Emergent BioSolutions Inc.
Form 10-K
March 27, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT

PURSUANT TO SECTIONS 13 OR 15(d)

OF THE SECURITIES EXCHANGE ACT OF 1934

(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, 2006

OR

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

Commission file number: **001-33137**

EMERGENT BIOSOLUTIONS INC.

(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Organization)	**14-1902018** (IRS Employer Identification No.)

2273 Research Boulevard, Suite 400

Rockville, Maryland (Address of Principal Executive Offices)	**20850** (Zip Code)

Registrant s telephone number, including area code**(301) 795-1800**

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common stock, $0.001 par value per share	**New York Stock Exchange**
Series A junior participating preferred stock purchase rights	**New York Stock Exchange**

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

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

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

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

Indicate by check mark 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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant as of March 15, 2007 was approximately $66,322,000 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 March 15, 2007, the registrant had 28,000,552 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement for its 2007 annual meeting of stockholders scheduled to be held on June 14, 2007, 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, 2006, 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 2007 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, 2006

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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 performance under existing BioThrax sales contracts with the U.S. government, including the timing of deliveries under these contracts;
- our ability to obtain new BioThrax sales contracts with the U.S. government;
- 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 biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics, which are a subset of products that are known as biologics. Immunobiotics are biologics that induce or assist the body s immune system to prevent or treat disease,

consisting of vaccines and certain therapeutic products, including immune globulins. We operate in two business segments: biodefense and commercial. In our biodefense business, we develop, manufacture and commercialize immunobiotics for use against biological agents that are potential weapons of bioterrorism and biowarfare. In our commercial business, we develop immunobiotics for use against infectious disease. Our commercial immunobiotic product candidates are designed to address significant unmet or underserved public health needs. Our marketed product, BioThrax, is the

only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. In addition to BioThrax, our biodefense product portfolio includes multiple biodefense product candidates in preclinical development and a next generation anthrax vaccine program, which includes a product candidate in Phase I clinical development. Our commercial product portfolio includes a typhoid vaccine candidate and a hepatitis B therapeutic vaccine candidate, both of which are in Phase II clinical development, one vaccine candidate in Phase I clinical development and two vaccine candidates in preclinical development.

We manufacture and market BioThrax, also referred to as anthrax vaccine adsorbed, the only FDA-approved anthrax vaccine. BioThrax was originally approved in the United States in 1970. There have been more than 20 published studies of the use of BioThrax in humans. In December 2005, based on a review of the human efficacy data used to support the approval of BioThrax and other studies of BioThrax, the FDA reaffirmed that BioThrax is safe and effective for the prevention of anthrax infection by all routes of exposure, including inhalation. Our total revenues from BioThrax sales were $81.0 million in 2004, $127.3 million in 2005 and $148.0 million in 2006.

The U.S. Department of Defense, or DoD, and the U.S. Department of Health and Human Services, or HHS, have been the principal customers for BioThrax. Under two contracts with the DoD, we have supplied over nine million doses of BioThrax through December 2006 for immunization of military personnel. Since March 1998, the DoD has vaccinated more than 1.5 million military personnel with more than 5.7 million doses of BioThrax. Our most recent contract with the DoD provides for the supply of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. We delivered to the DoD approximately 480,000 of these doses in December 2006, and expect to deliver the balance by September 2007. The DoD s right to order additional doses of BioThrax under this contract expired in February 2007. In April 2006, the DoD issued a notice that it intends to negotiate a sole source fixed price contract for the purchase of up to an additional 11 million doses of BioThrax over one base contract year plus four option years. Since May 2005, we have supplied 10 million doses of BioThrax to HHS for inclusion in the strategic national stockpile, or SNS. In May 2005, we entered into an agreement to supply five million doses of BioThrax for the SNS for a fixed price of $123 million. We completed delivery of all five million doses by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax for the SNS by May 2007 for a fixed price of $120 million. We delivered approximately four million of those doses in 2006 and the balance in February 2007, more than two months earlier than required.

The September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks significantly affected political and budgetary attitudes toward the threat of bioterrorism. Following these attacks, the U.S. government enacted measures to provide incentives for private industry to develop and manufacture biodefense products. In particular, in 2004, the Project BioShield Act, or Project BioShield, became law, providing $5.6 billion in appropriations over ten years and authorizing the procurement of countermeasures for biological, chemical, radiological and nuclear attacks. Project BioShield provides for the procurement of countermeasures for anthrax and botulism, which are two of the biological agents that the Centers for Disease Control and Prevention, or CDC, has identified as the greatest possible threat to public health. The U.S. government procures most biodefense countermeasures through HHS, the CDC and the DoD and provides biodefense research and development funding through the National Institute of Allergy and Infectious Diseases, or the NIAID, of the National Institutes of Health, or NIH, and the DoD.

In addition to our anthrax vaccine program, we have three biodefense immunobiotic product candidates in preclinical development:

- *Anthrax immune globulin* for post-exposure treatment of anthrax infection, which we are developing in part with funding from the NIAID;
- *Botulinum immune globulin* for post-exposure treatment of illness caused by botulinum toxin, which we are developing based on a new botulinum toxoid vaccine that we are developing in collaboration with the U.K. Health Protection Agency, or HPA; and
- *Recombinant bivalent botulinum vaccine* a prophylaxis for illness caused by botulinum toxin, which we also are developing in collaboration with HPA.

We also have established a program to develop additional anthrax vaccine product candidates that would incorporate advanced characteristics, including one or more of the following: novel delivery, reduced number of doses, enhanced immune response, longer shelf life, and room temperature storage. Our most advanced product candidate in this program is based on BioThrax combined with VaxImmune . VaxImmune, a product of Coley Pharmaceutical Group, is an adjuvant intended to enhance immune response. We are also evaluating several novel delivery devices and an anthrax vaccine product candidate based on a recombinant protective antigen.

In our commercial business, we are developing a range of immunobiotic product candidates that are designed to address significant unmet or underserved public health needs caused by infectious diseases. Our commercial product candidates in clinical development are:

Typhoid vaccine a single dose, drinkable vaccine, for which we have completed a Phase I clinical program, with trials in the United States, the United Kingdom and Vietnam, and initiated a Phase II clinical development program with initial clinical testing in Vietnam and subsequent clinical testing anticipated in India;

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

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

In addition, we are developing a chlamydia vaccine and a meningitis B vaccine, each of which is currently in preclinical development.

We have established collaborations and funding arrangments for certain of our product candidates. The Wellcome Trust provided funding for our Phase I clinical trial of our typhoid vaccine candidate in Vietnam and has agreed to provide funding for our Phase II clinical trial of this vaccine candidate in Vietnam. In the fourth quarter of 2006, the NIAID agreed to fund, manage and conduct a Phase I clinical study of our group B streptococcus vaccine candidate. In May 2006, we entered into a license and co-development agreement with Sanofi Pasteur, the vaccines business of Sanofi-Aventis, under which we granted Sanofi Pasteur an exclusive, worldwide license under our proprietary technology to develop and commercialize a meningitis B vaccine candidate.

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:

Maximize the commercial potential of BioThrax. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers and pursuing label expansions and improvements for BioThrax. The potential label expansions and improvements for BioThrax include an extension of shelf life, reductions in the number of required doses, addition of another method of administration and use as a post-exposure prophylaxis for anthrax infection in combination with antibiotic therapy.

Continue to develop a balanced portfolio of immunobiotic products. We seek to maintain a balanced product portfolio that includes both biodefense and commercial immunobiotic product candidates consisting of vaccines and therapeutics to diversify product development and commercialization risk. We use multiple technologies to develop and manufacture our product candidates, which we believe significantly reduces our risk in these activities. We expect that biodefense product candidates may generate revenues from product sales sooner than commercial product candidates because of Project BioShield, which allows the U.S. government to purchase biodefense products for the SNS before they are approved by the FDA.

Focus on core capabilities in product development and manufacturing. We focus our efforts on immunobiotic product development and manufacturing, which we believe are our core capabilities. This approach enables us to avoid the expense and time entailed in early stage research activities and, we believe, reduces product development and commercialization risk. We seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties. We believe that we have secured, and will be able to continue to secure, rights to a diverse product pipeline focused on immunobiotics for use against biological agents that are potential weapons of bioterrorism or biowarfare or that address significant unmet or undeserved public health needs. We also believe that this approach may enable us to accelerate product development timelines.

Build a large scale manufacturing infrastructure. To augment our existing manufacturing capabilities, we are constructing a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus. We also own two buildings in Frederick,

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Maryland that are available to support our future manufacturing requirements. We are constructing our new facility in Lansing as a large scale commercial manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures. We anticipate that we will initiate large scale manufacturing of BioThrax for commercial sale at the new Lansing facility in 2008. We are constructing this facility to accommodate production of up to 40 million doses of BioThrax per year on a single production line, which we could expand for production of up to 80 million doses per year through the addition of a second production line. In comparison, our current facility has a maximum production capacity of approximately nine million doses of BioThrax per year.

Selectively establish collaborations. For each of our product candidates, we plan to evaluate the merits of retaining commercialization rights for ourselves or entering into collaboration arrangements with leading pharmaceutical or biotechnology companies or non-governmental organizations. We expect that we will selectively pursue collaboration arrangements in situations in which the collaborator has particular expertise or resources for the development or commercialization of our products and product candidates or to access particular markets. In 2006, we entered into a collaboration with Sanofi Pasteur for our meningitis B vaccine candidate as we believe that the value of this vaccine candidate may be maximized if it is sold in combination with other vaccines offered by Sanofi Pasteur. We are currently collaborating with HPA for the development of both a new botulinum toxoid vaccine, which we plan to use to develop our botulinum immune globulin candidate, and our recombinant bivalent botulinum vaccine candidate, which has given us access to HPA s technology and manufacturing capabilities.

Seek governmental and other third party grants and support. We seek non-dilutive arrangements, including grants and clinical trial support, with governmental and non-governmental agencies to advance the development of both our biodefense and commercial product candidates. The biodefense immunobiotic product candidates that we are developing are of significant interest to the U.S. and potentially other governments. The CDC currently is independently conducting a clinical trial to evaluate 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, the NIAID has completed an independent animal efficacy study of BioThrax in combination with antibiotics as a post-exposure prophylaxis for anthrax infection. The NIAID has awarded us grant funding for animal efficacy studies of our anthrax immune globulin candidate. We believe that some of our commercial immunobiotic product candidates are of interest to governments and philanthropic organizations. The Wellcome Trust provided funding for our Phase I clinical trial of our typhoid vaccine candidate in Vietnam and has agreed to provide funding for our Phase II clinical trial of this vaccine candidate in Vietnam. In addition, the NIAID has agreed to fund, manage and conduct a Phase I clinical study of our group B streptococcus vaccine. We plan to encourage government entities and non-government and philanthropic organizations to continue to conduct studies of, and pursue other development efforts and provide development funding for, BioThrax and our other biodefense and commercial immunobiotics product candidates.

Market Opportunity

We focus on the biodefense and commercial markets for immunobiotics.

