we can use to produce multiple fermentation based vaccine products, subject to complying with appropriate change-over procedures.

We also own two buildings in Frederick, Maryland that are available to support our future manufacturing requirements. We have incurred costs of approximately $4 million through December 2007 related to initial engineering design and preliminary utility build out of one of these buildings. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that would be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project. We may elect to lease all or a substantial portion of, or sell, one of these facilities to third parties.

Critical Accounting Policies and Estimates

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

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

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

Revenue Recognition

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

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

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

Under previous contracts with HHS, we invoiced HHS and recognized the related revenues upon delivery of the product to the government carrier, at which time title to the product passed to HHS. Under our current 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.

Under the collaboration agreement that we entered into with Sanofi Pasteur in May 2006 for our meningitis B vaccine candidate, we received an upfront license fee and are entitled to additional payments for development work under the collaboration and upon achieving contractually defined development and commercialization milestones. We evaluated the various components of the collaboration in accordance with Emerging Issues Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables,* or EITF No. 00-21, which addresses whether, for revenue recognition purposes, there is one or several units of accounting in an arrangement. We concluded that under EITF No. 00-21, the upfront license fee, the development work and the milestone payments under our agreement with Sanofi Pasteur should be accounted for as a single unit of accounting. We recognize amounts received under this agreement over the estimated development period as we perform services. We recorded the amount of the upfront license fee as deferred revenue. We are recognizing this revenue over the estimated development period under the contract, currently estimated at seven years, as adjusted from time to time for any delays or acceleration in the development of the product candidate. Under the collaboration agreement, we are entitled to payments up to specified levels for development work we perform on behalf of Sanofi Pasteur. We generally invoice Sanofi Pasteur in advance of each quarter for the estimated work to occur in the upcoming quarter. We record the invoice amount as deferred revenue and, as services are completed, recognize the amount of the related deferred revenue as period revenues. Under the collaboration agreement, we also will be entitled to royalty payments on any future net sales of this product candidate.

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

Accounts Receivable

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

Inventories

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

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

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for such service where we have not yet been invoiced or otherwise notified of actual cost. We make these estimates as of each balance sheet date in our financial statements. Examples of estimated accrued expenses include:

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

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

Purchased In-process Research and Development

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

Under these standards, we are required to determine whether the technology relating to a particular research and development project we acquire has an alternative future use. If we determine that the technology has no alternative future use, we expense the value of the research and development project not directly attributed to tangible assets. Otherwise, we capitalize the value of the research and development project not attributable to tangible assets as an intangible asset and conduct an impairment analysis at least annually. In connection with our acquisitions of ViVacs GmbH, in July 2006, and Microscience Limited, or Microscience, in June 2005, we allocated the value of the purchase consideration to current assets, current liabilities, fixed assets and development programs. Because we determined that the development programs at ViVacs and Microscience had no future alternative use, we charged the value attributable to the development programs as in-process research and development. The ViVacs acquisition was a cash transaction, and therefore no fair value determination was necessary. For the Microscience acquisition, which was a share exchange, our board of directors determined the fair value of our shares issued in the exchange for financial statement purposes.

Stock-based Compensation

We adopted SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS No. 123(R), on January 1, 2006 using the modified prospective method. SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their estimated grant date fair values.

We value our share-based payment transactions using the Black-Scholes valuation model. Under the modified prospective method, we recognize compensation cost in our financial statements for all awards granted after January 1, 2006 and for all awards outstanding as of January 1, 2006 for which the requisite service had not been rendered as of the date of adoption. 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. As of December 31, 2007, total compensation expense not yet recognized related to unvested options is approximately $2.9 million after tax. This expense is expected to be recognized over a weighted-average period of 3.0 years.

The effect of adopting SFAS No. 123(R) on net income (loss) and net income (loss) per share is not necessarily representative of the effects in future years due to, among other things, the vesting period of the stock options and the fair value of additional stock option grants in future years.

Income Taxes

We account for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes,* or SFAS No. 109. Under the asset and liability method of SFAS No. 109, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases 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 in the balance sheet. Our deferred tax assets include the unamortized portion of in-process research and development expenses, the anticipated future benefit of the net operating losses that we have incurred and other timing differences between the financial reporting basis of assets and liabilities.

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

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

We account for uncertainty in income taxes in accordance with FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109, Accounting for Income Taxes,* or FIN 48. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Under FIN 48, we recognize in our financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure.

Financial Operations Overview

Revenues

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

On September 25, 2007, we entered into an agreement with HHS to supply 18.75 million doses of BioThrax to HHS for placement into the SNS. The term of the agreement is from September 25, 2007 through September 24, 2010. The first 5.5 million doses delivered under this contract were sold to HHS at a discounted price, as specified in the contract, due to the limited remaining shelf-life for these specific doses. This discounted price does not apply to the remaining 13.25 million doses that will be sold to HHS under the contract. The firm fixed price for the 18.75 million doses, including the discount, is $400 million in the aggregate. If we receive FDA approval of our pending application to extend the expiry dating of BioThrax from three years to four years, HHS has agreed to increase the price per dose under the agreement for the remaining 13.25 million doses. In that event, HHS would make a lump sum payment to us reflecting an increase in the price per dose for specified doses delivered prior to approval and pay an increased price per dose for doses delivered following the date of such approval. The aggregate value of such price adjustment is $34 million. If we do not receive FDA approval of four-year expiry dating during the term of the agreement there will be no adjustment in the price per dose under the agreement. We delivered over 6 million doses of BioThrax to HHS under this agreement in 2007. Under this agreement, we have also agreed to provide all shipping services related to delivery of doses into the SNS over the term of the agreement, for which HHS has agreed to pay approximately $2.2 million. We invoice HHS for each delivery upon acceptance of BioThrax doses delivered into the SNS. The agreement also provides for HHS to pay up to $11.5 million in milestone payments in connection with us advancing a program to obtain a post-exposure prophylaxis indication for BioThrax. These funds are payable upon achievement of specific program milestones. In October 2007, we achieved the initial milestone and invoiced HHS for $8.8 million. We received this payment from HHS and revenue was recognized in November 2007.

Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we have supplied approximately 10 million doses of BioThrax for immunization of military personnel. Our most recent contract with the DoD, as amended in October 2006, provided for the supply of a minimum of approximately 1.5 million doses of BioThrax to the DoD through September 2007. As a result of a further amendment of the DoD contract in June 2007, we completed delivery of all doses to the DoD under this contract prior to June 30, 2007. We are not currently party to a procurement contract with the DoD.

We believe that the DoD has a continued commitment to procure BioThrax for its active immunization program. We believe that, as a result of the October 2007 Presidential Directive, in the future the DoD will likely procure additional doses of BioThrax to satisfy ongoing requirements for its active immunization program directly from HHS and not from us. We believe that these purchases by DoD from HHS may result in additional purchases by HHS from us.

In May 2006, we entered into a collaboration agreement with Sanofi Pasteur relating to the development and commercialization of our meningitis B vaccine candidate under which we granted Sanofi Pasteur an exclusive, worldwide license under our proprietary technology to develop and commercialize our meningitis B vaccine candidate and received a $3.8 million upfront license fee. This agreement also provides for a series of milestone payments upon the achievement of specified development and commercialization objectives, payments for development work under the collaboration and royalties on net sales of this product. We defer the upfront license fee, milestone payments and development reimbursement payments under this agreement, and record revenue in accordance with our revenue recognition policies. We are currently in negotiations with Sanofi Pasteur to amend this agreement.

In September 2007, we received a development contract from NIAID, valued at up to $9.5 million, in support of non-clinical and clinical studies of our anthrax immune globulin therapeutic candidate. Under terms of the development contract, we will use the funds to conduct various studies on this product candidate, including animal efficacy studies and clinical trials. Through December 31, 2007, we have invoiced $61,000 under this contract.

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 attributable facilities, utilities and salaries and personnel-related expenses for indirect manufacturing support staff. Variable manufacturing costs for BioThrax consist primarily of costs for materials, direct labor and contract filling operations.

We determine the cost of product sales for doses sold during a reporting period based on the average manufacturing cost per dose for the specific earlier period in which the doses sold 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;
- costs of contract manufacturing services;
- costs of materials used in clinical trials and research and development;
- depreciation of capital assets used to develop our products; and
- operating costs, such as the operating cost of facilities and the legal costs of pursuing patent protection of our intellectual property.

We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to be in a position to realize the potential of our product candidates. We expect that development spending for both our advanced stage products and earlier stage products will increase as our product development activities continue and 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 program that we may initiate, costs associated with manufacturing our product candidates on a large scale basis for later stage clinical trials, our ability to use data generated by government agencies, such as the ongoing studies with BioThrax being conducted by the Centers for Disease Control and Prevention, or CDC, and our ability to rely upon and utilize clinical and non-clinical data, such as the data generated by CDC from use of the pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan.

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 the 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 principally of interest income and interest expense. We earn interest on our cash, cash equivalents and short-term investments, and we incur interest expense on our indebtedness. We capitalize interest expense in accordance with SFAS No. 34, *Capitalization of Interest Cost*, based on the cost of major ongoing projects which have not yet been placed in service, such as our new manufacturing facility. Our total interest cost will increase in future periods as compared to prior periods as a result of the term loan that we entered into in June 2007, as well as any borrowings under our revolving line of credit. In addition, some of our existing debt arrangements provide for increasing amortization of principal payments in future periods. See Liquidity and Capital Resources Debt Financing for additional information.

Results of Operations

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

Revenues

Product sales revenues increased by $21.8 million, or 15%, to $169.8 million for 2007 from $148.0 million for 2006. This increase in product sales revenues was primarily due to a 41% increase in the number of doses of BioThrax delivered, offset by a 19% decrease in the average sales price per dose attributable to a discounted price provided to HHS due to the limited remaining shelf life for those certain doses delivered in the third quarter and first part of the fourth quarter of 2007. Product sales revenues in 2007 consisted of BioThrax sales to HHS of $141.6 million, sales to the DoD of $26.2 million and aggregate international and other sales of $2.0 million. Product sales revenues in 2006 consisted of BioThrax sales to HHS of $109.8 million, sales to the DoD of $37.4 million and aggregate international and other sales of $763,000.

Contracts and grant revenues increased by $8.4 million, or 177%, to $13.1 million in 2007 from $4.7 million in 2006. Contracts and grants revenues for 2007 consisted of a milestone payment of $8.8 million from HHS in connection with the Company advancing a program to obtain a post-exposure prophylaxis indication for BioThrax, $3.1 million from the Sanofi Pasteur collaboration, related to recognition of deferred revenue associated with the upfront payment received in 2006 as well as development service revenue, and $1.2 million in grant revenue from the NIH and the Wellcome Trust. Contracts and grant revenues for 2006 consisted of $3.2 million in upfront and development program revenue from the Sanofi Pasteur collaboration and $1.5 million in grant revenue from the Wellcome Trust.

Cost of Product Sales

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

Research and Development Expenses

Research and development expenses increased by $8.5 million, or 19%, to $54.0 million for 2007 from $45.5 million for 2006. This increase reflects additional personnel and contract service costs, and includes increased expenses of $2.5 million on product candidates that are categorized in the biodefense segment, $3.7 million on product candidates categorized in the commercial segment, and $2.2 million in other research and development expenses, which are in support of technology platforms and central research and development activities.

The increase in spending on candidates in the biodefense and commercial segments, detailed in the table below, was attributable to increased efforts on various programs as we completed various studies and began subsequent studies and trials. The spending for BioThrax enhancements is related to preparing for and conducting animal efficacy studies to support applications for marketing approval of these enhancements, which we expect to submit to the FDA in late 2008 or 2009. The spending for our immune globulin therapeutic candidate development programs related primarily to costs associated with the plasma collection and fractionation program for our anthrax immune globulin therapeutic. The spending for the recombinant botulinum vaccine program resulted from advancing this program to the process development stage and the manufacture of clinical trial material. The spending for the next generation anthrax vaccine program resulted from feasibility studies and formulation development of product candidates. We continue to assess, and may alter, our future development plans for our products based on the interest of the U.S. government or other non-governmental organizations in providing funding for further development or procurement.

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

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

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

(in thousands)	Year ended December 31, 2007	2006
Biodefense:		
BioThrax enhancements	$ 5,175	$ 7,232
Immune globulin therapeutic development	13,619	11,289
Recombinant bivalent botulinum vaccine	3,231	2,610
Next generation anthrax vaccine	2,719	1,088
Total biodefense	24,744	22,219
Commercial:		
Typhoid vaccine	9,641	9,642
Hepatitis B therapeutic vaccine	5,370	4,058
Group B streptococcus vaccine	6,790	3,759
Chlamydia vaccine	3,146	1,991
Meningitis B vaccine	1,212	2,975
Total commercial	26,159	22,425
Other	3,055	857
Total	$ 53,958	$ 45,501

Selling, General and Administrative Expenses

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

segment increased by $3.6 million, or 40%, to $12.5 million for 2007 from $9.0 million for 2006.

Purchased In-process Research and Development

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

Total Other Income (Expense)

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

Income Taxes

Provision for income taxes decreased by $2.2 million, or 14%, to $13.1 million for 2007 from $15.2 million for 2006. The provision for income taxes for 2007 resulted primarily from our income before provision for income taxes of $36.0 million and an effective annual tax rate of 36%. The provision for income taxes for 2006 resulted primarily from our income before provision for income taxes of $38.0 million and an effective annual tax rate of 40%. The decrease in the effective annual tax rate is due primarily to a reduction in state valuation allowances related to the expected utilization of net operating losses. The provision for income taxes also reflects research and development tax credits of $880,000 for 2007 and $759,000 for 2006.

Year Ended December 31, 2006 Compared to Year Ended December 31, 2005

Revenues

Product sales revenues increased by $20.7 million, or 16%, to $148.0 million for 2006 from $127.3 million for 2005. This increase in product sales revenues was primarily due to a 18% increase in the number of doses of BioThrax delivered. Product sales revenues in 2006 consisted of BioThrax sales to HHS of $109.8 million, sales to the DoD of $37.4 million and aggregate international and other sales of $763,000. Product sales revenues in 2005 consisted of BioThrax sales to HHS of $111.2 million, sales to the DoD of $14.5 million and aggregate international and other sales of $1.6 million.

Contracts and grants revenues increased by $1.3 million, or 39%, to $4.7 million in 2006 from $3.4 million in 2005. Contracts and grants revenues for 2006 consisted of $3.2 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 $1.5 million in grant revenue from the Wellcome Trust. Contracts and grants revenues for 2005 resulted from reimbursement from the DoD for expenses related to production development and supply chain management improvements for BioThrax incurred in prior periods, and for additional work that we performed on a project basis for the DoD s DARPA, to evaluate a new vaccine adjuvant for BioThrax.

Cost of Product Sales

Cost of product sales decreased by $7.5 million, or 24%, to $24.1 million for 2006 from $31.6 million for 2005. This decrease was attributable to improved utilization of our manufacturing capacity for BioThrax, partially offset by an increase of approximately 900,000 BioThrax doses delivered. Manufacturing efficiencies resulted in a cost savings of $13.1 million. The increase in the number of doses delivered resulted in an increase of costs of approximately $5.6 million.

Research and Development Expenses

Research and development expenses increased by $27.1 million, or 148%, to $45.5 million for 2006 from $18.4 million for 2005. This increase reflects additional personnel and contract service costs, and includes increased expenses of $11.9 million on product candidates that are categorized in the biodefense segment and $15.9 million on product candidates that are categorized in the commercial segment, offset by a reduction of $633,000 in other research and development expenses.

The increase in spending on candidates in the biodefense segment was attributable to increased efforts on all our programs as we completed various studies and began subsequent studies and trials. The increase in spending for BioThrax enhancements is related to preparing for animal efficacy studies to support applications for marketing approval of these enhancements, which we expect to submit to the FDA in late 2008 or 2009. The increase in spending for immune globulin therapeutic development related primarily to costs associated with our plasma collection program for our anthrax immune globulin therapeutic candidate. The increase in spending for the recombinant botulinum vaccine program, which is in preclinical development, resulted from advancing this program to the process development stage and the manufacture of clinical trial material. The increase in spending for the next generation anthrax vaccine program, which has product candidates in preclinical and Phase I clinical development, resulted from feasibility studies and formulation development of product candidates.

The increase in commercial spending was mainly attributable to spending on the commercial products listed in the table below following our acquisition of Microscience in June 2005. Research and development spending by Microscience prior to our acquisition of Microscience in June 2005 is not included in our results for 2005. The spending for our typhoid vaccine candidate resulted from ongoing work for the Phase I clinical trial in Vietnam that we completed in 2006 and preparing for our Phase II clinical trial in Vietnam that we initiated in the first quarter of 2007. The spending in 2006 for our hepatitis B therapeutic vaccine candidate resulted from preparing for our Phase II clinical trial, which we received regulatory clearance to commence in the fourth quarter of 2006. The spending in 2006 for our group B streptococcus vaccine candidate resulted from costs associated with our analysis of results from the Phase I clinical trial for one of the protein components of the vaccine candidate and preparation for Phase I clinical trials for two of the protein components of the vaccine candidate. In December 2006, we signed an agreement with the NIAID under which the NIAID has agreed to sponsor a Phase I clinical trial of each of the two components separately and the two proteins in combination in healthy human volunteers. Both our chlamydia and meningitis B vaccine candidates are in preclinical development.

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

Our principal research and development expenses for 2006 and 2005 are shown in the following table:

(in thousands)	Year ended December 31, 2006	2005
Biodefense:		
BioThrax enhancements	$ 7,232	$ 2,883
Immune globulin therapeutic development	11,289	5,309
Recombinant bivalent botulinum vaccine	2,610	1,708
Next generation anthrax vaccine	1,088	427
Total biodefense	22,219	10,327
Commercial:		
Typhoid vaccine	9,642	1,477
Hepatitis B therapeutic vaccine	4,058	1,884
Group B streptococcus vaccine	3,759	1,032
Chlamydia vaccine	1,991	837
Meningitis B vaccine	2,975	1,334
Total commercial	22,425	6,564
Other	857	1,490
Total	$ 45,501	$ 18,381

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $1.8 million, or 4%, to $44.6 million for 2006 from $42.8 million for 2005. The increase in selling, general and administrative expenses was primarily attributable to an increase in general and administrative expenses of $1.0 million resulting from the addition of personnel and increased legal and other professional services for our headquarters organization, and an increase of $937,000 related to the addition of personnel for Emergent Product Development UK. Selling, general and administrative expenses related to our biodefense segment decreased by $397,000, or 1%, to $35.6 million for 2006 from $36.0 million for 2005. Selling, general and administrative expenses related to our commercial segment increased by $2.2 million, or 33%, to $9.0 million for 2006 from $6.8 million for 2005.

Purchased In-process Research and Development

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

In June 2005, we recorded a non-cash charge for purchased in-process research and development of $26.6 million associated with our acquisition of Microscience. We valued the 3,636,801 shares of class A common stock that we issued in the acquisition at $28.2 million after the inclusion of acquisition costs. Of this amount, we identified $1.4 million as current assets, $863,000 as fixed assets, $684,000 as current liabilities and $26.6 million as the value attributable to development programs. Because we determined that the development programs had no future alternative use, we charged the value attributable to the development programs as purchased in-process research and development.

Litigation Settlement

In 2005, we recorded a gain of $10.0 million relating to a settlement of a litigation matter that we initiated to resolve a contract and intellectual property dispute.

Total Other Income (Expense)

Total other expense decreased by $214,000, or 94%, to $13,000 for 2006 from $227,000 for 2005. This decrease resulted primarily from an increase in interest income of $361,000 as a result of higher investment return on increased average cash balances, including the net proceeds of our initial public offering, and an increase in other income of $238,000, offset by an increase in interest expense of $385,000 related primarily to the mortgage loan we entered into in April 2006 and the term loan we entered into in August 2006.

Income Taxes

Provision for income taxes increased by $9.9 million, or 186%, to $15.2 million for 2006 from $5.3 million for 2005. The provision for income taxes for 2006 resulted primarily from our income before provision for income taxes of $38.0 million and an effective annual tax rate of 40%. The provision for income taxes for 2005 resulted primarily from our income before provision for income taxes of $21.1 million and an effective annual tax rate of 25%. The increase in the effective annual tax rate is due primarily to the impact of foreign and state net operating losses and an increase in permanent differences, including incentive stock options. The provision for income taxes also reflects research and development tax credits of $759,000 for 2006 and $474,000 for 2005.

Liquidity and Capital Resources

Sources of Liquidity

We require cash to meet our operating expenses and for capital expenditures, acquisitions and principal and interest payments on our debt. We have funded our cash requirements from inception through December 31, 2007 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases, revenues under our collaboration agreement with Sanofi Pasteur, development funding from government entities and non-government and philanthropic organizations, the net proceeds from our initial public offering and, to a lesser extent, from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the years in the three year period ended December 31, 2007.

As of December 31, 2007, we had cash and cash equivalents of $105.7 million. On November 20, 2006, we completed our initial public offering, in which we raised $54.2 million, net of issuance costs.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2007, 2006 and 2005.

	Year ended December 31,		
(in thousands)	**2007**	**2006**	**2005**
Net cash provided by (used in):			
Operating activities(1)	$ 54,790	$ (4,258)	$ 41,974
Investing activities	(43,969)	(41,446)	(7,091)
Financing activities	18,491	85,828	(5,410)
Total net cash provided	$ 29,312	$ 40,124	$ 29,473

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

Net cash provided by operating activities of $54.8 million in 2007 resulted principally from our net income of $22.9 million, a decrease in accounts receivable of $24.5 million due to amounts billed primarily to HHS in December 2006 that were collected in 2007, partially offset by amounts billed in December 2007 and outstanding at year end, a decrease in inventory of $7.8 million related to increased product sales in 2007, and $4.8 million from the impact of non-cash depreciation and amortization, partially offset by a decrease in income taxes payable of $5.2 million due to the timing of payment of the 2006 income tax liability offset by the pending payable for 2007 income taxes.

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

Net cash provided by operating activities of $42.0 million in 2005 resulted principally from our net income of $15.8 million, a non-cash charge for purchased in-process research and development related to the Microscience acquisition, which reduced net income by $26.6 million, and a reduction of accounts receivable of $16.1 million as a result of the collection of amounts due from the DoD during 2005 for invoices outstanding at the end of 2004 for progress in the manufacture of BioThrax lots, offset by a reduction of deferred revenue of $10.9 million, reflecting the delivery to the DoD in the first quarter of 2005 of BioThrax lots for which we had previously invoiced the DoD for progress payments and been paid, and an increase in deferred tax assets of $11.0 million, reflecting a deferred tax asset recorded to reflect the timing differences between the book charge and the tax deferral of expense related to the purchased in-process research and development expense related to the Microscience acquisition.

Net cash used in investing activities for the years ended December 31, 2007, 2006 and 2005 resulted principally from the purchase of property, plant and equipment. Capital expenditures in 2007 include $30.3 million in construction and related costs for our new manufacturing facility in Lansing and approximately $13.7 million in infrastructure investments and other equipment. Capital expenditures in 2006 relate primarily to $25.7 million for construction of our new building in Lansing, Michigan, $10.2 million related to the acquisition of our second facility in Frederick, Maryland, and approximately $5.3 million in infrastructure investments and other equipment. Capital expenditures in 2005 were primarily attributable to investments in information technology upgrades and miscellaneous facility enhancements.