The Biodefense Market

The biodefense market for immunobiotics has grown dramatically as a result of the increased awareness of the threat of global terror activity in the wake of the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. The letter attacks involved the delivery of mail contaminated with anthrax spores to government officials and members of the media in the United States. As a result of the letter attacks, 22 people became infected with anthrax, including 11 with inhalational anthrax, and five people died.

The U.S. government is the principal source of worldwide biodefense spending. Most U.S. government spending on biodefense programs results from procurement of countermeasures by HHS, the CDC and the DoD and development funding from the NIAID and the DoD. The U.S. government is now the largest source of funding for academic institutions and biotechnology companies conducting biodefense basic research or developing novel vaccines and immunobiotic therapeutics.

Department of Health and Human Services. In 2004, Project BioShield became law. This statute provides $5.6 billion in appropriations over ten years and authorizes the procurement of countermeasures for biological, chemical, radiological and nuclear attacks. Pursuant to Project BioShield, HHS has begun to procure vaccines and other products for the SNS. The SNS is a national repository of medical assets and countermeasures designed to provide state and local public health agencies with medical supplies needed to treat those affected by terrorist attacks, natural disasters, industrial accidents and other public health emergencies, such as a flu epidemic. Materials from the SNS were deployed following both the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. We expect that HHS will procure supplies of vaccines for the SNS on an ongoing basis and replenish the stockpile as the existing inventories reach the end of their shelf lives.

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Pursuant to Project BioShield, the CDC has categorized bioterrorism agents into three categories, from A to C, based on the perceived risk of the agent to national security. The highest risk category is category A. The six agents that the CDC has classified as category A are anthrax, botulism, plague, smallpox, tularemia and viral hemorrhagic fevers. The Secretary of HHS has directed most of the Project BioShield procurement efforts and funding to date to category A agents. Under Project BioShield, the Secretary of HHS can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. To be eligible for purchase under these provisions, the Secretary of HHS must determine that there are sufficient and satisfactory research data, including data, if available, from preclinical and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years, even though the product has not completed clinical trials and has not yet been approved by the FDA. Project BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA.

Separate from Project BioShield, in December 2006, President Bush signed the Pandemic and All-Hazards Preparedness Act. This Act supplements the funding available under Project BioShield for radiological, nuclear, chemical and biological countermeasures and also includes funding for infectious disease pandemics. The Act establishes the Biomedical Advanced Research and Development Authority, or BARDA, which is responsible for awarding contracts and grants for advanced research and development in these areas. Advanced research and development eligible for funding under BARDA for medical countermeasures includes clinical studies, design and development of animal models in support of product approval, manufacturing scale-up, and improvements relating to administration of countermeasures.

Although the Act authorizes over $1 billion of resources for fiscal years 2006 through 2008, funding for BARDA remains subject to the annual appropriations process. The President s fiscal year 2008 budget request, which is subject to Congressional approval, includes a proposed $211 million for the Assistant Secretary for Preparedness and Response to target advanced research and development on promising medical countermeasures and to manage the Project BioShield program. If appropriated by Congress, these funds would be available to BARDA in fiscal year 2008.

Centers for Disease Control. Congress appropriates annual funding for the CDC for the procurement of medical assets and countermeasures for the SNS. This appropriation funding supplements amounts available under Project BioShield for procurement of countermeasures. Congress appropriated funding for the CDC of $525 million in fiscal year 2006 and $467 million in fiscal year 2005 for this purpose.

Department of Defense. The DoD procures biodefense immunobiotics that it administers primarily through the Military Vaccine Agency, or MilVax. MilVax administers various vaccination programs for military personnel, including vaccines for common infectious diseases, such as influenza, and vaccines to protect against specific bioterrorism threats, such as anthrax and smallpox. The DoD has included anthrax at the top of its biological threat list. The level of spending by the DoD for MilVax is a function of the size of the U.S. military and the approach of the DoD with respect to vaccine stockpile and use, particularly whether, and to what extent, the DoD mandates that members of the military participate in vaccination programs. The DoD provides development funding for biodefense vaccines through its Joint Vaccine Acquisition Program, or JVAP.

National Institute of Allergy and Infectious Diseases. Beginning with fiscal year 2003, Congress added over $1.5 billion per year to the biodefense research funding budget for the NIAID. In fiscal year 2006, Congress appropriated approximately $1.9 billion in biodefense funding to the NIAID.

There are also a number of potential additional customers for biodefense immunobiotics. These include:

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

Although there have been minimal sales to these customers to date, we believe that they may comprise an important component of the overall biodefense market in the future.

Commercial Market

Vaccines have long been recognized as a safe and cost-effective method for preventing infection caused by various bacteria and viruses. Because of an increased emphasis on preventative medicine in industrialized countries, vaccines are now well recognized as an important part of public health management strategies. According to Frost & Sullivan, a market research

organization, from 2002 to 2005, annual worldwide vaccine sales increased from $6.7 billion to $9.9 billion, a compound annual growth rate of approximately 14%. Frost & Sullivan estimates that the worldwide sales of vaccines will grow at a compound annual rate of approximately 10.5% from 2005 through 2012. As of 2005, Frost & Sullivan estimates that approximately two-thirds of global vaccine sales were attributable to pediatric vaccines. In addition, vaccines sold in developed markets represented approximately 80% of worldwide vaccine revenues. New vaccine technologies and a greater understanding of how 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 purchased and paid for, or reimbursed by, managed care organizations, other private health plans or public insurers or paid for directly by patients. With respect to some diseases affecting the public health generally, particularly in developing countries, public health authorities or non-governmental, charitable or philanthropic organizations fund the cost of vaccines. According to a report issued by Frost & Sullivan in 2006, public purchases of vaccines, including for immunization programs and government stockpiles, account for approximately 90% of the total volume of worldwide vaccine sales. Although accounting for only 10% of the total volume of worldwide vaccine sales, private market purchases of vaccines accounted for approximately 60% of total worldwide vaccine sales revenues in 2005.

Scientific Background

The Immune System

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

Vaccines

A vaccine is normally given to a healthy person as a prophylaxis in order to generate immune responses that will protect against future infection and disease caused by pathogens. Following vaccination, the immune system s memory of antigens presented by a vaccine allows for an immune response to be generated to a pathogen to provide protection against disease. Therapeutic vaccines also are being developed to strengthen or modify the immune response in patients already infected with bacterial and viral pathogens to clear the pathogens from their bodies. Without treatment, these patients can be subject to recurring bouts of the disease.

There are three basic types of vaccines: live attenuated vaccines, inactivated whole cell vaccines and subunit vaccines. Live attenuated vaccines are made from weakened, or attenuated, viruses or bacteria that are designed to mimic some of the early stages of infection without causing disease. Inactivated whole cell vaccines are made by growing the infectious organism in culture media or mammalian cells and then inactivating the organisms. Subunit vaccines are derived from individual antigens that can be purified and used as vaccines. Culture filtrate vaccines are a type of subunit vaccine. These vaccines are based on components that are secreted by pathogens grown in a culture media and then purified by filtration of the culture media.

Live attenuated vaccines can produce stronger, longer lasting immunity than inactivated whole cell vaccines and often are effective after only a single dose. However, live attenuated vaccines are subject to safety concerns related to the risk that they may revert to the virulent form or cause disease in patients with weakened immune systems. Inactivated whole cell vaccines have been successfully developed for some pathogens, but large quantities of the infectious organism have to be grown to make the vaccine. This poses a safety risk for people involved in the manufacturing process and requires high levels of containment. Subunit vaccines generally produce fewer side effects than vaccines that use the whole organism, but often are not as immunogenic as inactivated whole cell or live attenuated vaccines. Adjuvants, which augment or enhance

the immune responses to vaccine antigens, are often used in combination with weaker antigens, such as subunit vaccines.

Scientists have applied recombinant technology, which allows for the manipulation of the genetic material of pathogens, in the development of new live attenuated and subunit vaccines. For live attenuated vaccines, genes involved in virulence can be

completely deleted from a pathogen so that the organism can no longer cause disease or revert to the virulent form. For subunit vaccines, the gene directing the production of the antigen can be isolated and moved into a harmless organism where it can be expressed at high levels and purified. In addition, scientists have used recombinant technology to develop vector systems to deliver multiple vaccine antigens from different disease-causing organisms in a single live attenuated vaccine by inserting genes that code for these antigens into the genetic material of the vector. We believe that the primary application for recombinant technology in the vaccine field will be for the development of vaccines in situations in which other vaccine technologies have not been successful or in which recombinant technology permits vaccine production with a lower level of safety containment.

Immune Globulins

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

Products

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

Immunobiotic Product/Product Candidate	Therapeutic/ Prophylactic	Stage of Development
BIODEFENSE		
Anthrax		
BioThrax (Anthrax Vaccine Adsorbed)	Pre-exposure prophylactic	FDA approved
BioThrax (Anthrax Vaccine Adsorbed)	Pre-exposure prophylactic	Post-approval label expansion; BLA supplement submitted for extended shelf life, additional route of administration and dose reduction
BioThrax (Anthrax Vaccine Adsorbed)*	Post-exposure prophylactic	Post-approval label expansion; animal efficacy and human safety and immunogenicity studies ongoing
Next generation anthrax vaccine*	Pre-exposure and post-exposure prophylactic	Preclinical and Phase I
Anthrax immune globulin*	Therapeutic	Preclinical
Botulinum		
Recombinant bivalent botulinum vaccine*	Prophylactic	Preclinical
Botulinum immune globulin*	Therapeutic	Preclinical
COMMERCIAL		
Typhoid vaccine	Prophylactic	Phase II
Hepatitis B therapeutic vaccine	Therapeutic	Phase II
Group B streptococcus vaccine	Prophylactic	Phase I
Chlamydia vaccine	Prophylactic	Preclinical
Meningitis B vaccine	Prophylactic	Preclinical

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

No assessment of the safety or efficacy of our vaccine candidates can be considered definitive until all clinical trials needed to support a submission for marketing approval are completed. The results of our completed preclinical tests and Phase I clinical trials do not ensure that our

planned later stage clinical trials for our vaccine candidates will be successful. A failure of one or more of our clinical trials can occur at any stage of testing.

Biodefense Business

In our biodefense business, we are developing, manufacturing and commercializing immunobiotics for use against biological agents that are potential weapons of bioterrorism or biowarfare. We have focused our biodefense portfolio on category A biological agents, which are agents in the class that the CDC has identified as the greatest possible threat to public health.

Anthrax

Disease overview. Anthrax is a potentially fatal disease caused by the spore forming bacterium *Bacillus anthracis*. Anthrax bacteria are naturally occurring, and spores are found in soil throughout the world. Anthrax spores can withstand extreme heat, cold and drought for long periods without nutrients or air. Anthrax infections occur if the spores enter the body through a cut, abrasion or open sore, referred to as cutaneous anthrax, or by ingestion or inhalation of the spores. Once inside the body, anthrax spores germinate into bacteria that then multiply. Anthrax bacteria secrete three proteins: protective antigen, lethal factor and edema factor, which are individually non-toxic but can become highly toxic if allowed to interact on the surface of human or animal cells.