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

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

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

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2007:

	Payments due by period						
(in thousands)	**Total**	**2008**	**2009**	**2010**	**2011**	**2012**	**After 2012**
Contractual obligations:							
Short and long-term debt(1)	$ 46,102	$ 3,514	$ 6,049	$ 3,585	$ 16,203	$ 16,751	$ -
Operating lease obligations	13,983	2,048	1,436	1,453	1,471	1,489	6,086
Contractual settlement liabilities	50	50	-	-	-	-	-
Total contractual obligations	$ 60,135	$ 5,612	$ 7,485	$ 5,038	$ 17,674	$ 18,240	$ 6,086

(1) Includes scheduled interest payments.

The preceding table excludes contingent contractual payments that we may become obligated to make upon achievement of specified research, development and commercialization milestones and contingent contractual royalty payments. The amount of contingent contractual milestone payments that we may become obligated to make is variable based on the actual achievement and timing of the applicable milestones and the characteristics of any products or product candidates that are developed, including factors such as number of products or product candidates developed, type and number of components of each product or product candidate, ownership of the various components and the specific markets affected. We are not obligated to pay any minimum royalties under our existing contracts.

Debt Financing

As of December 31, 2007, we had $57.9 million principal amount of debt outstanding, comprised primarily of the following:

$2.5 million outstanding under a forgivable loan from the Department of Business and Economic Development of the State of Maryland used to finance eligible costs incurred to purchase the first facility in Frederick, Maryland;
$6.6 million outstanding under a mortgage loan from PNC Bank (formerly Mercantile Potomac Bank) used to finance the remaining portion of the purchase price for the first Frederick facility;
$8.2 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance the purchase price for the second facility on the Frederick site;
$28.8 million outstanding under a term loan from HSBC Realty Credit Corporation used to finance a portion of the costs of our facility expansion in Lansing, Michigan; and
$11.8 million outstanding under a $15.0 million revolving line of credit with Fifth Third Bank. This balance was repaid in January 2008.

We can borrow under the line of credit with Fifth Third Bank through May 2008.

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

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

Under our term loan with HSBC Realty Credit Corporation, we are required to maintain on an annual basis a book leverage ratio of less than 1.25. This ratio is calculated by dividing total liabilities, excluding deferred revenues specific to contracts with the U.S. government, by total net worth. In addition, we are required to maintain on a quarterly basis a debt coverage ratio of not less than 1.25 to 1.00 or maintain $5.0 million in a cash collateral account. This ratio is calculated by dividing earnings before interest, taxes, depreciation and amortization for the most recent four quarters by the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable for the following four quarters.

Under our revolving line of credit with Fifth Third Bank, our wholly owned subsidiary, Emergent BioDefense Operations, is required to maintain at all times a ratio of total liabilities to tangible net worth of not more than 2.5 to 1.0.

Our debt instruments also contain negative covenants restricting our activities. Our term loan with HSBC Realty Credit Corporation limits the ability of Emergent BioDefense Operations to incur indebtedness and liens, sell assets, make loans, advances or guarantees, enter into mergers or similar transactions and enter into transactions with affiliates. Our line of credit with Fifth Third Bank limits the ability of Emergent BioDefense Operations to incur indebtedness and liens, sell assets, make loans, advances or guarantees, enter into mergers or similar transactions, enter into transactions with affiliates and amend the terms of any government contract.

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

Under our mortgage loan from PNC Bank, we began to make monthly principal payments beginning in November 2006. A residual principal repayment of approximately $5.0 million is due upon maturity in October 2011. Interest is payable monthly and accrues at an annual rate of 6.625% through October 2009. In October 2009, the interest rate is scheduled to be adjusted to a fixed annual rate equal to 3.20% over the yield on U.S. government securities adjusted to a constant maturity of two years.

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

Under our term loan with HSBC Realty Credit Corporation, we are required to make monthly payments in the amount of $250,000 in principal plus accrued interest beginning August 2007, with a residual principal payment due upon maturity in June 2012. Interest on the loan accrues at an annual rate equal to LIBOR plus 2.75%.

Under our revolving line of credit with Fifth Third Bank, any outstanding principal is due upon maturity in May 2008. The principal amount outstanding at any time under the line of credit may not exceed 75% of total eligible accounts receivable under the DoD and HHS contracts. Consistent with the terms of this agreement, we repaid $11.8 million of outstanding principal under the line of credit in January 2008. Interest is payable monthly and accrues at an annual rate equal to 0.375% less than the prime rate of interest established from time to time by Fifth Third Bank.

Tax Benefits

In connection with our facility expansion in Lansing, the State of Michigan and the City of Lansing have provided us a variety of tax credits and abatements. We estimate that the total value of these tax benefits may be up to $18.5 million over a period of up to 15 years, beginning in 2006. These tax benefits are primarily based on our $75 million planned investment in our Lansing facility. In addition, we must maintain a specified number of employees in Lansing to continue to qualify for these tax benefits.

Funding Requirements

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

We may seek to raise additional external debt financing to provide additional financial flexibility. Our committed external sources of funds consist of the remaining borrowing availability under our revolving line of credit with Fifth Third Bank, development funding under our collaboration agreement with Sanofi Pasteur and funding from the NIAID, including for studies related to our anthrax immune globulin therapeutic product candidate. Our ability to borrow additional amounts under our loan agreements is subject to our satisfaction of specified conditions.

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

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

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

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

Effects of Inflation

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

Recent Accounting Pronouncements

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

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

In June 2007, the FASB issued EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, or EITF No. 07-3. EITF No. 07-3 states that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. The provisions of EITF No. 07-3 are effective for fiscal years beginning after December 15, 2007. We anticipate that the adoption of the provisions of EITF No. 07-3 will not have a material impact on our financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115*, or SFAS No. 159. SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The provisions of SFAS No. 159 are effective for fiscal years beginning after November 15, 2007. We anticipate that the adoption of this statement will not have a material impact on our financial statements.

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We also have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. and Subsidiaries as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Emergent BioSolutions Inc. and Subsidiaries at December 31, 2007 and 2006, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 11 to the consolidated financial statements, in 2007 the Company changed its method of accounting for uncertain tax provisions. As discussed in Note 2 to the consolidated financial statements, in 2006 the Company changed its method of accounting for share-based payments.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Emergent BioSolutions Inc. and Subsidiaries internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 6, 2008 expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

McLean, Virginia

March 6, 2008

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

	December 31, 2007	2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 105,730	$ 76,418
Accounts receivable	18,817	43,331
Inventories	16,897	24,721
Income taxes receivable	-	869
Deferred tax assets	-	295
Prepaid expenses and other current assets	2,866	1,703
Total current assets	144,310	147,337
Property, plant and equipment, net	110,218	78,174
Deferred tax assets, net of current	12,397	11,477
Restricted cash	5,200	192
Other assets	1,383	1,075
Total assets	$ 273,508	$ 238,255
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 17,979	$ 27,366
Accrued expenses and other current liabilities	4,056	3,270
Accrued compensation	9,502	7,190
Indebtedness under lines of credit	11,832	8,930
Long-term indebtedness, current portion	3,514	2,456
Income taxes payable	7,665	13,703
Deferred tax liabilities	211	-
Deferred revenue, current portion	902	1,432
Total current liabilities	55,661	64,347
Long-term indebtedness, net of current portion	42,588	31,368
Deferred revenue, net of current portion	2,473	2,997
Other liabilities	1,627	1,071
Total liabilities	102,349	99,783
Commitments and contingencies	-	-
Stockholders equity:		
Preferred Stock $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2007 and 2006, respectively	-	-
Common Stock, $0.001 par value; 100,000,000 shares authorized, 29,750,237 and 27,596,249 shares issued and outstanding at December 31, 2007 and 2006, respectively	30	28
Additional paid-in capital	101,933	90,920
Accumulated other comprehensive loss	(1,130)	(473)
Retained earnings	70,326	47,997
Total stockholders equity	171,159	138,472
Total liabilities and stockholders equity	$ 273,508	$ 238,255

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

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

	Year Ended December 31,		
	2007	**2006**	**2005**
Revenues:			
Product sales	$ 169,799	$ 147,995	$ 127,271
Contracts and grants	13,116	4,737	3,417
Total revenues	182,915	152,732	130,688
Operating expense (income):			
Cost of product sales	40,309	24,125	31,603
Research and development	53,958	45,501	18,381
Selling, general and administrative	55,555	44,601	42,793
Purchased in-process research and development	-	477	26,575
Litigation settlement	-	-	(10,000)
Income from operations	33,093	38,028	21,336
Other income (expense):			
Interest income	2,809	846	485
Interest expense	(71)	(1,152)	(767)
Other income (expense), net	156	293	55
Total other income (expense)	2,894	(13)	(227)
Income before provision for income taxes	35,987	38,015	21,109
Provision for income taxes	13,051	15,222	5,325
Net income	$ 22,936	$ 22,793	$ 15,784
Earnings per share - basic	$ 0.79	$ 0.99	$ 0.77
Earnings per share - diluted	$ 0.77	$ 0.93	$ 0.69
Weighted-average number of shares - basic	28,995,667	23,039,794	20,533,471
Weighted-average number of shares - diluted	29,663,127	24,567,302	22,751,733
Cash dividends per share - basic	$ -	$ -	$ 0.26

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

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

	Year Ended December 31,		
	2007	**2006**	**2005**
Cash flows from operating activities:			
Net income	$ 22,936	$ 22,793	$ 15,784
Adjustments to reconcile net income to net cash provided by (used in) operating activities (net of effects of acquisitions):			
Stock-based compensation expense (credit)	2,541	723	(17)
Depreciation and amortization	4,817	4,715	3,549
Deferred income taxes	5,589	987	(10,968)
Loss on disposal of property and equipment	24	27	32
Purchased in-process research and development	-	477	26,575
Excess tax benefits from stock-based compensation	(6,003)	(789)	-
Changes in operating assets and liabilities:			
Accounts receivable	24,514	(40,801)	16,107
Inventories	7,825	(8,280)	(3,189)
Income taxes	(5,169)	11,463	(2,390)
Prepaid expenses and other assets	(1,316)	(792)	(865)
Accounts payable	(2,303)	5,801	5,463
Accrued compensation	2,312	1,013	2,466
Accrued expenses and other liabilities	734	1,513	619
Deferred revenue	(1,054)	(2,911)	(10,916)
Net cash provided by (used in) operating activities	55,447	(4,061)	42,250
Cash flows from investing activities:			
Purchases of property, plant and equipment	(43,969)	(41,228)	(6,532)
Acquisitions, net of cash received	-	(218)	(559)
Net cash used in investing activities	(43,969)	(41,446)	(7,091)
Cash flows from financing activities:			
Restricted cash deposits	(5,008)	(192)	1,250
Proceeds from borrowings on long term indebtedness and lines of credit	33,195	32,430	31
Proceeds from notes payable to employees	-	-	123
Issuance of common stock in initial public offering (net of issuance cost)	-	54,229	-
Issuance of common stock subject to exercise of stock options	2,471	590	33
Redemption of Class B common stock	-	(192)	(337)
Principal payments on long term indebtedness, notes payable to employees, and lines of credits	(18,015)	(1,569)	(1,110)
Excess tax benefits from stock-based compensation	6,003	789	-
Debt issuance costs	(155)	(257)	-
Payment of dividend	-	-	(5,400)
Net cash provided by (used in) financing activities	18,491	85,828	(5,410)
Effect of exchange rate changes on cash and cash equivalents	(657)	(197)	(276)
Net increase (decrease) in cash and cash equivalents	29,312	40,124	29,473
Cash and cash equivalents at beginning of year	76,418	36,294	6,821
Cash and cash equivalents at end of year	105,730	76,418	36,294
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ 3,094	$ 1,681	$ 696
Cash paid during the year for income taxes	$ 14,329	$ 2,788	$ 17,985
Supplemental information on non-cash investing and financing activities:			
Issuance of common stock to acquire Microscience Limited	$ -	$ -	$ 27,001
Purchases of property, plant and equipment unpaid at year end	$ 7,084	$ 11,140	$ -

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

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

	Class A $0.001 Par Value Common Stock Shares	Amount	Class B $0.01 Par Value Common Stock Shares	Amount	$0.001 Par Value Common Stock Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
Balance at December 31, 2004	18,666,479	19	-	-	-	-	7,610	-	15,320	22,949
Issuance of common stock to acquire Microscience Limited	3,636,801	3	-	-	-	-	26,998	-	-	27,001
Exercise of stock options	-	-	133,451	1	-	-	32	-	-	33
Redemption of common stock	-	-	(112,168)	(1)	-	-	(28)	-	(308)	(337)
Forfeiture of stock options	-	-	-	-	-	-	(17)	-	-	(17)
Payment of dividend	-	-	-	-	-	-	-	-	(5,400)	(5,400)
Net income	-	-	-	-	-	-	-	-	15,784	15,784
Foreign currency translation	-	-	-	-	-	-	-	(276)	-	(276)
Comprehensive income	-	-	-	-	-	-	-	-	-	15,508
Balance at December 31, 2005	22,303,280	$ 22	21,283	$ -	-	$ -	$ 34,595	$ (276)	$ 25,396	$ 59,737
Exercise of stock options	-	-	95,858	1	175,828	-	589	-	-	590
Redemption of common stock	-	-	-	-	-	-	-	-	(192)	(192)
Conversion of class A $0.001 and class B par value $0.001 to common stock $.001 par value common stock	(22,303,280)	(22)	(117,141)	(1)	22,420,421	23		-		-
Issuance of common stock in initial public offering (net of issuance cost)	-	-	-	-	5,000,000	5	54,224	-	-	54,229
Stock-based compensation expense	-	-	-	-	-	-	723	-	-	723
Excess tax benefits from exercises of non-qualified stock options	-	-	-	-	-	-	789	-	-	789
Net income	-	-	-	-	-	-	-	-	22,793	22,793
Foreign currency translation	-	-	-	-	-	-	-	(197)	-	(197)
Comprehensive income	-	-	-	-	-	-	-	-	-	22,596
Balance at December 31, 2006	-	$ -	-	$ -	27,596,249	$ 28	$ 90,920	$ (473)	$ 47,997	$ 138,472
Exercise of stock options	-	-	-	-	2,153,988	2	2,469	-	-	2,471
Stock-based compensation expense	-	-	-	-			2,541		-	2,541
Cumulative effect of change in accounting principle (FIN 48)	-	-	-	-			-		(607)	(607)
Excess tax benefits from exercises of non-qualified stock options	-	-	-	-			6,003		-	6,003
Net income	-	-	-	-					22,936	22,936
Foreign currency translation	-	-	-	-				(657)	-	(657)
Comprehensive income	-	-	-	-	-	-	-	-	-	22,279
Balance at December 31, 2007	-	$ -	-	$ -	29,750,237	$ 30	$ 101,933	$ (1,130)	$ 70,326	$ 171,159

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

Emergent BioSolutions Inc. and Subsidiaries

Notes to consolidated financial statements

1. Nature of the business and organization

Emergent BioSolutions Inc. (the Company or Emergent) is a biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics. The Company is developing products to be offered both to the biodefense and commercial markets. The Company commenced operations as BioPort Corporation (BioPort) in September 1998 through an acquisition from the Michigan Biologic Products Institute of rights to the marketed product, BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how. In December 2001, the U.S. Food and Drug Administration (FDA) approved a supplement to the Company s manufacturing facility license for the manufacture of BioThrax at the renovated facilities. In June 2004, the Company completed a corporate reorganization (Reorganization).

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

2. Summary of significant accounting policies

Basis of presentation and consolidation

The accompanying consolidated financial statements include the accounts of Emergent and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and cash equivalents

Cash equivalents are highly liquid investments with a maturity of 90 days or less at the date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions. Also, the Company maintains cash balances with financial institutions in excess of insured limits. The Company does not anticipate any losses with such cash balances. At December 31, 2007 and 2006 the Company maintained all of its cash and cash equivalents in four financial institutions.

Fair value of financial instruments

The carrying amounts of the Company s short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair values due to their short maturities. The fair value of the Company s long-term indebtedness is estimated based on the quoted prices for the same or similar issues or on the current rates offered to the Company for debt of the same remaining maturities. The carrying value and fair value of long-term indebtedness were $46.1 million and $45.6 million, respectively, at December 31, 2007 and $33.8 million and $33.2 million, respectively, at December 31, 2006.

Restricted cash

Restricted cash at December 31, 2007 and 2006 includes a certificate of deposit held by a bank as collateral for a letter of credit acting as a security deposit on a loan. Restricted cash at December 31, 2007 also includes $5.0 million in a pledged bank deposit account as collateral for a term loan. As of December 31, 2007 and 2006 the Company had restricted cash of $5.2 million and $192,000, respectively.

Significant customers and accounts receivable

The Company s primary customers are the U.S. Department of Defense (the DoD) and U.S. Department of Health and Human Services (HHS). For the years ended December 31, 2007, 2006 and 2005, sales of BioThrax to the DoD and HHS comprised 97%, 97% and 96%, of total revenues, respectively. As of December 31, 2007 and 2006, the Company s receivable balances were comprised of 84% and 100%, respectively, from these customers. Unbilled accounts receivable, included in accounts receivable, totaling $1.1 million and $26,000 as of December 31, 2007 and 2006, respectively, relate to various service contracts for which product has been delivered or work has been performed, though invoicing has not yet occurred. Accounts receivable are stated at invoice amounts and consist primarily of amounts due from the DoD and HHS as well as amounts due under reimbursement contracts with other government entities and non-government and philanthropic organizations. If necessary, the Company records a provision for doubtful receivables to allow for any amounts which may be unrecoverable. This provision is based upon an analysis of the Company s prior collection experience, customer creditworthiness and current economic trends. As of December 31, 2007 and 2006, an allowance for doubtful accounts was not recorded, as the collection history from these customers indicates collection is probable.

Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company places its cash and cash equivalents with high quality financial institutions. Management believes that the financial risks associated with its cash and cash equivalents are minimal. Because accounts receivable consist of amounts due from the U.S. federal government for product sales and from government agencies under government grants, management deems there to be minimal credit risk.

Inventories

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

Property, plant and equipment

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

Buildings	39 years
Furniture and equipment	3-7 years
Software	Lesser of 3 years or product life
Leasehold improvements	Lesser of the asset life or lease term

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred.

Income taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled.

The Company records valuation allowances to reduce deferred tax assets to the amounts that more likely than not will be realized. The Company considers future taxable income and ongoing tax planning strategies in assessing the need for valuation allowances. In general, if the Company determines that it is able to realize more than the recorded amounts of net deferred tax assets in the future, net income will increase in the period in which the determination is made. Likewise, if the Company determines that it is not able to realize all or part of the net deferred tax asset in the future, net income will decrease in the period in which the determination is made. The Company applies any reversals of valuation allowance related to an acquired deferred tax asset against other intangibles before impacting net income.

Under sections 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a loss corporation , as defined, there are annual limitations on the amount of net operating losses and deductions that are available. Due to the acquisition of Microscience in 2005 and the Company s initial public offering, the Company believes the use of the operating losses will be significantly limited.

The Company s ability to realize deferred tax assets depends upon future taxable income as well as the limitations discussed above. For financial reporting purposes, a deferred tax asset must be reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized prior to expiration.

Revenue recognition

The Company recognizes revenues from product sales in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB No. 104). SAB No. 104 requires recognition of revenues from product sales that require no continuing performance by the Company if four basic criteria have been met:

- there is persuasive evidence of an arrangement;
- delivery has occurred and title has passed to the Company s customer;
- the fee is fixed and determinable and no further obligation exists; and
- collectibility is reasonably assured.

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

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

In December 2005, the Securities and Exchange Commission released an interpretation with respect to the accounting for sales of vaccines and bioterror countermeasures to the federal government for placement into the Strategic National Stockpile (SNS). This interpretation provides for revenue recognition for specifically identified products purchased for the SNS in the event that all requirements for revenue recognition, as specified in Statement of Financial Accounting Concepts No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises,* are not met. While the Company s contracts with HHS are for qualifying sales of vaccine for placement into the SNS, the Company meets all requirements for revenue recognition upon delivery of product to HHS, and therefore has not applied this guidance.

Collaborative research and development agreements can provide for one or more of up-front license fees, research payments, and milestone payments. Agreements with multiple components (deliverables or items) are evaluated in accordance with Emerging Issues Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF No. 00-21), to determine if the deliverables can be divided into more than one unit of accounting. An item can generally be considered a separate unit of accounting if all of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis; (2) there is objective and reliable evidence of the fair value of

the undelivered items(s); and (3) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in control of the Company. Items that cannot be divided into separate units are combined with other units of accounting, as appropriate. Consideration received is allocated among the separate units based on their respective fair values or based on the residual value method and is recognized in full when the criteria in the discussion of SAB No. 104 above are met. The Company deems service to have been rendered if no continuing obligation exists on the part of the Company.

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

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

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

Impairment of long-lived assets

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144), the Company assesses the recoverability of its long-lived assets for which an indicator of impairment exists by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If the Company concludes that the carrying value will not be recovered, the Company measures the amount of such impairment by comparing the fair value to the carrying value. The Company has recorded no impairment losses for the years ended December 31, 2007, 2006 and 2005.

Research and development

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

Purchased in-process research and development

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

Comprehensive income

SFAS No. 130, *Reporting Comprehensive Income,* requires the presentation of the comprehensive income and its components as part of the financial statements. Comprehensive income is comprised of net income and other changes in equity that are excluded from net income. The Company includes gains and losses on intercompany transactions with foreign subsidiaries that are considered to be long-term investments and translation gains and losses incurred when converting its subsidiaries financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income (loss).

Foreign currencies

The local currency is the functional currency for the Company s foreign subsidiaries and, as such, assets and liabilities are translated into U.S. dollars at year-end exchange rates. Income and expense items are translated at average exchange rates during the year. Translation adjustments resulting from this process are charged or credited to other comprehensive income (loss).

Capitalized interest

The Company capitalizes interest in accordance with SFAS No. 34, *Capitalization of Interest Cost*, based on the cost of major ongoing capital projects which have not yet been placed in service. For the years ended December 31, 2007, 2006 and 2005, the Company incurred interest expense of $3.2 million, $1.9 million and $767,000, respectively. Of these amounts, the Company capitalized $3.1 million, $759,000 and $0, respectively.

Certain risks and uncertainties

The Company has derived substantially all of its revenue from sales of BioThrax under contracts with the DoD and HHS. The Company s ongoing U.S. government contract does not necessarily increase the likelihood that it will secure future comparable contracts with the U.S. government. The Company expects that a significant portion of the business that it will seek in the near future, in particular for BioThrax, will be under government contracts that present a number of risks that are not typically present in the commercial contracting process. U.S. government contracts for BioThrax are subject to unilateral termination or modification by the government. The Company may fail to achieve significant sales of BioThrax to customers in addition to the U.S. government, which would harm its growth opportunities. The Company may not be able to sustain or increase profitability. The Company is spending significant amounts for the expansion of its manufacturing facilities. The Company may not be able to manufacture BioThrax consistently in accordance with FDA specifications. Other than BioThrax, all of the Company s product candidates are undergoing clinical trials or are in early stages of development, and failure is common and can occur at any stage of development. None of the Company s product candidates other than BioThrax has received regulatory approval.