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

Inhalational anthrax is the most lethal form of anthrax. We believe that aerosolized anthrax spores are the most likely method to be used in a potential anthrax bioterrorism attack. Inhalational anthrax has been reported to occur from one to 43 days after exposure to aerosolized spores. Initial symptoms of inhalational anthrax are non-specific and may include sore throat, mild fever, cough, achiness or weakness, lasting up to a few days. After a brief period of improvement, the release of anthrax toxins may cause an abrupt deterioration of the infected person, with the sudden onset of symptoms, including fever, 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, including both the DoD and HHS. We believe that federal, state, local, and 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 prevent anthrax disease by killing the anthrax bacteria before the bacteria can release anthrax toxins into the body. However, antibiotics are not effective against anthrax toxins after the toxins have been released into the body and do not kill anthrax spores that may remain in the body for extended periods after exposure. In addition, antibiotics may not be effective against antibiotic resistant strains of anthrax. Anthrax spores that remain in the body can potentially lead to infection following the end of antibiotic treatment. Infection also may occur if patients do not adhere to the prolonged course of antibiotic treatment or are not able to remain on antibiotics for extended periods of time. Because of these limitations, the CDC recommends administering BioThrax in combination with antibiotics under an investigational 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 as a therapeutic for post-exposure use. Several other companies also are developing anthrax therapeutic products for post-exposure use. For example, 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; 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. In August 2004, HHS issued a request for proposals in which HHS indicated that it was seeking between 10,000 and 200,000 therapeutic courses of treatment of a product to treat inhalational anthrax disease. The products sought by HHS included monoclonal antibodies, polyclonal antibodies, including human immune globulin, and other protein therapeutic products. Pursuant to this request for proposals, HHS awarded a contract to Cangene in 2005 to supply anthrax immune globulin for evaluation of efficacy as a post-exposure therapeutic for anthrax infection. In July 2006, HHS exercised an option under this contract for Cangene to supply 10,000 doses of anthrax immune globulin for the SNS. This contract modification has a total value of approximately $143 million. HHS has advised us that it is supplying Cangene with BioThrax doses that we delivered to HHS for placement into the SNS so that Cangene can immunize donors and obtain plasma for its anthrax immune globulin product candidate. Cangene has announced that it expects to deliver anthrax immune globulin to the SNS beginning in late 2007 through the end of 2009. HHS also

awarded a contract to Human Genome Sciences in 2005 to supply ABthrax for evaluation of efficacy as a post-exposure therapeutic for

anthrax infection. In June 2006, HHS exercised an option under this contract for Human Genome Sciences to supply 20,000 treatment courses of ABthrax for the SNS. This contract modification has a total value of approximately $165 million. HHS has announced that ABthrax deliveries to the SNS will begin in 2009.

BioThrax (Anthrax Vaccine Adsorbed)

Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we supplied over nine million doses of BioThrax through December 2006 to the DoD for immunization of military personnel. Since March 1998, the DoD has vaccinated more than 1.5 million military personnel with more than 5.7 million doses of BioThrax. 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. For personnel not deployed in high threat areas or no longer assigned to designated special mission roles, vaccination will be on a voluntary basis. Our most recent supply agreement with the DoD provides for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. We delivered to the DoD approximately 480,000 of these doses in December 2006, and expect to deliver the balance by September 2007. The DoD s right to order additional doses of BioThrax under this contract expired in February 2007.

Since May 2005, we have supplied 10 million doses of BioThrax to HHS for inclusion in the SNS. In May 2005, we entered into an agreement to supply five million doses of BioThrax for the SNS for a fixed price of $123 million. We completed delivery of all five million doses by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax for the SNS by May 2007 for a fixed price of $120 million. We delivered approximately four million of those doses in 2006, and the balance in February 2007, more than two months earlier than required.

In addition to our sales of BioThrax to the DoD and HHS, we have supplied small amounts of BioThrax directly to several foreign governments. It is our understanding that the DoD also has sold BioThrax to the governments of a number of other foreign countries for the protection of military personnel.

Our total revenues from BioThrax sales were $81.0 million in 2004, $127.3 million in 2005 and $148.0 million in 2006.

Description and benefits of BioThrax. BioThrax is the only FDA-approved vaccine for the prevention of anthrax infection. It is approved by the FDA as a pre-exposure prophylaxis for use in adults who are at high risk of exposure to anthrax spores. BioThrax is manufactured from a culture filtrate, made from a non-virulent strain of *Bacillus anthracis,* and contains no dead or live bacteria. BioThrax is administered by subcutaneous injection in three initial doses followed by three additional doses, with an annual booster dose recommended thereafter. The three initial doses are given two weeks apart followed by three additional doses given at six, 12 and 18 months following the first vaccination. BioThrax includes aluminum hydroxide, or alum, as an adjuvant. 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, 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 event. These serious adverse events, including diabetes, heart attacks, autoimmune diseases, including Guillian Barre syndrome, lupus and multiple sclerosis, lymphoma and death, have not been causally linked to the administration of BioThrax.

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

Extend shelf life. In 2005, the FDA approved an extension of BioThrax shelf life from two years to three years, which will allow BioThrax to be stockpiled for a longer period of time. In December 2006, based on data generated in ongoing stability studies, we submitted a supplement to our biologics license application, or BLA, for BioThrax to extend the shelf life of BioThrax from three years to four years.

Add second route of administration. We also have applied to the FDA to add a second route of administration of BioThrax to include intramuscular injection in addition to subcutaneous injection. We believe that intramuscular injection may result in fewer local reactions than subcutaneous injection.

Reduce doses for pre-exposure prophylaxis. In addition, 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 an 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 are being further analyzed, and we plan to submit an amendment to our application when this analysis is completed. If the final data from the CDC dose-reduction trial, which we expect at the end of 2008, are favorable, we plan to file a BLA supplement with FDA for approval of a three-dose regimen, with booster doses thereafter up to three years apart.

Post-exposure prophylaxis. We also plan to seek approval of BioThrax in combination with antibiotic therapy as a post-exposure prophylaxis for anthrax infection. We expect that we will use three doses of BioThrax given two weeks apart for this indication. In 2005, NIAID completed a proof-of-concept study of BioThrax in which rabbits infected with anthrax were treated with the antibiotic levofloxacin or with levofloxacin in combination with two doses of BioThrax in one of three dose amounts. One of the dose amounts tested was a dilution of BioThrax designed to elicit an immune response that is proportional to the effect of an undiluted dose in humans. This is referred to as a humanized dose. Only 44% of the rabbits treated with antibiotics alone survived, while 100% of the rabbits treated with either humanized doses or undiluted 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.

To advance the development of BioThrax as a post-exposure prophylaxis, we are currently conducting pivotal animal studies 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 pivotal studies in non-human primates. The timing of such studies depends upon the successful development of a non-human primate model by NIAID. In June 2006, we filed an IND for the post-exposure prophylaxis indication for BioThrax, and, in September 2006, we initiated a Phase I trial for this indication using three doses of BioThrax given two weeks apart. The purpose of this trial is to collect data that, in combination with data from our animal model, will be used to

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design a pivotal Phase I trial. We believe that, if the results of our Phase I studies are favorable, the rabbit and non-human primate animal efficacy studies together with the human immunogenicity data would be sufficient to support the filing with the FDA of a BLA supplement for marketing approval of BioThrax for this indication. In February 2007, the FDA granted Fast Track designation for BioThrax as a post-exposure prophylaxis for anthrax infection.

Additional anthrax vaccine developments. We have established a program to develop additional anthrax vaccine product candidates that would incorporate advanced characteristics, including one or more of the following: a novel delivery system, reduced number of doses, enhanced immune response, longer shelf life and room temperature storage. Our most advanced product candidate in this program is based on BioThrax combined with VaxImmune. VaxImmune, a product of Coley Pharmaceuticals Group, is an adjuvant intended to enhance an immune response. We are also evaluating an anthrax vaccine product candidate based on a recombinant protective antigen of *Bacillus anthracis*.

The DoD s Defense Advanced Research Projects Agency, or DARPA, previously funded a double-blind Phase I clinical trial of BioThrax plus VaxImmune pursuant to a collaboration among DARPA, Coley Pharmaceutical and us. This 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 VaxImmune alone. In this trial, the product candidate was administered in three doses by intramuscular injection. The immunogenicity results from this trial were statistically significant.

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

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

In June 2006, NIAID issued a request for proposals for the advanced development and testing of a third generation anthrax vaccine. In September 2006, we submitted three separate responsive proposals to NIAID. In February 2007, NIAID withdrew its request for proposals for a third generation anthrax vaccine for programmatic reasons.

Anthrax Immune Globulin

We are developing an anthrax immune globulin as an intravenous therapeutic for treatment of patients who present with symptoms of anthrax disease resulting from the release of anthrax toxins into the body. If successfully developed, we expect our anthrax immune globulin therapeutic to be prescribed for administration in these circumstances either as a monotherapy or in conjunction with an antibiotic. We are developing our anthrax immune globulin therapeutic using plasma produced by healthy donors who have been immunized with BioThrax. We have collected a sufficient amount of plasma to initiate manufacturing of the anthrax immune globulin under current good manufacturing practices, or cGMP, using a validated and approved process. The manufacturing process entails fractionating the plasma and purifying the immune globulin. We have engaged Talecris Biotherapeutics, Inc. to fractionate, purify and fill our anthrax immune globulin candidate at Talecris s FDA-approved facilities. We have manufactured and filled the first full-scale lot of this product candidate under cGMP requirements at Talecris.

We plan to rely on the FDA animal rule in connection with the development of our anthrax immune globulin 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 March 2007, we filed an IND for a Phase I clinical trial to evaluate the safety and pharmacokinetics of our anthrax immune globulin candidate in healthy human volunteers. NIAID has provided us grant funding of up to $3.7 million for the studies designed to assess the tolerability, pharmacokinetics and efficacy of this product candidate in

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infected rabbits and the development and validation of product assays. The initial award amount is approximately $2 million, with the potential for up to an additional $1.7 million, based on the availability of future funds and satisfactory progress of the project.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 our anthrax immune globulin candidate. We believe that our anthrax immune globulin candidate would be eligible to be procured by HHS under Project BioShield for inclusion in the SNS prior to receiving marketing approval.

Botulism

Disease overview. Botulism is a frequently fatal disease caused by botulinum toxins produced by the bacterium *Clostridium botulinum*. *Clostridium botulinum* is widely distributed in soil and aquatic environments throughout the world. Botulinum bacteria produce seven distinct serotypes, each of which elicits a distinct antibody response. Naturally occurring outbreaks of botulism in humans have been reported from exposure to four of the seven serotypes: A, B, E and F. Botulism normally occurs when an individual consumes contaminated food containing botulinum toxin. Once consumed, the toxin rapidly attacks nerve cells, resulting in paralysis of peripheral muscles, including the muscles involved in respiration. Botulism can also be contracted if botulinum bacteria contaminate wounds or colonize in the intestine of infants, which is referred to as infant botulism.