Earnings per share

Basic net income per share of common stock excludes dilution for potential common stock issuances and is computed by dividing net income by the weighted average number of shares outstanding for the period. Diluted net income per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock.

The following table presents the calculation of basic and diluted net income per share:

(in thousands, except share and per share data)	Year Ended December 31, 2007	2006	2005
Numerator:			
Net Income	$ 22,936	$ 22,793	$ 15,784
Denominator:			
Weighted-average number of shares basic	28,995,667	23,039,794	20,533,471
Dilutive securities stock options	667,460	1,527,508	2,218,262
Weighted-average number of shares diluted	29,663,127	24,567,302	22,751,733
Earnings per share-basic	$ 0.79	$ 0.99	$ 0.77
Earnings per share-diluted	$ 0.77	$ 0.93	$ 0.69

For the years ending December 31, 2007, 2006 and 2005, outstanding stock options to purchase approximately 463,000, 160,000 and 21,000 shares, respectively, of common stock are not considered in the diluted earnings per share calculation because the exercise price of these options is greater than the average per share closing price during the year.

Accounting for stock-based compensation

As of December 31, 2007, the Company has two stock-based employee compensation plans, the Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the 2006 Plan) and the Emergent BioSolutions Employee Stock Option Plan (the 2004 Plan), described more fully in Note 10 Stockholders Equity. Through December 31, 2005, the Company accounted for grants under the 2004 Plan using the intrinsic value method in

accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25) and provided the pro forma disclosures of net income and net income per share in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123) as amended by SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosures* using the fair value method. Under APB No. 25, compensation expense is based on the difference, if any, on the date of the grant between the fair value of the Company s stock and the exercise price of the option and is recognized ratably over the vesting period of the option.

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

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

Results for prior periods have not been restated. Based on options granted to employees as of December 31, 2007, total compensation expense not yet recognized related to unvested options is approximately $2.9 million, after tax. The Company expects to recognize that expense over a weighted average period of 3.0 years.

The Company has utilized the Black-Scholes valuation model for estimating the fair value of all stock options granted. The fair value of each option is estimated on the date of grant. Set forth below are the weighted-average assumptions used in valuing the stock options granted and a discussion of the Company s methodology for developing each of the assumptions used:

	Year Ended December 31,		
	2007	**2006**	**2005**
Expected dividend yield	0%	0%	0%
Expected volatility	50%	50%	50%
Risk-free interest rate	2.99-5.09%	4.58-5.21%	3.33-4.32%
Expected average life of options	3.0 years	3.0 years	2.9 years

Expected dividend yield The Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.

Expected volatility Volatility is a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company analyzed the expected historical volatility used by similar companies at a similar stage of development to estimate expected volatility. The volatility used by these similar companies ranged from 33% to 79%, with an average estimated volatility of 53%.

Risk-free interest rate This is the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date in which the option was granted.

Expected average life of options This is the period of time that the options granted are expected to remain outstanding. This estimate is based primarily on the employee position profile of option holders and the trading lock out periods that result from the employee s access to stock price sensitive information.

Prior to the adoption of SFAS No. 123(R), the Company presented all tax benefits of deductions resulting from the exercise of stock options as operating cash flows in the statement of cash flows. SFAS No. 123(R) requires the cash flows resulting from the tax benefits of deductions in excess of the compensation cost recognized for those options (excess tax benefits from stock-based compensation) to be classified as financing cash flows.

The following table illustrates the effect on net income and net income per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation for the year ended December 31, 2005.

(in thousands, except per share data)	**Year Ended December 31, 2005**
Net income, as reported	$ 15,784
Add: Stock-based compensation in reported net income, net of taxes	-
Deduct: Total stock-based compensation expense determined under the fair value based method for all awards, net of taxes	(258)
Pro forma net income	$ 15,526

Net income per common share	basic	$ 0.77
Net income per common share	diluted	$ 0.69
Pro forma net income per common share	basic	$ 0.76
Pro forma net income per common share	diluted	$ 0.68

Reclassifications

Restricted cash deposits in the consolidated statements of cash flows for the years ended December 31, 2006 and 2005 have been reclassified from investing cash flows to financing cash flows, to conform to current period presentation.

Recent accounting pronouncements

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

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

In June 2007, the FASB issued EITF No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (EITF No. 07-3). EITF No. 07-3 states that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. Such amounts should be recognized as an expense as the related goods are delivered or the related services are performed. The provisions of EITF No. 07-3 are effective for fiscal years beginning after December 15, 2007. The Company anticipates that the adoption of the provisions of EITF No. 07-3 will not have a material impact on its financial statements.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The provisions of SFAS No. 159 are effective for fiscal years beginning after November 15, 2007. The Company anticipates that the adoption of this statement will not have a material impact on its financial statements.

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

3. Acquisitions

ViVacs GmbH

On July 13, 2006, Emergent International, Inc., a wholly owned subsidiary of the Company, incorporated in Delaware (EII), completed the acquisition of ViVacs GmbH, a German limited liability company, to expand the Company s commercial vaccine portfolio, pursuant to the terms and conditions of the Share Purchase and Assignment Agreement dated July 13, 2006 by and between EII and ViVacs. EII paid $150,000 in cash on the closing date of the agreement and agreed to pay $50,000 on each of the first and second anniversaries of the closing date. The acquisition agreement also provides for a potential variable earn-out purchase price of up to $220,000, based on future payments from third party licensees of the technology. As of December 31, 2007, the Company has not received any such payments from third party licensees. Because ViVacs was a development stage company and had not commenced its planned principal operations, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded.

Total purchase consideration consisted of:

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

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

The purchase price was allocated as follows:

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

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

Microscience Limited

On June 23, 2005, Emergent Europe, Inc., a wholly owned subsidiary of the Company incorporated in Delaware (EEI), completed the acquisition of Microscience pursuant to the terms and conditions of the Share Exchange Agreement dated June 23, 2005 by and between EEI and Microscience Holdings PLC, a public limited liability company incorporated in England. At the closing date, the Company, through EEI, issued Microscience shareholders 3,636,801 shares of the Company s Class A Common Stock in exchange for all of the outstanding stock of Microscience. Shares of Class A Common Stock of the Company were valued for financial statement purposes at $7.42 per share based on a determination of the estimated fair value by the Company s board of directors. Because Microscience was a development stage company and had not commenced its planned principal operations, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded.

Total purchase consideration consisted of:

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

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

(in thousands)		
Current assets	$	1,441
Property and equipment		863
Current liabilities		(684)
Net assets acquired		1,620
In-process research and development		26,575
Total purchase consideration	$	28,195

In connection with the transaction, the Company recorded a charge of $26.6 million for acquired research projects associated with products in development for which, at the acquisition date, technological feasibility had not been established and, for accounting purposes, no alternative future use existed.

4. Accounts receivable

Accounts receivable consist of the following:

(in thousands)	December 31, 2007	2006
Billed	$ 17,741	$ 43,305
Unbilled	1,076	26
Total	$ 18,817	$ 43,331

5. Inventories

Inventories consist of the following:

(in thousands)	December 31, 2007	2006
Raw materials and supplies	$ 2,463	$ 2,133
Work-in-process	11,483	22,239
Finished goods	2,951	349
Total inventories	$ 16,897	$ 24,721

6. Property, plant and equipment

Property, plant and equipment consist of the following:

(in thousands)	December 31, 2007	2006
Land and improvements	$ 4,974	$ 5,173
Buildings and leasehold improvements	26,410	25,074
Furniture and equipment	19,626	15,963
Software	5,866	3,937
Construction-in-progress	71,129	41,563
	128,005	91,710
Less: Accumulated depreciation and amortization	(17,787)	(13,536)
Total Property, plant and equipment, net	$ 110,218	$ 78,174

Depreciation and amortization expense was $4.8 million, $4.7 million and $3.5 million for the years ended December 31, 2007, 2006 and 2005, respectively. For the years ended December 31, 2007, 2006 and 2005, depreciation and amortization expense included approximately $1.0 million, $1.3 million and $1.3 million, respectively, related to the amortization of internal-use software. As of December 31, 2007 and 2006, unamortized software cost was $0 and $1.2 million, respectively.

7. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following:

(in thousands)	December 31, 2007	2006
Contract costs	$ 1,962	$ 1,218
Professional fees	723	1,115
Interest payable	259	222
Property taxes and other	1,112	715
Total	$ 4,056	$ 3,270

8. **Long-term debt**

The components of long term-debt are as follows:

(in thousands)	December 31, 2007	2006
Term Loan dated June 2007; Libor plus 2.75%, due June 2012	$ 28,750	$ -
Term Loan dated August 2006; Libor plus 3.75%, due August 2011	-	10,000
Revolving credit loan; Libor plus 3.75%	-	5,000
Term Loan dated April 2006; Libor plus 3.0%, due April 2011	8,167	8,383
Forgivable Loan dated October 2004; 3.0%, due March 2013	2,500	2,500
Term Loan dated October 2004; 6.625%, due October 2011	6,671	6,955
ERP Term Loan; Prime less 0.375%, due September 2007	-	960
Other	14	26
Total long-term indebtedness	46,102	33,824
Less current portion of long-term indebtedness	(3,514)	(2,456)
Noncurrent portion of long-term indebtedness	$ 42,588	$ 31,368

In June 2007, the Company entered into a loan agreement with HSBC Realty Credit Corporation (USA) ("HSBC"), under which HSBC provided the Company with a term loan of $30 million. This loan replaced a prior loan arrangement with HSBC under which HSBC agreed to loan the Company $15 million, consisting of a $10 million term loan and a $5 million revolving line of credit. Under the new loan agreement, the Company is required to maintain a minimum balance of $5 million in a deposit account pledged to HSBC and to make monthly payments in the amount of $250,000 in principal plus accrued interest beginning in August 2007, with a residual principal payment due upon maturity in June 2012. Payment of the loan is secured by substantially all of the assets of Emergent BioDefense Operations, other than accounts receivable under BioThrax supply contracts with the DoD and HHS that are pledged as collateral to secure the $15 million revolving line of credit with Fifth Third Bank. Interest on the loan accrues at an annual rate of LIBOR plus 2.75% (7.73% as of December 31, 2007).

Under this term loan, the Company is required to maintain a book leverage ratio of less than 1.25. This ratio is calculated by dividing total liabilities, excluding deferred revenues specific to contracts with the U.S. government, by total net worth. In addition, the Company is required to maintain a debt coverage ratio of not less than 1.25 to 1.00. This ratio is calculated by dividing earnings before interest, taxes, depreciation and amortization for the most recent four quarters by the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable for the following four quarters. The Company is in compliance with these covenants as of December 31, 2007.

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

In April 2006, the Company completed the acquisition of a 145,000 square foot facility in Frederick, Maryland for $9.8 million. This facility was previously under a lease which contained an option to purchase the facility. The Company paid $1.3 million in cash and financed the remaining balance with a bank loan in the amount of $8.5 million. This loan requires monthly principal and interest payments from May 2006 through April 2011 of $72,000 with a balloon payment for the remaining unpaid principal and interest due in April 2011. The interest rate is a floating rate based on the three month LIBOR plus 3.0% (7.98% as of December 31, 2007). The loan is collateralized by the facility. The loan requires the Company to comply with certain non-financial covenants. The Company is in compliance with these covenants as of December 31, 2007.