Botulinum toxins are among the most potent and dangerous of potential biological weapons. Exposure to very small quantities of botulinum toxin can cause the rapid onset of life threatening paralytic disease syndrome. It has been estimated that a single gram of toxin evenly dispersed and inhaled could kill more than one million people.

Market opportunity and current treatment. As with anthrax countermeasures, we believe that the U.S. and foreign federal, 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. The DoD, through its Joint Vaccine Acquisition Program, provides development funding for various biodefense vaccines, including botulinum vaccines. In November 1997, DoD awarded a $322 million contract to DynPort Vaccine Company for the development of various biodefense vaccines. In April 2005, the DoD provided additional funding to DynPort for the continued development of a recombinant bivalent botulinum vaccine for protection against botulinum serotypes A and B. This vaccine is called bivalent because it addresses two of the seven serotypes of botulinum neurotoxin. 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 immune globulin product for the treatment of infant botulism caused by type A or type B *Clostridium botulinum.* The supply of this product is limited. The product was derived from plasma taken from individuals who had been vaccinated with an experimental pentavalent botulinum toxoid vaccine that is no longer in production. In addition, the CDC manages a supply of experimental botulinum immune globulin derived from equine plasma. However, the experimental equine immune globulin is subject to important shortcomings. First, because the human body recognizes the equine immune globulin as a foreign substance, its efficacy may be limited. In addition, the antibody immune response against the equine immune globulin can lead to potential severe side effects, including anaphylactic shock, if the equine immune globulin is administered more than once. To screen for sensitivity to the equine immune globulin, patients are given small challenge doses of the equine immune globulin before receiving a full dose.

In June 2006, HHS awarded a five-year development and supply contract with a base value of $362 million to Cangene for a heptavalent botulinum immune globulin derived from equine plasma. The contract provides for the supply of 200,000 doses of a botulinum immune globulin for the SNS. Cangene has announced that it expects to produce and deliver usable product to the SNS from mid to late 2007. The contract also provides for optional task orders worth up to an extra $234 million, which may be awarded at the sole discretion of HHS. Cangene previously began development work on the project under a research and development contract with the CDC.

Botulinum Toxoid Vaccine and Botulinum Immune Globulin

We are developing a human botulinum immune globulin candidate in collaboration with HPA as an intravenous therapeutic for treatment of symptomatic botulinum exposure. We believe that a human intravenous botulinum immune globulin has the potential to provide immediate protection from the effects of botulinum toxin. A third party s FDA-approved infant botulinum immune globulin was tested in a five-year,

randomized, double-blind, placebo controlled trial in 122 infants with infant botulism and a subsequent six-year, open-label study in 382 infants. In the placebo controlled trial, infants treated with the botulinum

immune globulin had statistically significant reductions in the average length of hospital stay, duration of intensive care, duration of mechanical ventilation, duration of tube or intravenous feeding and hospital charges. In the open-label study, the early treatment of patients with infant botulism shortened the average length of stay significantly more than later treatment.

We plan to rely on the FDA animal rule in connection with the development of our botulinum immune globulin candidate. Specifically, we plan to conduct efficacy studies of this product candidate in an infected rodent population and then infected non-human primates. Concurrently, we expect to file an IND for a Phase I clinical trial to evaluate the safety and pharmacokinetics of the botulinum immune globulin in healthy volunteers. We believe that favorable data from these animal efficacy studies and the safety and pharmacokinetic clinical trial would be sufficient to support an application to the FDA for marketing approval.

As the first step in the development of our botulinum immune globulin candidate, we are initiating production of a bivalent botulinum toxoid vaccine using a combination of 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 plan to conduct a preclinical proof-of-concept study of this vaccine candidate in mice to confirm the suitability of the vaccine for further development. If the results of this proof-of-concept study are favorable, based on a demonstration of protective efficacy or an immune response associated with protection, we plan to file an IND to initiate a Phase I clinical trial to evaluate the safety of this vaccine in healthy volunteers. We expect that the Phase I clinical trial will provide data sufficient to support an acceptable dose for the vaccine and the optimal dosing schedule. If the results of the Phase I clinical trial are favorable, we intend to initiate a donor stimulation program in which we will immunize healthy volunteers with the vaccine and collect plasma for fractionation for the manufacture of our botulinum immune globulin candidate. We expect to rely on safety and immunogenicity data from a pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan in the development of this bivalent botulinum toxoid vaccine. This data includes the results of a Phase II safety and immunogenicity clinical trial conducted by the DoD from July 1998 to May 2000, animal efficacy data and the extensive use of the pentavalent vaccine by the CDC in immunizing at risk laboratory personnel. As a result, we anticipate that the FDA will not require us to conduct a Phase II clinical trial for the bivalent botulinum toxoid vaccine before permitting us to initiate the donor stimulation program. However, the FDA has not approved our plan to proceed directly to a donor stimulation program without conducting a Phase II clinical trial for the botulinum toxoid vaccine and may not do so.

Our current plan is to develop the botulinum toxoid vaccine that we are using in the development of our botulinum immune globulin candidate through Phase I clinical trials. At that point, we expect to assess our future development plans based on the U.S. government s interest in providing funding for the further development or procurement of this toxoid vaccine, either instead of or in addition to a recombinant botulinum vaccine, as a pre-exposure prophylaxis for botulinum toxin. We believe that this type of government funding may become available as there is currently no botulinum vaccine available for the military or the SNS. Moreover, we believe that the well-established nature of the manufacturing process for a toxoid vaccine, the availability of safety data from the pentavalent botulinum vaccine, our access to know-how from the development and manufacturing of the pentavalent botulinum vaccine by the State of Michigan and access to HPA technology would all facilitate our development of a bivalent botulinum toxoid vaccine.

Recombinant Botulinum Vaccine

Description and development status. We are developing a recombinant protein subunit bivalent botulinum vaccine for protection against botulinum serotypes A and B in collaboration with HPA. We hold an exclusive license from HPA to the recombinant technology that we are using in the development of our vaccine candidate. HPA is also providing us with process development and toxicology expertise, access to its facilities and specialized manufacturing capabilities. We are designing our vaccine candidate to be administered by intramuscular injection with an alum adjuvant in a three-dose regimen. Our recombinant vaccine candidate is based on a fragment of the botulinum toxin that we have selected as an antigen because we believe it to be non-toxic and immunogenic. We are producing this recombinant antigen in an *E. coli* expression system. We believe that our technology will allow us to develop a stable product with possible cross-protection against a range of toxin subtypes and ease of formulation into a multivalent vaccine.

We plan to rely on the FDA animal rule in connection with the development of our recombinant bivalent botulinum vaccine candidate. We have completed initial proof-of-concept studies of this vaccine candidate in mice for botulinum serotypes A and B. In these studies, the vaccine elicited antibodies and provided protection against challenge with the botulinum toxin. We have established a small scale production process for botulinum serotypes A and B. 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.

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We continue to assess, and may alter, our future development plans for our recombinant botulinum vaccine candidate based on the U.S. government s interest in providing funding for the further development or procurement of this vaccine.

Commercial Business

In our commercial business, we are developing a range of commercial immunobiotic product candidates that are designed to address significant unmet or underserved public health needs.

Typhoid Vaccine

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

Market opportunity and current treatment. An estimated 22 million cases of typhoid occur per year worldwide, resulting in approximately 200,000 deaths annually. 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. U.S. military personnel deployed in these areas are also at risk of infection.

One oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in both the United States and Europe. The approved oral typhoid vaccine is available in liquid and capsule formulations. Both formulations require 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 poorly immunogenic in children, requires a booster dose every three years thereafter and was effective in only 55% to 75% of recipients in clinical trials. Both approved vaccines have good safety profiles with relatively few adverse events reported. Antibiotics are used to treat typhoid after infection and usually lead to recovery commencing within four days. Without antibiotic therapy, the CDC estimates that the mortality rate of a typhoid infection is as high as 20%.

Description and development status. We are developing a live attenuated typhoid vaccine that contains deletions in two genes of the *Salmonella typhi* bacterium designed to eliminate virulence. We have designed our vaccine candidate to be administered in a single drinkable dose prior to travel to countries where typhoid is endemic. We believe that, if approved, the method of administration of our vaccine candidate would provide a competitive advantage compared to both currently approved typhoid vaccines. 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 immunogenicity, and well tolerated.
- A double-blind, placebo controlled, single dose escalating Phase I clinical trial conducted in the United States in 60 healthy adult volunteers. The purpose of this trial was to evaluate the safety, tolerability and immunogenicity of three dose levels of our vaccine candidate. In this trial, our vaccine candidate was immunogenic and well tolerated at all dose levels. The immunogenicity parameter for this trial was the proportion of trial participants with an immune response to the product candidate on day seven after dosing or day 28 after dosing. To be considered adequately immunogenic, 50% of the participants receiving a vaccine dose had to satisfy the primary immunogenicity endpoint. We performed analyses on both an intent to treat and a per protocol basis. An intent to treat analysis is based on the participants who receive a dose of vaccine. A per protocol analysis is based on the participants who complete a trial and substantially comply with the trial protocol. In both the intent to treat population and the per protocol population, 100% of the trial participants in the highest dose group and 56% of the participants in the lowest dose group had an immune response on day seven or day 28. The immune response rate for the highest dose group was statistically significantly greater than the immune response rate for the lowest dose group. 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

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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 vaccine candidate demonstrated immunogenicity response levels following a single drinkable dose similar to those seen with multiple doses of the currently approved oral vaccine. As a result of these trials, we were able to establish the dose and regimen for our vaccine candidate with a formulation that we believe is appropriate for commercialization.

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

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

Phase II clinical trials. In the first quarter of 2007, we initiated a single-blind, placebo controlled Phase II clinical trial in Vietnamese children between five and 14 years of age. The Wellcome Trust is providing funding for this trial. We also plan to conduct a Phase II clinical trial in India in children between two and five years of age as a step towards conducting a Phase III clinical study where the incidence of disease is prevalent. The purpose of both of these trials is to evaluate the safety and immunogenicity of our vaccine candidate.

Disease surveillance study. We plan to conduct a disease surveillance study in the endemic areas where we are considering conducting a Phase III clinical trial of our vaccine candidate to confirm that a sufficient number of subjects will be included in the Phase III trial. The Wellcome Trust has agreed to provide 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 Phase III clinical trial in an endemic area, 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

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infection, with over 90% becoming chronically infected. According to the World Health Organization, approximately 25% of people with chronic hepatitis B infection develop serious liver disease, including cirrhosis and liver cancer.

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

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

There is no vaccine currently on the market that is licensed for therapeutic use for chronic hepatitis B infection. Currently available therapies for this patient population consist mainly of antiviral drugs 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 responses to the hepatitis B virus, they cannot clear the virus. Our vaccine candidate is intended to redirect the immune system to make strong cellular responses to a hepatitis B antigen known as hepatitis B core in chronic carriers, leading to suppression of viral replication and associated liver damage.

Our vaccine candidate uses our proprietary *spi*-VEC oral delivery system technology to deliver hepatitis B core antigen to the human immune system. *Spi*-VEC is based on our live attenuated typhoid vaccine and employs recombinant technology to insert the gene for hepatitis B core into the live attenuated *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 vaccine.

We have completed a program of pharmacology and toxicity studies of our hepatitis B therapeutic vaccine candidate in animals. In mice that were administered our vaccine candidate, the hepatitis B core antigen was 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 hepatitis B at any point during the trial. In this trial, 100% of the participants in the high dose group and 90% of the participants in the low dose group demonstrated such a response. We did 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 hepatitis B 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 in Europe 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

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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.

Market opportunity and current treatment. The NIH has identified prevention of group B streptococcus infection in newborns as a major vaccine objective. Concern about the number of group B streptococcus neonatal infections prompted the CDC to recommend routine screening of pregnant women for group B streptococcus bacteria and preventative antibiotic treatment at the time of labor for women found to be infected. Screening of pregnant women for infection is recommended during weeks 35 to 37 of pregnancy. Approximately 10% to 30% of women are found to be carrying the bacterium as a normal component of the vaginal microflora. These women are offered intravenous antibiotics throughout their labor as a preventative measure. In the absence of antibiotic treatment, the CDC estimates that the risk is one in 200 of delivering a baby with group B streptococcus infection. While the level of group B streptococcus disease decreased in the United States from 1.7 cases per 1,000 live births in 1993 to 0.4 cases per 1,000 live births in 2002, the CDC projects that there are approximately 2,750 neonatal infections each year in the United States. In a study of 338 of these cases of neonatal infections, the death rate was approximately 6%. We expect the target market for our vaccine candidate to be women of childbearing age.

The existing method of prevention of group B streptococcus infection in neonates is the targeted administration of intravenous antibiotics to women during labor. However, this approach is invasive and only partially effective. In addition, antibiotics create the risk of possible adverse reactions and may lead to the development of antibiotic resistant strains of the disease. Direct vaccination of newborns is not effective because their immune system is too immature to respond to the vaccine. Antibiotics are used to treat babies after infection.

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

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

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We have completed an open-label, dose escalating Phase I clinical trial of the first protein component of our vaccine candidate in the United Kingdom in 47 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of this protein as an individual recombinant protein. We adjuvanted the protein with alum and tested it at four different strengths, with two doses given 28 days apart. In this trial, the protein was immunogenic at all doses tested. We performed analyses on both an intent to treat and a per protocol basis. In both the intent to treat population and the per protocol population, the 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 events 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 two recombinant proteins individually, including the protein that we tested in our Phase I clinical trial, and the two proteins in combination. 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.

Chlamydia Vaccine

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

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

Description and development status. We are developing a recombinant protein subunit chlamydia vaccine for all clinically relevant strains of *Chlamydia trachomatis*, including strains that cause ocular disease. We are designing our vaccine candidate to be administered by injection with a novel adjuvant in a three-dose regimen. We are currently evaluating in-license opportunities for the adjuvant. We have cloned our vaccine candidate and produced it in *E. coli*. In studies in mice, our vaccine candidate protected against both upper reproductive tract disease and lower reproductive tract infection induced by *Chlamydia trachomatis*. In addition, 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 World Health Organization, group B is the most common cause of endemic meningitis in industrialized countries, accounting for 30% to 40% of cases in North America and 30% to 80% of cases in Europe. Meningococcal disease has a fatality rate of approximately 10%. The infection can develop very rapidly and cause death within 24 hours of the symptoms first becoming apparent. Children from six months to two years of age are at the highest risk of group B meningococcal infection, with teenagers also at enhanced risk.

Market opportunity and current treatment. The World Health Organization estimates that approximately 1.2 million cases of bacterial meningitis occur annually worldwide, resulting in approximately 135,000 deaths. The World Health Organization estimates that approximately 500,000 of these cases and 50,000 of these deaths are caused by the bacterium *Neisseria meningitidis*. In the United States, 2,333 cases of meningococcal

disease were reported in 2001, with approximately one-third due to group B. In 2003, 1,756 cases of meningococcal disease were reported in the United States. Currently, there is no meningitis vaccine on the market that is protective against group B meningococcal infection. Current meningitis B treatments include

antibiotics and clinical support. The rapid progression of the infection means that antibiotic therapy can be ineffective in preventing serious morbidity and mortality.

Description and development status. We are developing a recombinant protein subunit meningitis B vaccine for babies, children and adolescents. We are designing our vaccine candidate to be administered by injection with an alum adjuvant in a two-dose regimen for children under age five and a single-dose regimen for children over age five. We do not expect that a booster dose will be required. We anticipate that the vaccine will consist of two or three protein antigens. We are currently evaluating a pool of 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.

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

A steering committee made up of an equal number of representatives from us and Sanofi Pasteur oversees all development and commercialization activities under the agreement. The steering committee has the authority to make strategic decisions by unanimous vote relating to the development of a meningitis vaccine. Sanofi Pasteur has ultimate decision-making authority over matters that are not resolved at the steering committee and executive officer levels, but does not have the unilateral authority to amend the agreement or the development plan in a manner that would alter our 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 received approximately £1.6 million during 2006 under 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 beginning April 1, 2007 upon six months prior written notice. Sanofi Pasteur also may terminate the agreement upon any change of control involving us or as a result of our uncured material breach of the agreement or bankruptcy.

Manufacturing

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

Hollister-Stier Laboratories LLC performs the contract filling operation for BioThrax vials at its FDA-approved facility located in Spokane, Washington. Hollister-Stier has agreed to meet all of our firm purchase orders for contract filling of BioThrax based on a good faith annual estimate that we provide prior to each calendar year. In addition, Hollister-Stier has agreed to accommodate fill requests in excess of our annual estimate subject to its available production capacity. Our contract with Hollister-Stier expires December 31, 2007. The contract also can be

terminated by either party following an uncured material breach by the other party.

Talecris Biotherapeutics has agreed to perform plasma fractionation and purification and contract filling relating to the manufacture of our anthrax immune globulin candidate at its FDA-approved facilities located in Melville, New York and Clayton, North Carolina. Subject to limited exceptions, we have agreed to obtain all of our anthrax immune globulin requirements exclusively from Talecris. While our agreement with Talecris remains in effect, Talecris has agreed not to market, sell or acquire any competing product that contains anthrax immune globulin as an active ingredient. Talecris has agreed to perform plasma fractionation and purification and contract filling for the manufacture of our anthrax immune globulin candidate for preclinical or animal studies, for clinical use or for non-clinical testing required for clinical trials and for commercial sale. We have agreed to pay Talecris royalties on net sales on a country-by-country basis for commercial product manufactured by Talecris under the contract. Our contract with Talecris expires December 31, 2013 or five years following initiation of commercial manufacturing. We have the option to extend the term for an additional five-year period upon notice to Talecris at least 12 months prior to the expiration of the initial term. After three years following initiation of commercial manufacturing, either party may terminate the contract upon two years advance notice. The contract can also be terminated by either party following an uncured material breach by the other party. We have the right to terminate the contract, under specified circumstances, if we discontinue our production of anthrax immune globulin source plasma or the development of our anthrax immune globulin candidate.

We expect to engage one or more third parties to perform the plasma fractionation and purification processes and contract filling for our botulinum immune globulin candidate.

We used a contract manufacturer for the supply of our typhoid vaccine candidate for the Phase I studies and Phase II trial in Vietnam. We may use a different contract manufacturer for the supply of this vaccine candidate for the Phase II study in India, for 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.

To augment our existing manufacturing capabilities, we are constructing a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus. We expect the construction of the facility to cost approximately $75 million, including approximately $55 million for the building and associated capital equipment, with the balance related to validation and qualification activities required for regulatory approval and initiation of manufacturing. We incurred approximately $37 million for these purposes through 2006. We substantially completed construction of this facility in 2006, and expect to conduct installation, validation and qualification activities required for regulatory approval during 2007 and 2008. We are constructing this new facility as a large-scale manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures. We anticipate that we will initiate large scale manufacturing of BioThrax for commercial sale at the new facility in 2008. 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 for commercial sale at our new facility will be delayed and we will incur additional unanticipated costs.

We also own two buildings in Frederick, Maryland that are available to support our future manufacturing requirements. We incurred approximately $1 million related to initial engineering design and preliminary utility build out for these facilities during 2006. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that will be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project. We may elect to lease all or a substantial portion of one of these facilities to third parties.

Marketing and Sales

We currently market and sell BioThrax directly to the DoD and HHS with a small, targeted marketing and sales group. We plan to continue to do so and expect that we will use a similar approach for sales to the U.S. government of any other biodefense product candidates that we successfully develop. We plan to expand our sales and marketing organization as we broaden our sales activities of biodefense products at the state and local level, where we expect there will be interest in these products to protect first responders and emergency personnel, 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 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 establish a separate internal organization 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, such as the market for typhoid vaccines and other vaccines for travelers to developing countries, that overlap with markets for our biodefense products. 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 development or commercialization of our products or product candidates or to access particular markets.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience, and resources provide us with competitive advantages, we face potential competition from many different sources, including commercial pharmaceutical and biotechnology companies, academic institutions, government agencies and private and public research institutions.

GlaxoSmithKline, Sanofi-Aventis, Wyeth, Merck and Novartis, generated approximately 85% of total vaccine revenues in 2005. The concentration of the industry reflects a number of factors, including:

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

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

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

BioThrax

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Although BioThrax is the only product approved by the FDA for human use for the prevention of anthrax infection, we face significant competition for the supply of this vaccine to the U.S. government. The NIAID Biodefense Research Agenda for CDC Category A Agents includes the development of an anthrax vaccine based on recombinant protective antigen. In September 2003, NIAID awarded joint three-year contracts totaling $151.6 million to VaxGen and Avecia to fund development of a recombinant protective antigen anthrax vaccine. In November 2004, HHS awarded VaxGen a contract with a value of $877.5 million to supply a recombinant protective antigen vaccine for the SNS. Avecia submitted a competing proposal to supply vaccine for the SNS, which HHS did not accept. In December 2006, HHS terminated the contract with VaxGen for default. VaxGen has appealed the termination.

HPA manufactures an anthrax vaccine for use by the government of the United Kingdom. In addition, other countries may have anthrax vaccines for use by or in development for their own internal purposes.

Other Biodefense Products

We face significant competition for U.S. government funding for development of our biodefense product candidates and potential supply of our biodefense product candidates to the U.S. government, including for potential placement in the SNS. For more information, see -Products-Biodefense Business-Anthrax-Anthrax Vaccine, -Products-Biodefense Business-Anthrax-Anthrax Immune Globulin, -Products-Biodefense Business-Botulism-Botulinum Toxoid Vaccine and Botulinum Immune Globulin, and -Products-Biodefense Business-Botulism-Recombinant Botulinum Vaccine. Our biodefense product candidates also face competition for government funding from other defensive measures, including medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures.

Commercial Products

The competition for our commercial immunobiotic product candidates includes the following:

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

Hepatitis B therapeutic vaccine. There is no vaccine currently on the market that is licensed for therapeutic use for hepatitis B infection. Currently available therapies for this patient population consist mainly of antiviral drugs and immunotherapies, such as interferons.