In October 2004, the Company entered into a Secured Conditional Loan with the Maryland Economic Development Assistance Fund for $2.5 million. The proceeds of the loan were used to reimburse the Company for eligible costs it incurred to purchase a building in Frederick, Maryland. The loan is secured by a $1.3 million letter of credit and a security interest in the building. The Company is required to pay an annual fee of 1.0% to maintain the letter of credit. The borrowing bears interest at 3.0% per annum, and the term of the loan ends March 31, 2013. The principal and related accrued interest may be forgiven if specified employment levels are achieved and maintained through December 2012, at least $42.9 million in project costs are expended prior to December 2009, and the Company occupies the building through December 2012. For the loan to be forgiven, the Company must employ at least 280 full-time employees at the Company s facilities in Frederick, Maryland as of December 31, 2009 and maintain at least 280 full-time employees through December 31, 2012. If as of December 31, 2009, 2010, 2011 or 2012 the Company employs fewer than 280 and more than 225 full-time employees at the Company s facilities in Frederick, Maryland, then the Company will be required to repay $9,000 of principal plus accrued interest for each position not filled below the target level of 280 employees. If as of December 31, 2009, 2010, 2011 or 2012 the Company employs fewer than 225 full-time employees at the Company s facilities in Frederick, Maryland, then the Company will be required to repay the entire outstanding principal amount of the loan plus accrued interest. This loan is guaranteed by all of the subsidiaries of the Company.

In connection with the 2004 purchase of the building in Frederick, Maryland discussed above, the Company entered into a loan agreement for $7 million with a bank to finance the remaining portion of the purchase price. The borrowing accrued interest at 6.625% per annum through October 2006. The Company was required to make interest only payments through that date. Beginning in November 2006, the Company began to make monthly payments of $62,000, based upon a 15 year amortization schedule. In November 2009, the monthly payments will be adjusted based upon a 12 year amortization schedule. Beginning in November 2009, the loan will bear interest at a fixed rate equal to 3.2% over the yield on actively traded U.S. Government securities issues adjusted to a constant maturity of two years, rounded up to the nearest one-eighth of one percent (1/8 of 1%). All unpaid principal and interest is due in full in October 2011. The Company is required to maintain certain financial and non-financial covenants including a minimum tangible net worth of not less than $5.0 million and a debt coverage ratio of not less than 1.1 to 1. The Company is in compliance with these covenants as of December 31, 2007. This loan is guaranteed by all of the subsidiaries of the Company.

During 2004, the Company implemented an Enterprise Resource Planning (ERP) system. The Company financed $2.3 million of the costs through the issuance of a term loan. The loan bore interest at prime less 0.375%, and was fully repaid in September 2007.

Scheduled principal repayments and maturities on long-term debt as of December 31, 2007 are as follows:

(in thousands)	
2008	$ 3,514
2009	6,049
2010	3,585
2011	16,203
2012	16,751
	$ 46,102

9. Line of credit

In June 2007, the Company entered into a loan agreement with Fifth Third Bank, whereby Fifth Third Bank agreed to extend to the Company a revolving line of credit up to $15 million. Collateral for this line of credit consists of accounts receivable under supply contracts with the DoD and HHS. The Company can borrow under this line of credit through May 2008, at which time the agreement expires. The line of credit is secured by accounts receivable under the Company s DOD and HHS contracts and bears interest at the prime rate less 0.375% (7.68% as of December 31, 2007). The Company is subject to certain covenants, including maintenance of specified equity levels on a quarterly basis, and is currently in compliance with those covenants. At December 31, 2007 and 2006, $11.8 million and $8.9 million, respectively, were outstanding under the line of credit. These amounts were repaid in January 2008 and 2007, respectively.

10. Stockholders equity

Preferred stock

The Company is authorized to issue up to 15,000,000 shares of preferred stock, $0.001 par value per share (Preferred Stock). Any preferred stock issued may have dividend rates, voting rights, conversion privileges, redemption characteristics, and sinking fund requirements as approved by the Company s board of directors. As of December 31, 2007 and 2006, no preferred stock has been issued.

Common stock

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

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

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

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

Holders of Common Stock are entitled to receive dividends as and when declared by the Company s board of directors. On June 15, 2005, the Company s board of directors declared a special cash dividend to the holders of outstanding shares of Class A Common Stock and Class B Common Stock in an aggregate amount of $5.4 million. The Company s board of directors declared this special dividend in order to distribute the net proceeds of a payment received as a result of the settlement of litigation initiated in 2002 by the Company against Elan Pharmaceuticals, Inc., Athena Neurosciences, Inc. and Solstice Neurosciences, Inc. in an effort to clarify intellectual property rights, including the recovery of royalties and other costs and fees, to which the Company believed it was entitled under a series of agreements regarding the development of botulinum toxin products. The Company paid the special cash dividend on July 13, 2005 to stockholders of record as of June 15, 2005. No regular dividends have been declared or paid.

Stock options

As of December 31, 2007, the Company has two stock-based employee compensation plans, the 2006 Plan and the 2004 Plan (together, the Emergent Plans), under which the Company has granted options to purchase shares of Common Stock. The Emergent Plans have both incentive and non-qualified stock option features.

The 2006 Plan, established in connection with the Company s initial public offering in November 2006, initially authorized the issuance of up to 1,089,461 shares of Common Stock. In addition, the 2006 Plan contains an evergreen provision that allows for increases in the number of shares authorized for issuance under the 2006 Plan in the first and third quarter of each year from 2007 through 2009. Each semi-annual increase in the number of shares will be equal to the lowest of: (1) a specified number of shares stipulated in the 2006 Plan; (2) a specified percentage of the aggregate number of shares outstanding; and (3) an amount determined by the Company s Board of Directors. The maximum specified number of shares per semi-annual increase ranges from 428,700 to 937,900. The maximum specified percentage of outstanding shares for each semi-annual increase ranges from 1.5% to 3.0%. Accordingly, an aggregate of 1,949,362 shares of Common Stock are authorized for issuance under the 2006 Plan as of December 31, 2007. The Company has granted options to purchase a total of 1,380,111 shares of Common Stock under the 2006 Plan as of December 31, 2007. The maximum number of options that may be granted per year under the 2006 Plan to a single participant is 287,700. The exercise price of each incentive option must be not less than 100% of the fair market value of the shares on the date of grant. Options granted under the 2006 Plan have a vesting period of no more than 5 years and a contractual life of no more than 10 years. The terms and conditions of stock options (including price, vesting schedule, term and number of shares) under the Emergent Plans are determined by the Company s compensation committee, which administers the Emergent Plans. Following the closing of the Company s initial public offering, the Company no longer granted options pursuant to the 2004 Plan.

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

	2006 Plan Number of Shares		**Weighted-Average Exercise Price**	**2004 Plan Number of Shares**		**Weighted-Average Exercise Price**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2006	1,030,500	$	10.13	2,936,389	$	2.53	26,375,147
Exercisable at December 31, 2006	-	$	-	2,395,693	$	1.43	23,310,093
Granted	620,811		9.44	-		-	
Exercised	-		-	(2,153,988)		1.15	
Forfeited	(271,200)		10.41	(110,668)		8.31	
Cancelled	-		-	(5,214)		1.49	
Outstanding at December 31, 2007	1,380,111	$	9.77	666,519	$	6.04	743,995
Exercisable at December 31, 2007	289,900	$	10.27	507,802	$	4.94	682,439

The weighted average remaining contractual term of options outstanding as of December 31, 2007 and 2006 was 5.5 and 3.2 years, respectively. The weighted average remaining contractual term of options exercisable as of December 31, 2007 and 2006 was 4.6 and 1.1 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2007, 2006 and 2005 was $3.58, $3.94 and $1.37, respectively. The total intrinsic value of options exercised during the years ended December 31, 2007, 2006 and 2005 was $20.5 million, $2.3 million and $563,000, respectively. The total fair value of shares vested during 2007 was $1.9 million.

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

(in thousands)	**Years Ended December 31, 2007**		**2006**
Cost of sales	$	82	$ 3
Research and development		377	97
General and administrative		2,082	623
Total stock-based compensation expense	$	2,541	$ 723

A summary of the status of the Company s nonvested stock options at December 31, 2007 is presented below:

	2006 Plan			2004 Plan		
	Number of Shares		Weighted Average Grant Date Fair Value	Number of Shares		Weighted Average Grant Date Fair Value
Nonvested at December 31, 2006	1,030,500	$	3.09	537,532	$	5.30
Granted	620,811		3.58	-		-
Exercised	-		-	-		-
Vested	(289,900)		3.91	(278,598)		2.84
Forfeited	(271,200)		3.85	(100,217)		3.00
Nonvested at December 31, 2007	1,090,211	$	3.66	158,717	$	3.53

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

11. Income taxes

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

	Year Ended December 31,		
(in thousands)	2007	2006	2005
Current			
Federal	$ 11,189	$ 14,212	$ 16,093
State	2,275	812	200
Total Current	13,464	15,024	16,293
Deferred			
Federal	2,832	100	(9,769)
State	(3,245)	98	(1,199)
Total Deferred	(413)	198	(10,968)
Total Provision for Income Taxes	$ 13,051	$ 15,222	$ 5,325

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

	December 31,	
(in thousands)	2007	2006
Net operating loss carryforward	$ 6,361	$ 4,160
Research and development credit carryforward	511	549
Stock compensation	523	1,452
Foreign deferrals	39,044	32,534
Other	1,508	1,681
Deferred tax asset	47,947	40,376
Fixed assets	(756)	(888)
Other	(1,303)	(433)
Deferred tax liability	(2,059)	(1,321)
Valuation allowance	(33,702)	(27,283)
Net deferred tax asset	$ 12,186	$ 11,772

Net operating loss carryforwards consist of approximately $118 million for state jurisdictions and $100 million for foreign jurisdictions. The state net operating loss carryforwards will begin to expire in 2018. The foreign net operating loss carryforwards will have an indefinite life unless the foreign entities have a change in the nature or conduct of the business in the three years following a change in ownership. The use of the Company s net operating loss carryforwards may be restricted due to changes in Company ownership.

The provision for income taxes differs from the amount of taxes determined by applying the U.S. federal statutory rate to loss before provision for income taxes as a result of the following:

	Year ended December 31,		
(in thousands)	**2007**	**2006**	**2005**
US	$ 62,016	$ 56,698	$ 54,259
International	(26,029)	(18,683)	(33,150)
Earnings before taxes on income	35,987	38,015	21,109
Federal tax at statutory rates	$ 12,595	$ 13,305	$ 7,388
State taxes, net of federal benefit	701	(395)	(2,329)
Impact of foreign operations	(7,106)	(6,050)	(17,982)
Change in valuation allowance	6,419	6,605	18,995
Effect of change in rates	493	-	-
Effect of foreign rates	154	752	264
Tax credits	(880)	(759)	(474)
Other differences	(617)	1,044	(212)
Permanent differences	1,292	720	(325)
Provision for income taxes	$ 13,051	$ 15,222	$ 5,325

The effective annual tax rate for the years ended December 31, 2007, 2006 and 2005 was 36%, 40% and 25%, respectively. The decrease in the effective rate from 2006 to 2007 was due primarily to a reduction in state valuation allowances related to the expected utilization of net operating losses.

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

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

A reconciliation of the beginning and ending balances of the total amounts of gross unrecognized tax benefits is as follows:

(in thousands)	
Gross unrecognized tax benefits at January 1, 2007	$ 607
Increases for tax positions for prior years	262
Decreases for tax positions for prior years	(65)
Increases for tax positions for current year	100
Settlements	(201)
Lapse of statue of limitations	(426)

Gross unrecognized tax benefits at December 31, 2007	$	277

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

The Company s federal and state income tax returns for the tax years 2006-2004 remain open to examination. The Company s tax returns in the United Kingdom remain open to examination for the tax years 2006-2001, and tax returns in Germany remain open indefinitely. A federal income tax audit of the Company's tax return for the 2004 tax year was completed in March 2007. As a result of this audit, the Company paid an assessment of $722,000, including $96,000 of interest. The Company is the subject of an ongoing federal income tax audit for the tax year ended December 31, 2005. The financial statement impact of the audit has been estimated at approximately $451,000, including $56,000 of interest. This amount has been accrued as of December 31, 2007.

12. 401(k) savings plan

The Company has established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers substantially all employees. Under the 401(k) Plan, employees may make elective salary deferrals. The Company provides for matching of qualified deferrals up to 50% of the first 6% of the employee s salary. During the years ended December 31, 2007, 2006 and 2005, the Company made matching contributions of approximately $682,000, $573,000 and $520,000, respectively.

13. Commitments and settlement gains

Leases

The Company leases laboratory and office facilities, office equipment and vehicles under various operating lease agreements. The Company leases office and laboratory space in Gaithersburg, Maryland under a non-cancelable operating lease that contains a 3% annual escalation and expires in November 2008. The Company leases office and laboratory space in Wokingham, England under two coterminous non-cancelable operating leases that expire in November 2016. The Company leases office space in Rockville, Maryland under a non-cancelable operating lease that contains a 3% annual escalation clause over the ten year term of the lease, which expires in December 2016 and the Company has a five year renewal option at the end of the initial term. For the years ended December 31, 2007, 2006 and 2005, total rent expense was $3.4 million, $2.4 million and $2.5 million, respectively.

Future minimum lease payments under operating lease obligations as of December 31, 2007 are as follows:

(in thousands)	
2008	$ 2,048
2009	1,436
2010	1,453
2011	1,471
2012	1,489
2013 and beyond	6,086
Total minimum lease payments	$ 13,983

Litigation

In June 2002, the Company initiated a lawsuit against Élan Pharmaceuticals and related entities in an effort to clarify intellectual property rights, including the recovery of royalties and other costs and fees, to which the Company believed it was entitled under a series of agreements and to clarify intellectual property rights associated with those agreements. The Company sought damages, injunctive relief and declaratory relief. On June 27, 2005, the Company obtained a settlement pursuant to which Élan and related entities agreed to pay the Company $10.0 million. Payment of such settlement was received by the Company in July 2005. The agreement also clarified the parties intellectual property rights. Upon receipt of the settlement from Élan Pharmaceuticals and related entities, the Company distributed a net settlement amount (total proceeds from the settlement less reserves for applicable federal and state income taxes, legal expenses related to the suit and other miscellaneous expenses) of $5.4 million to all Company stockholders of record as of June 15, 2005.

From time to time, the Company is involved in product liability claims and other litigation considered normal in the nature of its business. The Company does not believe that any such proceedings would have a material, adverse effect on the results of its operations. For claims filed against the Company for use of BioThrax by the DoD, the Company expects to rely on contractual indemnification provisions with the DoD and statutory protections to limit our potential liability resulting from the pending lawsuits.

14. Related party transactions

The Company has engaged Wilmer Cutler Pickering Hale and Dorr LLP ("WilmerHale") to provide certain legal services to the Company. The Company's Senior Vice President Legal Affairs and General Counsel is married to a partner at WilmerHale, who has not participated in providing legal services to the Company. The Company has incurred fees for legal services rendered by WilmerHale of approximately $1.0 million for the year ended December 31, 2007. Of this amount, approximately $131,000 was in accounts payable at December 31, 2007.

The Company has entered into marketing and sales contracts with entities controlled by family members of the Chief Executive Officer to market and sell BioThrax in certain international territories if certain conditions are met. A consulting arrangement with the Chief Executive Officer s sister required a payment of 4% of net sales, not to exceed $2.00 per dose, under the agreement. This arrangement terminated in 2006. A marketing arrangement with an entity affiliated with the family of Chief Executive Officer required a payment of 40% of gross sales in countries in the Middle East and North Africa, except Israel. This arrangement terminated in 2007. A similar marketing arrangement with the same entity was entered into in 2008 that requires a payment of 17.5% of net sales and reimbursement of certain expenses, for certain countries in the Middle East and North Africa, excluding countries to which export is prohibited by the U.S. government. No royalty payments under these agreements have been triggered for the years ended December 31, 2007, 2006 and 2005.

The Company has entered into consulting, lease and transportation arrangements with various persons or entities affiliated with the Chief Executive Officer and two members of the board of directors. At December 31, 2007 and 2006, there was $18,000 and $17,000, respectively, in accounts payable for these services. For the years ended December 31, 2007, 2006 and 2005, the Company paid approximately $200,000, $387,000 and, $625,000, respectively, to various persons or entities affiliated with two members of our board of directors. For the years ended December 31, 2007, 2006 and 2005, the Company paid approximately $33,000, $33,000 and $169,000, respectively, to entitles owned by or affiliated with the Chief Executive Officer. The Company currently has an agreement with a director to perform corporate strategic issues consultation and directed project support to the marketing and communications group and an agreement with a company owned by the Chief Executive Officer to provide transportation and logistical support.

Simba LLC, a Maryland based limited liability company 100% owned by the Company s Chief Executive Officer and his wife, provides chartered air transportation. Simba offers its services to the Company on a discount from Simba s normal commercial rate. For the years ended December 31, 2006 and 2005, the Company paid approximately $13,000 and $34,000, respectively, for transportation on an as needed basis for business purposes. In May 2006, this arrangement was terminated.

15. Segment information

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

	Reportable Segments			
(in thousands)	**Biodefense**	**Commercial**	**All Other**	**Total**
Year Ended December 31, 2007				
External revenue	$ 179,738	$ 3,177	$ -	$ 182,915
Intersegment revenue (expense)	-	-	-	-
Research and development	24,744	26,159	3,055	53,958
Interest revenue	-	-	2,809	2,809
Interest expense	-	-	(71)	(71)
Depreciation and amortization	3,445	947	425	4,817
Net Income (loss)	76,397	(38,213)	(15,248)	22,936
Assets	133,692	21,672	118,144	273,508
Expenditures for long-lived assets	38,880	1,991	3,098	43,969
Year Ended December 31, 2006				
External revenue	$ 147,707	$ 5,025	$	$ 152,732
Intersegment revenue (expense)	-	-	-	-
Research and development	22,219	22,425	857	45,501
Interest revenue	-	-	846	846
Interest expense	-	-	(1,152)	(1,152)
Depreciation and amortization	3,586	830	299	4,715

Net income (loss)	55,074	(24,538)	(7,743)	22,793
Assets	125,562	13,732	98,961	238,255
Expenditures for long-lived assets	29,273	1,455	10,500	41,228

The accounting policies of the segments are the same as those described in Note 2 Summary of significant accounting policies. There are no inter-segment transactions.

16. Quarterly financial data (unaudited)

Quarterly financial information for the years ended December 31, 2007 and 2006 is presented in the following tables:

(in thousands)	Three months ended March 31,	June 30,	September 30,	December 31,
Fiscal year 2007				
Revenue	$ 26,448	$ 23,186	$ 43,644	$ 89,637
Income (loss) from operations	(5,831)	(8,657)	4,422	43,159
Net income (loss)	(2,690)	(4,961)	2,845	27,742
Net income (loss) per share, basic	(0.10)	(0.17)	0.10	0.93
Net income (loss) per share, diluted	(0.10)	(0.17)	0.10	0.93
Fiscal year 2006				
Revenue	$ 12,223	$ 11,446	$ 42,174	$ 86,889
Income (loss) from operations	(9,398)	(6,194)	9,720	43,900
Net income (loss)	(4,636)	(3,054)	4,354	26,129
Net income (loss) per share, basic	(0.21)	(0.14)	0.19	1.04
Net income (loss) per share, diluted	(0.21)	(0.14)	0.18	0.99

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2007. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2007, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed

the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework*. Based on this assessment, our management concluded that, as of December 31, 2007, our internal control over financial reporting is effective based on those criteria.

Ernst & Young LLP, the independent registered public accounting firm that has audited our consolidated financial statements included herein, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2007, a copy of which is included in this annual report on Form 10-K.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the fiscal quarter ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

We have audited Emergent BioSolutions Inc. and Subsidiaries internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Emergent BioSolutions Inc. and Subsidiaries management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, Emergent BioSolutions Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Emergent BioSolutions Inc. and Subsidiaries as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2007 of Emergent BioSolutions Inc. and Subsidiares and our report dated March 6, 2008 expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

McLean, Virginia

March 6, 2008

ITEM 9B. OTHER INFORMATION

Marketing Agreement

On March 6, 2008, we entered into an amended and restated marketing agreement (the Marketing Agreement) with Intergen N.V.("Intergen"). The Marketing Agreement amends and restates a prior amended and restated marketing agreement (the Prior Agreement). The Marketing Agreement is effective as of November 5, 2007, the date the Prior Agreement expired in accordance with its terms. Yasmine Gibellini, the chairperson and a major shareholder of Intergen is the sister of Fuad El-Hibri, our chief executive officer and chairman of our board of director. Ms. Gibellini is also an owner of Biologika L.L.C.

Under the Marketing Agreement, we appointed Intergen as our marketing representative for the sale and promotion of BioThrax, anthrax immune globulin, recombinant botulinum vaccine and botulinum immune globulin in a territory comprised of specified countries in the Middle East and North Africa, excluding countries to which export is prohibited by the U.S. government. The appointment is exclusive until November 5, 2008. If the Marketing Agreement is extended beyond November 5, 2008, the appointment will become non-exclusive. We agreed to pay Intergen a fee equal to 17.5% of net sales of the marketed products pursuant to customer contracts in these countries. The fee is only payable pursuant to customer contracts entered into after the exclusivity period if Intergen introduces the customer to us and engages in meaningful activity that leads to the purchase transaction. Under the Marketing Agreement, we agreed to reimburse Intergen for out-of-pocket expenses attributable to a particular purchase contract up to a specified percentage of net sales under that contract.

The term of the Marketing Agreement is scheduled to expire on November 5, 2008. The Marketing Agreement provides for an extension of an additional three years until November 5, 2011 if on or prior to November 5, 2008 we enter into customer contracts for the sale of marketed products in the territory with a committed dollar amount of at least $15.0 million. This automatic extension also applies if Intergen procures a written firm order for the purchase of a marketed product from a customer in the territory prior to November 5, 2008 and such order results in the execution on or before May 5, 2009 of a customer contract for the sale of the marketed product in the territory with a committed dollar amount of a least $15.0 million.

Executive Compensation

On March 3, 2008, the Compensation Committee awarded cash bonuses to the following executives in the following amounts: Fuad El-Hibri, $307,857; Daniel J. Abdun-Nabi, $179,570; R. Don Elsey, $91,313; Denise Esposito, $66,582; Kyle W. Keese, $67,066; Robert Kramer, $150,842. Also on March 3, 2008, the Compensation Committee approved the following base salaries and target bonus percentages for the following executives, all effective as of January 1, 2008: Fuad El-Hibri, $538,750 and 50%; Daniel J. Abdun-Nabi, $391,388 and 45%; R. Don Elsey, $296,400 and 40%; Denise Esposito, $270,400 and 35%; Kyle W. Keese, $275,600 and 35%.