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

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

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

Intellectual Property and Licenses

Our success, particularly with respect to our commercial business, depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions, and improvements that are important to the development of our business.

U.S. patents generally have a term of 20 years from the date of nonprovisional filing. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of March 19, 2007, we owned or exclusively licensed exclusively a total of 14 U.S. patents and 24 U.S. patent applications relating to our biodefense and commercial product candidates, as well as numerous foreign counterparts to many of these patents and patent applications. Our patent portfolio includes patents and patent applications with claims directed to compositions of matter, pharmaceutical formulations and methods of use.

We consider the patent rights that we own or exclusively licensed from HPA relating to our recombinant bivalent botulinum vaccine candidate and our botulinum toxoid vaccine, which we plan to use in the development of our botulinum immune globulin candidate, to be important to the protection of our biodefense product portfolio.

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 20 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 33 foreign patent applications that, if issued, would expire, between 2015 and 2020. We exclusively own the composition of matter patents covering the specific combination of mutations employed in our typhoid vaccine and hepatitis B therapeutic vaccine candidates. 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 employs recombinant technology to insert the gene for hepatitis B core 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 expires in 2019.We also have one pending U.S. patent application relating to our hepatitis B therapeutic vaccine candidate, which if issued also would expire in 2019. We have four foreign patent applications relating to our hepatitis B therapeutic vaccine candidate that, if issued, would expire in 2019.

G*roup B streptococcus vaccine*. We hold two U.S. patents relating to our group B streptococcus vaccine candidate with claims to the composition of matter of the vaccine candidate and methods of use for the prevention or treatment of infection caused by *Streptococcus agalactiae*. In addition, we have five 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 20 foreign counterpart patents relating to our group B streptococcus vaccine candidate, including counterpart under the European Patent Convention and in Japan, that expire, and 40 foreign patent applications that, if issued, would expire, in 2019.

STM technology. We jointly own with Imperial College Innovations Limited, or ICIL, two 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 jointly own with ICIL 11 foreign counterpart patents, including counterparts under the European Patent Convention and in Japan. These patents relating to the STM method will expire in 2015. Two of the three U.S. patents relating to our typhoid vaccine candidate and our U.S. patent relating to our hepatitis B therapeutic vaccine candidate also are jointly owned with ICIL. Our rights under these jointly owned patents currently are non-exclusive, because ICIL has licensed limited rights under these patents to third parties to practice the STM method with respect to specific microorganisms, not including *Salmonella typh*i or hepatitis.

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

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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.

License Agreements

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

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

The licensed patent portfolio includes four 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 four foreign applications, which if issued would expire in 2016.

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

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

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

The term of each development agreement lasts until the development activities are completed. HPA may terminate each development agreement as a result of our uncured material breach or insolvency. Each of the development agreements automatically terminates if the applicable license agreement is terminated.

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

MVA Platform Technology. In July 2006, in connection with our acquisition of ViVacs GmbH, a German limited liability company, we acquired a license agreement with StMUGV that provides us the non-exclusive, worldwide right to develop and produce viruses and viral products, including recombinant viral vectors, using the modified vaccinia 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. Each party may terminate the license agreement as a result of an uncured material breach by the other party. In addition, StMUGV may terminate the license agreement upon the insolvency or liquidation of our wholly owned subsidiary, Emergent Product Development GmbH, formerly ViVacs GmbH. 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 Contracts

We have supplied BioThrax to the DoD, which purchases BioThrax for immunization of military personnel, and to HHS for placement into the SNS.

Department of Defense. Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. We have completed delivery of all of the doses of BioThrax under our first contract with the DoD. In November 2003, we entered into a follow-on, second supply contract with the DoD. This second contract is referred to as an indefinite delivery/indefinite quantity contract. Under this contract, the DoD is obligated to acquire a minimum number of doses of BioThrax and has the right to acquire up to a maximum number of doses. We invoice the DoD for progress payments under the contract upon reaching pre-determined process stages in the manufacture of BioThrax. We amended this contract in October 2006. As amended, this contract provides for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. We delivered to the DoD approximately 480,000 of these doses in December 2006, and expect to deliver the balance by September 2007. The DoD s right to order additional doses under this contract expired in February 2007.

Department of Health and Human Services. In May 2005, we entered into an agreement to supply five million doses of BioThrax to HHS for placement into the SNS for a fixed price of $123 million. We completed delivery of all five million doses of BioThrax by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax for the SNS by May 2007 for a fixed price of $120 million. We delivered approximately four million of those doses in 2006 and the balance in February 2007, more than two months earlier than required. Our contract with HHS did not provide for progress payments. We invoiced HHS under the contract upon completing delivery of the specified doses of BioThrax.

U.S. government indemnification. 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 DoD for uninsured costs incurred in defending these claims.

Safety Act and other statutory protections. In August 2006, the Department of Homeland Security approved our application under the Safety Act enacted by the U.S. Congress in 2002 for liability protection for sales of BioThrax. The Safety Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. In addition, the Safety Act provides a process by which an anti-terrorism technology may be certified as an approved product by the Department of Homeland Security and therefore entitled to a rebuttable presumption that the government contractor defense applies to sales of the product. The government contractor defense, under specified circumstances, extends the sovereign immunity of the United States to government contractors who manufacture a product for the government. Specifically, for the government contractor defense to apply, the government must approve reasonably precise specifications, the product must conform to those specifications and the supplier must warn the government about known dangers arising from the use of the

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product. We have successfully asserted the government contractor defense in product liability litigation in a federal district court in Michigan.

As part of the 2006 Defense Authorization Act, the U.S. Congress adopted the Public Readiness and Emergency Preparedness Act, or PREP Act, which offers targeted liability protections to those involved in the development, manufacturing and deployment of pandemic or PREP Act products and bioterrorism countermeasures. The PREP Act provides immunity, subject to limited exceptions, for claims arising out of, related to or resulting from the administration or use of a covered countermeasure.

Government Regulation

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

U.S. Government Regulation

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

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

- preclinical laboratory and animal tests;
- submission to the FDA of an IND, which must become effective before clinical trials may begin;
- completion of human clinical trials and other studies to establish the safety and efficacy of the proposed product for each intended use;
- FDA review of facilites 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

Preclinical studies include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to assess its potential safety and efficacy. We submit the results of the preclinical studies, together with manufacturing information, analytical data and any available clinical data or literature to the FDA as part of an IND, which must become effective before we may begin human clinical trials. The IND submission also contains clinical trial protocols, which describe the design of the proposed clinical trials. The IND becomes effective 30 days after the FDA receives the filing, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the preclinical trials or the design of the proposed clinical trials as outlined in the IND. In such a case, the IND sponsor and the FDA

must resolve any outstanding concerns before clinical trials can begin. In addition, an independent Institutional Review Board charged with protecting the welfare of human subjects involved in research at each medical center proposing to conduct the clinical trials must review and approve any clinical trial. Furthermore, study subjects must provide informed consent for their participation in the clinical trial.

Clinical Trials

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

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

U.S. law requires that trials to support approval for product marketing be adequate and well controlled. In general, this means that pivotal clinical trials typically must be prospective, randomized, blinded and controlled. The design of the clinical trials must be described in appropriate protocols submitted to the FDA and approved by an Institutional Review Board. Clinical trials typically compare the experimental product to either a placebo or, in some cases, a product already approved for the treatment of the applicable disease or condition. Trials must also be conducted in compliance with good clinical practice, or GCP, requirements.

In the case of product candidates that are intended to treat rare life-threatening diseases, such as infection caused by exposure to the anthrax toxin, conducting controlled clinical trials to determine efficacy may be unethical or infeasible. Under regulations issued by the FDA in 2002, often referred to as the animal rule, the FDA described the circumstances under which it will rely on evidence from studies in animals to provide substantial evidence of efficacy for products for which human efficacy studies are not ethical or feasible. The animal rule provides that, under these circumstances, approval of the product can be based on clinical data from trials in healthy subjects that demonstrate adequate safety and immunogenicity and efficacy data from adequate and well controlled animal studies. Among other requirements, the animal studies must establish that the biological product is reasonably likely to produce clinical benefits in humans. Because the FDA must agree that data derived from animal studies may be extrapolated to establish safety and effectiveness in humans, these studies add complexity and uncertainty to the testing and approval process. In addition, products approved under the animal rule are subject to additional regulation not normally required of other products. Additional regulation may include post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

We may not successfully complete Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all. Furthermore, the FDA or the Institutional Review Boards or the sponsor may prevent clinical trials from beginning or may place clinical trials on hold or terminate them at any point in this process if, among other reasons, they conclude that study subjects are being exposed to an unacceptable health risk.

Marketing Approval

In the United States, the results of product development, preclinical studies and clinical trials must be submitted to the FDA for review and approval prior to marketing and commercial shipment of the product candidate. If the product is regulated as a drug, an NDA must be submitted and approved before commercial marketing may begin. If the product is regulated as a biologic, a BLA must be submitted and approved before commercial marketing may begin. The NDA or BLA must include a substantial amount of data and other information concerning the safety and effectiveness and, in the case of a biologic, purity and potency of the product candidate from laboratory, animal and clinical testing, as well as data and information on the finished product, including manufacturing, product stability and proposed product labeling.

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

Under applicable laws and FDA regulations, each NDA or BLA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If deemed complete, the FDA will file the NDA or BLA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA or BLA that it deems incomplete or not properly reviewable.

The FDA may deny an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if additional clinical data is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the

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criteria for approval. If the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that contraindications, warning statements or precautions be included in the product labeling, require that additional studies be conducted following approval as a condition of the approval, impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan or otherwise limit the scope of any approval or post-approval, or limit labeling. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized. The FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies often takes many years and the actual time required may vary substantially, based upon the type, complexity and novelty of the product candidate. Government regulation may delay or prevent marketing of potential products for a considerable period of time or permanently and impose costly procedures upon our activities. The FDA or other regulatory agencies may not grant approval for any of our product candidates on a timely basis, or on a commercially viable basis, if at all. Success in preclinical testing or early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. Data obtained from preclinical and clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific indications. Furthermore, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

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.

The FDA s policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. Moreover, increased attention to the containment of health care costs in the United States and in foreign markets could result in new government regulations. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action in the United States or abroad. We and our product candidates are also subject to a variety of state laws and regulations in those states or localities where they are or will be marketed. Any applicable state or local regulations may hinder our ability to market our product candidates in those states or localities.

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 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

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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. Although HHS purchased 10 million doses of BioThrax for placement into the SNS in reliance on the authority prescribed in Project BioShield, we cannot predict whether these authorities would be applicable to any of our current product candidates.