Executive Resignation

On March 7, 2008, Shahzad Malik notified the Board of Directors that he would be resigning from the Board of Directors effective March 12, 2007.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

Information regarding our directors may be found under the caption "Election of Directors" in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Information regarding our executive officers may be found under the caption Executive Officers of the Registrant" in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Compliance with Section 16(a) of the Exchange Act

Information regarding compliance with Section 16(a) of the Exchange Act by our directors, officers and beneficial owners of more than 10% of our common stock may be found under the caption "Stock Ownership Information Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Code of Ethics

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

Director Nominees

Information regarding procedures for recommending nominees to the board of directors may be found under the caption Corporate Governance Director Nomination Process in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Audit Committee

We have separately designated a standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Additional information regarding the Audit Committee may be found under the captions Corporate Governance Board Committees Audit Committee and Corporate Governance Audit Committee Report in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Audit Committee Financial Expert

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

ITEM 11. EXECUTIVE COMPENSATION

Information with respect to this item may be found under the caption Information About Executive and Director Compensation in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference. The Compensation Committee Report contained in the Proxy Statement for our 2008 Annual Meeting of Stockholders shall be deemed furnished in this annual report on Form 10-K and shall not be deemed soliciting material or filed with the Securities and Exchange Commission or otherwise subject to the liabilities of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that we specifically request that such information be treated as soliciting material or specifically incorporate such information by reference into a document filed under the Securities Act or the Exchange Act.

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

Information with respect to this item may be found under the captions Stock Ownership Information and Information About Executive and Director Compensation Securities Authorized for Issuance Under Equity Compensation Plans in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

Information with respect to this item may be found under the captions Corporate Governance Transactions with Related Persons and Corporate Governance Board Determination of Independence in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information with respect to this item may be found under the captions Corporate Governance Registered Public Accounting Firm's Fees and Corporate Governance Pre-Approval Policy and Procedures in the Proxy Statement for our 2008 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statements

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets at December 31, 2007 and 2006

Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005

Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005

Consolidated Statement of Changes in Stockholders Equity for the years ended December 31, 2007, 2006 and 2005
Notes to Consolidated Financial Statements

Financial Statement Schedules

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

Exhibits

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

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

By: /s/Fuad El-Hibri

Fuad El-Hibri
Chief Executive Officer and
Chairman of the Board of Directors
Date: March 7, 2008

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

Signature	Title	Date
/s/Fuad El-Hibri Fuad El-Hibri	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 7, 2008
/s/R. Don Elsey R. Don Elsey	Senior Vice President Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 7, 2008
/s/Joe M. Allbaugh Joe M. Allbaugh	Director	March 7, 2008
/s/Zsolt Harsanyi, Ph.D. Zsolt Harsanyi, Ph.D.	Director	March 7, 2008
/s/Jerome M. Hauer Jerome M. Hauer	Director	March 7, 2008
/s/Shahzad Malik, M.D. Shahzad Malik, M.D.	Director	March 7, 2008
/s/Ronald B. Richard Ronald B. Richard	Director	March 7, 2008

/s/Louis W. Sullivan, M.D.		
Louis W. Sullivan, M.D.	Director	March 7, 2008
/s/Sue Bailey, M.D.		
Sue Bailey, M.D.	Director	March 7, 2008

EXHIBIT INDEX

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.1 to Amendment No. 5 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622 filed on October 30, 2006))
3.2#	Amended and Restated By-laws of the Registrant, as amended
4.1	Specimen Certificate Evidencing Shares of Common Stock (Incorporated by reference to Exhibit 4.1 to Amendment No. 3 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on October 20, 2006)
4.2	Registration Rights Agreement, dated June 23, 2005, between the Registrant and Microscience Investments Limited, formerly Microscience Holdings plc (Incorporated by reference to Exhibit 4.2 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
4.3	Registration Rights Agreement, dated September 22, 2006, among the Registrant and the entities listed on Schedule 1 thereto (Incorporated by reference to Exhibit 4.3 to Amendment No. 1 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
4.4	Rights Agreement, dated November 14, 2006, between the Registrant and American Stock Transfer & Trust Company (Incorporated by reference to Exhibit 4.4 to Amendment No. 5 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on October 30, 2006)
4.5	Assignment and Assumption Agreement by and between the Registrant, Microscience Investments Limited and the Investors named therin, dated March 8, 2007, relating to the Registration Rights Agreement, dated June 23, 2005, between the Registrant and Microscience Investments Limited (Incorporated by reference to Exhibit 4.5 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2006 (File No. 001-33137))
9.1	Voting and Right of First Refusal Agreement, dated October 21, 2005, between the William J. Crowe, Jr. Revocable Living Trust and Fuad El-Hibri (Incorporated by reference to Exhibit 9.1 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
9.2	Voting Agreement, dated June 30, 2004, between BioPharm, L.L.C. and Michigan Biologic Products, Inc. (Incorporated by reference to Exhibit 9.2 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
9.3	Voting Agreement, dated June 30, 2004, between BioPharm, L.L.C. and Biologika, L.L.C. (Incorporated by reference to Exhibit 9.3 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
9.4	Voting Agreement, dated June 30, 2004, by and among the stockholders named therein (Incorporated by reference to Exhibit 9.4 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.1*	Employee Stock Option Plan, as amended and restated (Incorporated by reference to Exhibit 10.1 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.2*	Form of Director Stock Option Agreement (Incorporated by reference to Exhibit 10.2 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.3*	2006 Stock Incentive Plan (Incorporated by reference to Exhibit 10.3 to Amendment No. 5 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on October 30, 2006)
10.4*	Form of Incentive Stock Option Agreement under 2006 Stock Incentive Plan (Incorporated by reference to Exhibit 10.4 to Amendment No. 5 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on October 30, 2006)
10.5*	Form of Nonstatutory Stock Option Agreement under 2006 Stock Incentive Plan (Incorporated by reference to Exhibit 10.5 to Amendment No. 5 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on October 30, 2006)
10.6#*	Director Compensation Program
10.7 *	Severance Plan and Termination Protection Program (Incorporated by reference to Exhibit 10.6 to Amendment No. 3 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on October 20, 2006)
10.8*	Election of Fuad El-Hibri to Participate in the Severance Plan and Termination Protection Program (Incorporated by reference to Exhibit 10.35 to Amendment No. 1 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
10.9	Form of Indemnity Agreement (Incorporated by reference to Exhibit 10.7 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)

10.10	Contract No. HHSO100200700037C, dated September 25, 2007, between Emergent BioDefense Operations Lansing Inc., and the Department of Health and Human Services (Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 (File No. 001-33137))
10.11	Filling Services Agreement, dated March 18, 2002, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Hollister-Stier Laboratories LLC, as amended (Incorporated by reference to Exhibit 10.10 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.12	Amendment No. 5 to the Filling Services Agreement, effective May 14, 2007 between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Hollister-Stier Laboratories LLC (Incorporated by reference to Exhibit 10.6 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137))
10.13	BT Vaccine License Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency (Incorporated by reference to Exhibit 10.11 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.14	BT Vaccine Development Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency (Incorporated by reference to Exhibit 10.12 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.15	rBot Vaccine License Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency (Incorporated by reference to Exhibit 10.13 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.16	rBot Vaccine Development Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency (Incorporated by reference to Exhibit 10.14 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.17	License and Co-development Agreement, dated May 6, 2006, between Emergent Product Development UK Limited, formerly Emergent Europe Limited, and Sanofi Pasteur, S.A (Incorporated by reference to Exhibit 10.33 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.18	Product Supply Agreement, dated June 12, 2006, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics, Inc. (Incorporated by reference to Exhibit 10.34 to Amendment No. 3 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on October 20, 2006)
10.19	Agreement, dated June 16, 2005, between the Free State of Bavaria and Emergent Product Development UK, formerly ViVacs GmbH (Incorporated by reference to Exhibit 10.43 to Amendment No. 3 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on October 20, 2006)
10.20	Exclusive Distribution Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency (Incorporated by reference to Exhibit 10.15 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.21	Investment Agreement relating to Microscience Holdings plc, dated March 18, 2005, among the Wellcome Trust, Microscience Investments Limited, formerly Microscience Holdings plc, and Emergent Product Development UK Limited, formerly Microscience Limited, as amended (Incorporated by reference to Exhibit 10.16 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.22	Consulting Services Agreement, dated March 1, 2006, between the Registrant and The Hauer Group (Incorporated by reference to Exhibit 10.19 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.23	Amendment to Consulting Services Agreement effective March 30, 2007, between the Registrant and The Hauer Group (Incorporated by reference to Exhibit 10.44 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2006 (File No. 001-33137))
10.24	Services Agreement, dated August 1, 2006, between East West Resources Corporation and the Registrant (Incorporated by reference to Exhibit 10.36 to Amendment No. 1 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
10.25	Lease, dated December 1, 1998, between ARE-QRS, Corp. and Antex Biologics Inc., as amended (Incorporated by reference to Exhibit 10.21 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.26	Lease (540 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire), dated December 13, 1996, between Slough Properties Limited and Azur Environmental Limited, as assigned to Emergent Product Development UK Limited, formerly Microscience Limited (Incorporated by reference to Exhibit 10.22 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.27	Lease (545 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire), dated December 13, 1996, between Slough Properties Limited and Azur Environmental Limited, as assigned to Emergent Product

	Development UK Limited, formerly Microscience Limited (Incorporated by reference to Exhibit 10.23 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.28	Lease Agreement, dated May 10, 2007, among Slough Estates (Winnerish) Limited, Emergent Product Development UK Limited and the Registrant (Incorporated by reference to Exhibit 10.5 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137))
10.29	Lease Agreement, dated June 27, 2006, between Brandywine Research LLC and the Registrant (Incorporated by reference to Exhibit 10.24 to Amendment No. 1 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
10.30	Loan and Security Agreement, dated October 14, 2004, among the Registrant, Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., Antex Biologics Inc., Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Mercantile Potomac Bank (Incorporated by reference to Exhibit 10.26 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.31	Promissory Note, dated October 14, 2004, from Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., to Mercantile Potomac Bank (Incorporated by reference to Exhibit 10.27 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.32	Loan Agreement, dated October 15, 2004, between Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., and the Department of Business and Economic Development (Incorporated by reference to Exhibit 10.28 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.33	Deed of Trust Note, dated October 14, 2004, between Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., and the Department of Business and Economic Development (Incorporated by reference to Exhibit 10.29 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.34	Term Note, dated August 10, 2004, from Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, to Fifth Third Bank (Incorporated by reference to Exhibit 10.30 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.35	Loan Agreement, dated April 25, 2006, among the Registrant, Emergent Frederick LLC and HSBC Realty Credit Corporation (USA) (Incorporated by reference to Exhibit 10.31 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.36	Bond Purchase Agreement, dated March 31, 2005, between the County Commissioners of Frederick County, Emergent Commercial Operations Frederick Inc., formerly Emergent Biologics Inc., and Mercantile Potomac Bank (Incorporated by reference to Exhibit 10.32 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.37	Promissory Note, dated April 25, 2006, from Emergent Frederick LLC to HSBC Realty Credit Corporation (USA) (Incorporated by reference to Exhibit 10.39 to Amendment No. 1 to the Registrant s Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
10.38	Loan Agreement, dated June 29, 2007, among the Registrant, Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and HSBC Realty Credit Corporation (USA) (Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137))
10.39	Promissory Note, dated June 29, 2007, from Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, to HSBC Realty Credit Corporation (USA) (Incorporated by reference to Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137))
10.40	Loan Agreement, dated June 8, 2007, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Fifth Third Bank (Incorporated by reference to Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137))
10.41	Revolving Credit Note, dated June 8, 2007, from Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, to Fifth Third Bank (Incorporated by reference to Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137))
21.1#	Subsidiaries of the Registrant
23.1#	Consent of Independent Registered Public Accounting Firm
31.1#	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)
31.2#	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)
32.1 #	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2 #	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Filed herewith
(1) Incorporated by reference to the exhibits to the Registrant s registration statement on Form S-1 (File No. 333-136622).
(2) Incorporated by reference to the exhibits to the Registrant s registration statement on Form S-8 (File No. 333-139190).
Confidential treatment granted by the Securities and Exchange Commission as to certain portions. Confidential materials omitted and filed separately with the Securities and Exchange Commission.
* Management contract or compensatory plan or arrangement filed herewith in response to Item 15(a) of Form 10-K.