Safety Act

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

Public Readiness and Emergency Preparedness Act

The 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. Covered countermeasures include security countermeasures and qualified pandemic or epidemic products, including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or credible risk of a future public health emergency. In the declaration, the Secretary may recommend the

manufacture, administration or use of one or more countermeasures. Once the Secretary issues a declaration invoking the immunity provisions of the Act for the specified countermeasures, immunity applies with regard to administration or use of those countermeasures during the effective period of the declaration and for the diseases specified in the declaration. However, injured persons may still bring a suit for willful misconduct against the manufacturer under some circumstances. A declaration also triggers the

establishment of a compensation program. If Congress funds the compensation program, persons injured by a qualified countermeasure must first seek compensation under the program before they may bring a suit alleging willful misconduct. On February 1, 2007, the Secretary of Health and Human Services 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 cannot predict whether the PREP Act will provide protections for our products or product candidates, whether Congress will fund the relevant compensation programs or if the necessary prerequisites for immunity would be triggered with respect to our products 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 procedure.

The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is currently mandatory for products developed by means of a biotechnological process, including recombinant DNA technology, the controlled expression of genes coding for biologically active proteins and monoclonal antibody methods, and new chemical entities for the treatment of acquired immune deficiency syndrome, cancer and neurodegenerative disorder or diabetes. Beginning in May 2008, the centralized procedure will be mandatory for products for the treatment of auto-immune diseases and other immune dysfunctions and viral diseases. The centralized process is optional for medicines that constitute a significant therapeutic, scientific or technical innovation or for which a centralized process is in the interest of patients.

The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and an assessment report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

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

Orphan Drugs

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

Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, reduced filing fees for marketing applications and a special seven-year period of market exclusivity after marketing approval. Orphan drug exclusivity prevents FDA approval of applications by others for the same drug or biologic intended for use for the designated orphan disease or condition. The FDA may approve a subsequent application from another person if the FDA

determines that the application is for a different product or different use, or if the FDA determines that the subsequent product is clinically superior or that the holder of the initial orphan

drug approval cannot assure the availability of sufficient quantities of the drug or biologic to meet the public s need. The FDA also may approve another application for the same drug or biologic that has orphan exclusivity but for a different use, in which case the competing drug or biologic could be prescribed by physicians outside its FDA approval for the orphan use notwithstanding the existence of orphan exclusivity. A grant of an orphan designation is not a guarantee that a product will be approved.

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

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

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

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

Reimbursement and Pricing Controls

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

In the United States, there has been an increased focus on drug and biologic pricing in recent years. Although there are currently no direct government price controls over private sector purchases in the United States, federal legislation requires pharmaceutical manufacturers to pay prescribed rebates on specified drugs and biologics to enable them to be eligible for reimbursement under public health care programs such as Medicaid. Vaccines are generally exempt from these programs. Various states have adopted further mechanisms that seek to control drug and biologic prices, including by disfavoring higher priced products and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place that increases downward pressure on the prices of pharmaceutical products. Federal legislation, enacted in December 2003, has altered the way in which physician-administered drugs and biologics covered by Medicare are reimbursed. Under the new reimbursement methodology, physicians are reimbursed based on a product s average sales price. This new reimbursement methodology has generally led to lower reimbursement levels. The new federal legislation also has added an outpatient prescription drug benefit to Medicare, which went into effect in January 2006. These benefits will be provided primarily through private entities, which we expect will attempt to negotiate price concessions from pharmaceutical manufacturers.

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

Most non-pediatric commercial vaccines are purchased and paid for, or reimbursed by, managed care organizations, other private health plans or public insurers or paid for directly by patients. In the United States, pediatric vaccines are funded by a

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variety of federal entitlements and grants, as well as state appropriations. The CDC currently distributes pediatric grant funding on a discretionary basis under the Public Health Service Act. Federal and state governments purchase the majority of all pediatric vaccines produced in the United States, primarily through the Vaccine for Children Program implemented by the U.S. Congress in 1994. The Vaccine for Children Program is designed to help pay for vaccinations to disadvantaged children, including uninsured children, children on Medicaid and underinsured children who receive vaccinations at federally qualified health centers.

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

Regulations Regarding Government Contracting

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

Vaccine Injury Compensation Program

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

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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, 2006, we had 494 employees, including 132 employees engaged in product development, 249 employees engaged in manufacturing, seven employees engaged in sales and marketing and 106 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 our BioThrax anthrax vaccine, our only marketed product, under contracts with the U.S. Department of Defense and the U.S. Department of Health and Human Services. If we are unable to obtain new contracts with and deliver BioThrax to these customers, our business, financial condition and operating results could be materially harmed.

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales of BioThrax, our FDA-approved anthrax vaccine and our only marketed product. We currently supply BioThrax to the DoD for immunization of military personnel and to HHS for placement into the SNS. In 2006, we derived substantially all of our revenue from our BioThrax contracts with the DoD and HHS. Our most recent contract with the DoD provides for the supply of BioThrax

to the DoD through September 2007. Although the DoD has issued a notice that it intends to pursue a sole source fixed price contract to purchase up to an additional 11 million doses of BioThrax over one base contract year plus four option years, the DoD has not issued a formal request for proposals for such a contract. We may not be awarded a follow-on contract by the DoD, or we may be awarded a contract by on less favorable terms than our prior contracts with DoD. For example, the DoD s minimum purchase obligations under any follow-on contract could be less than under our prior contracts with the DoD. We have completed delivery of all of the ten million doses of BioThrax that HHS agreed to purchase under a contract that we entered into with HHS in May 2005 and a subsequent contract modification that we entered into in May 2006. We may not be awarded a follow-on contract by HHS, or we may be awarded a contract on less favorable terms than our prior contract with HHS. Our 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. The success of our business and our operating results for the foreseeable future are substantially dependent on the number of doses of BioThrax that the U.S. government purchases from us.

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

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

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

The U.S. government may choose to award future contracts for the supply of anthrax vaccines and other biodefense product candidates that we are developing to our competitors instead of to us. If we are unable to win particular contracts, we may not be able to operate in the market for products that are provided under those contracts for a number of years. For example, if any other company is successful in developing a next generation anthrax vaccine, U.S. government customers may purchase only the next generation vaccine and not BioThrax.

If we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs and resources that will be required to secure such contract awards, our growth strategy and our business, financial condition, and operating results could be materially adversely affected.

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

Our principal customer for BioThrax, our only marketed product, is the U.S. government. We sell to the U.S. government under contracts with the DoD and HHS. In addition, we anticipate that the U.S. government will be the principal customer for any other biodefense products that we successfully develop. Accordingly, we are subject to a range of risks arising out of being a contractor to the U.S. government under U.S. government programs.

Over its lifetime, a U.S. government program may be implemented through the award of many different individual contracts and subcontracts. The funding of government programs is subject to Congressional appropriations. Congress generally appropriates funds on a fiscal year basis even though a program may continue for several years. For example, our DoD contracts for BioThrax have been structured with one base year during which the DoD agrees to purchase a minimum number of doses of BioThrax with options for the DoD to purchase further quantities in future years. Any future contract that we enter into with the DoD may be structured in a similar manner. Government programs are often only partially funded initially, and additional funds are committed only as Congress makes further appropriations. The termination of a program or failure to commit funds to a program would result in a loss of anticipated future revenues attributable to that program, which could materially harm our business. Our government customers are subject to stringent budgetary constraints and political considerations. If annual levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, our business, revenues and operating results may suffer.

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

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

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

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

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

Our prior contracts for the supply of BioThrax with the DoD and HHS were fixed price contracts. We expect that our future contracts with the U.S. government for biodefense product candidates that we successfully develop also may be fixed price contracts. Under a fixed price contract, we are required to deliver our products at a fixed price regardless of the actual costs we incur and 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 in 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

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control or prohibit the export of products.

Generally, government contracts, including our U.S. government contracts for BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the government s convenience. Under general principles of government contracting law, if the government terminates a contract for convenience, the terminated company may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. One or more of our government contracts could be terminated under these circumstances. In addition, if the U.S. government decides to withdraw military personnel from high threat areas, including Iraq, or otherwise determines that it will decrease the number of military personnel to be immunized with BioThrax, the DoD s demand for BioThrax may be reduced substantially. In addition, any follow-on contract with DoD may not provide sufficient indemnification, and DoD may require us to accept a greater risk of loss for the product manufacture, storage and delivery.

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 October 2004, a federal court issued the requested injunction. In December 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 2007, the government moved to dismiss the case. Although we are not a party to either of these lawsuits, if a court were to again enjoin DoD's use of BioThrax on a mandatory basis, the amount of future purchases of BioThrax could be affected. Lawsuits brought against us by third parties, even if not successful, require us to spend time and money defending the related litigation. 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

Risks Related to Our Financial Position and Need for Additional Financing

We have a limited operating history and may not maintain profitability in future periods or on a consistent basis.

We have a limited operating history. We commenced operations in 1998, and the FDA approved the manufacture of BioThrax at our renovated facilities in Lansing, Michigan in December 2001. Although we were profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis. Our profitability is substantially dependent on revenues from BioThrax product sales. Revenues from BioThrax product sales have fluctuated significantly in recent quarters, and 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. If we are unable to maintain profitability on a consistent basis, the market price of our common stock may decline, and you could lose part or all of your investment.

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

As of December 31, 2006, we had $42.8 million principal amount of debt outstanding and remaining borrowing availability of $1.1 million under our revolving lines of credit. We may seek to raise additional external debt financing of up to $20 million to fund our facility expansion in Lansing, Michigan and to provide additional financial flexibility. We also may incur additional indebtedness beyond such amount. Our leverage could have significant adverse consequences, including:

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

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

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

We expect our development expenses to increase in connection with our ongoing activities, particularly as we conduct additional and later stage clinical trials for our product candidates. In addition, we incur significant commercialization expenses for BioThrax product sales, marketing and manufacturing. We expect these commercialization expenses to increase in the future as we seek to broaden the market for BioThrax and if we receive marketing approval for additional products. We also are committed to substantial capital expenditures in connection with our facility expansion in Lansing, Michigan. We expect the construction of the facility to cost approximately $75 million, including approximately $55 million for the building and associated capital equipment, with the balance related to validation and qualification activities required for regulatory approval and initiation of manufacturing. We incurred approximately $37 million for these purposes through 2006. We also own two buildings in Frederick, Maryland that are available to support our future manufacturing requirements. We incurred approximately $1 million related to initial engineering design and preliminary utility build out for these facilities through 2006. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that will be necessary to complete this project.

We expect to continue to fund a significant portion of our development and commercialization costs for our product candidates with internally generated funds from sales of BioThrax. If we do not obtain future contracts with, and deliver BioThrax to, the DoD and HHS on terms consisitent with our current expectations, we will be forced to find additional sources of funding. We will not be able to obtain this funding or otherwise be able to raise capital when needed or on attractive terms, which would force us to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

As of December 31, 2006, we had $76.4 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, constructing 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.

To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. In addition to remaining payment obligations under our most recent contract with the DoD for the additional doses of BioThrax to be delivered by September 30, 2007, our only committed external sources of funds are remaining borrowing availability under our revolving lines of credit, development funding under our collaboration agreement with Sanofi Pasteur, funding from NIAID for animal efficacy studies of our anthrax immune globulin candidate and funding from the Wellcome Trust for our Phase II clinical trial of our typhoid vaccine candidate in Vietnam. Our ability to borrow additional amounts under our loan agreements is subject to our satisfaction of specified conditions. Additional equity or debt financing, grants, or corporate collaboration and licensing arrangements, may not be available on acceptable terms, if at all.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

Risks Related to Manufacturing and Manufacturing Facilities

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

We are spending significant amounts for the construction of a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus, which is being designed to enable us to manufacture BioThrax on a large scale for our existing and potential future customers. We are also constructing this new facility to accommodate large scale commercial manufacturing of multiple vaccine products, subject to complying with appropriate change-over procedures. We expect the construction of the facility to cost approximately $75 million, including approximately $55 million for the building and associated capital equipment, with the balance related to validation and qualification activities required for regulatory approval and initiation of manufacturing. We incurred approximately $37 million for these purposes through 2006. We also own two buildings in Frederick, Maryland that are available to address our future manufacturing requirements. We incurred approximately $1 million related to initial engineering design and preliminary utility build out for these facilities through 2006. Because we are in the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the timing and costs that will be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project and any delays in the construction or regulatory approval may adversely affect our ability to manufacture our commercial product candidates for clinical trials or commercial sale.

Constructing and preparing a facility for commercial vaccine manufacturing is a significant project. For example, constructing the new Lansing facility with increased manufacturing capacity requires that we scale up both fermentation and downstream processing compared to levels at our existing production facility. These projects may result in unanticipated delays and cost more than expected due to a number of factors, including regulatory requirements. The FDA must approve our new manufacturing facilities before they can be used to commercially manufacture our products. For example, we are required to show that the product we manufacture in our new Lansing facility is comparable to BioThrax manufactured at our existing facility, which 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 construction or regulatory approval of our new facility in Lansing is delayed, we may not be able to manufacture sufficient quantities of BioThrax to allow us to increase sales of BioThrax to the U.S. government and other customers, which would limit our opportunities for growth. 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 filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. From time to time, we experience deviations during the manufacturing process of BioThrax that can affect our release of the production lot according to our release protocols and other acceptance criteria. 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. Lot failures, 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 or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

For example, in late 2005, our standard product release testing identified BioThrax production lots for which follow up testing was required to determine whether we could submit these lots to the FDA for release for sale. We waited to conduct final release testing of these lots pending FDA review of an application that we submitted to amend the BioThrax release specifications. The FDA approved our amendment to the release specifications in May 2006, and we subsequently reinitiated release testing of these BioThrax lots. All lots of BioThrax that have been submitted to FDA for release have been released for sale by the FDA. We will not be able to sell any lots that in the future fail to satisfy release testing specifications or that are not released for sale by the FDA.

We are conducting a comparability program in connection with our plans to scale-up and manufacture BioThrax in our new large scale manufacturing facility in Lansing, Michigan. We are also conducting BioThrax characterization activities to identify the material proteins and components of BioThrax. The purpose of these initiatives is to demonstrate that BioThrax to be produced in our new facility will be bioequivalent to BioThrax as produced in our currently licensed manufacturing facility. We expect to present this data to the FDA, upon review of the data that we present, may require additional testing of, or manufacturing processes for, BioThrax that may be difficult to perform or that could affect our ability to obtain approval for our new large scale manufacturing facility.

In addition, because our immune globulin product candidates are produced from human plasma, we must immunize human donors and collect plasma on a regular basis to generate sufficient volumes of plasma to manufacture the immune glolulin product. If we are unable to recruit and retain donors, we may be unable to continue to manufacture our immune globulin product candidates in commercial quantities or at all.

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

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

- equipment malfunctions or failures;
- technology malfunctions;
- work stoppages or slow downs;
- protests, including by animal rights activists;
- damage to or destruction of the facility due to natural disasters;
- 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.

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

The timing and amount of customer demand is difficult to predict. We may not be able to scale up our production quickly enough to fill any new customer orders on a timely basis. This could cause us to lose new business and possibly existing business. For example, under our most recent BioThrax supply contract with the DoD, the DoD was obligated to acquire a minimum number of doses of BioThrax and had the right to acquire up to a maximum number of doses. Any future contract with the DoD may contain a similar provision. If in connection with such a contract, the DoD elects to purchase the maximum number of doses of BioThrax under the contract, we may not have sufficient available production capacity at our existing manufacturing facility in Lansing to increase sales of BioThrax to customers other than the U.S. government. In addition, we may not be able to scale up manufacturing processes for our product candidates to allow production of commercial quantities at a reasonable cost or at all. Furthermore, if we overestimate customer demand, we could incur significant unrecoverable costs from creating excess capacity. For example, if we do not maintain and increase sales of BioThrax to the U.S. government and other customers, we may not be able to generate an adequate return on the significant amounts that we are spending for construction of our new manufacturing facility in Lansing. In addition, if we do not successfully develop and commercialize any of our product candidates, we may never require the production capacity that we expect to have available at our Frederick site.

If third parties do not manufacture our product candidates 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 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 and plan to construct a pilot plant in Maryland for production of preclinical and clinical supplies of our product candidates, we expect that we will continue to use third parties for these purposes. In addition, we expect that we will rely on third parties for a portion of the manufacturing process for commercial supplies of product candidates that we successfully develop, including fermentation for some of our vaccine product candidates, plasma fractionation and purification for our immune globulin product candidates and contract fill and finish operations. 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 candidate, and our collaboration with HPA, under which HPA provides specialized manufacturing capabilities for our recombinant bivalent botulinum vaccine candidate and the bivalent botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin candidate.

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, Michigan 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.

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

We have outsourced the operation for filling BioThrax into vials to a single company, Hollister-Stier Laboratories LLC. Our contract with Hollister-Stier expires on December 31, 2007. We have not established internal redundancy for our filling functions and currently have no substitute provider that can handle our filling needs. If Hollister-Stier is unable to perform filling services for us or we are unable to enter into a new contract with Hollister-Stier, we would need to identify and engage an alternative filling company. Any new contract filling company will need to obtain FDA approval for filling BioThrax at its facilities. Identifying and engaging a new contract filling company and obtaining FDA approval could involve significant cost and delay. As a result, we might not be able to deliver BioThrax orders on a timely basis and our revenues could decrease.

Risks Related to Product Development

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

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

- successful development of animal models by the U.S. government;
- successful completion of non-clinical development, including in approved animal models;
- 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 or arrangements;
- 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. In addition, our development plans for our botulinum immune globulin candidate require the development of a new botulinum toxoid vaccine that we would use to vaccinate individuals who would then donate plasma for use in our botulinum immune globulin candidate. If the development of this new botulinum toxoid vaccine is delayed or not completed, for regulatory or other reasons, we may not be able to successfully develop our botulinum immune globulin candidate.

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

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

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive preclinical development, clinical trials to demonstrate the safety of our product candidates and clinical or animal trials to demonstrate the efficacy of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. A failure of one or more of our clinical trials or animal efficacy studies can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial or animal efficacy study process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we currently anticipate;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- 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.

For example, the FDA could require us to conduct additional clinical development in our botulinum immune globulin program that we currently do not plan to conduct. We expect to rely on safety and immunogenicity data from a pentavalent botulinum toxoid vaccine previously manufactured by the State of Michigan in the development of a new bivalent botulinum toxoid vaccine that we plan to use as the basis for our botulinum immune globulin candidate. We plan to conduct a Phase I clinical trial to evaluate the safety of the botulinum toxoid vaccine. If the results are favorable, we expect that the Phase I clinical trial will provide data sufficient to support an acceptable dose for the vaccine and the optimal dosing schedule. As a result, we anticipate that the FDA will not require us to conduct a Phase II clinical trial for the botulinum toxoid vaccine before permitting us to initiate a donor stimulation program for our botulinum immune globulin candidate. However, the FDA has not approved our plan to proceed directly to a donor stimulation program without conducting a Phase II clinical trial for the botulinum toxoid vaccine and may not do so. If the FDA requires us to conduct a Phase II clinical trial for the botulinum toxoid vaccine, the development plans for our botulinum immune globulin candidate will be delayed.

In addition, our development plan for BioThrax as a post-exposure prophylaxis for anthrax infection contemplates that we will conduct 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 Project BioShield, 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.

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Risks Related to Commercialization

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

An element of our business strategy is to establish a market for sales of BioThrax to customers in addition to the U.S. government. These potential customers include the U.S. Postal Service, foreign governments, state and local governments, which we expect will be interested in BioThrax to protect first responders and emergency personnel, such as police, fire and emergency medical personnel, multinational companies, non-governmental organizations and hospitals. The market for sales of BioThrax to customers other than the U.S. government is new and undeveloped, and we may not be successful in generating meaningful sales of BioThrax to these potential customers. To date, we have made only minimal sales to these customers.

In particular, we have supplied small amounts of BioThrax directly to several foreign governments. In 2006, our sales of BioThrax to customers other than the U.S. government represented less than one percent of our revenue. If we fail to significantly increase our sales of BioThrax to these customers, our business and opportunities for growth could be materially harmed.

Government regulations and the terms of our U.S. government contracts may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of BioThrax, the U.S. government may decide, particularly in the current environment of elevated concerns about global terrorism, to increase the scope of export prohibitions. These controls could limit our sales of BioThrax to foreign governments and other foreign customers.

In addition, the DoD has contractual and statutory rights that could interfere with sales of BioThrax to customers other than the U.S. government. For example, our efforts to develop domestic commercial and international sales may be impeded by the DoD s right under the Defense Production Act to require us to deliver more doses than are otherwise specified in our contract with the DoD. If the DoD required delivery of these additional doses, it could affect our production schedule and deplete BioThrax supplies that would otherwise be available for commercial sales. In addition, the DoD could either sell BioThrax directly to foreign governments at a lower price than we may offer or donate BioThrax to foreign governments under the DoD s Foreign Military Sales program.

Our ability to meet any 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, Michigan to manufacture BioThrax for sale to U.S. government customers. We substantially completed construction of our new manufacturing facility in Lansing in 2006, and expect to conduct installation, validation and qualification activities required for regulatory approval during 2007 and 2008. We anticipate that we will initiate large scale manufacturing of BioThrax for commercial sale at the new facility in 2008. We anticipate that we will be able to demonstrate in non-clinical studies that BioThrax manufactured at our new facility is comparable to BioThrax manufactured at our existing facility. As a result, we expect 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. 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 for commercial sale at our new facility will be delayed and we will incur additional unanticipated costs. Until the new manufacturing facility is available for commercial use, we will not have sufficient available production capacity to allow us to significantly increase sales of BioThrax to customers other than the U.S. government.

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

Any products that we bring to the market may not gain or maintain market acceptance by potential government customers, physicians, patients, healthcare payors and others in the medical community. In particular, our biodefense immunobiotic products and product candidates are subject to the product criteria that may be specified by potential U.S. government customers. The product specifications in any government procurement request may prohibit or preclude us from participating in the government program if our products or product candidates do not satisfy the stated criteria. For example, in 2004, HHS issued a request for proposals for the supply of anthrax vaccine for the SNS. The HHS request was limited to a recombinant anthrax vaccine. Because BioThrax is not a recombinant vaccine, BioThrax was precluded from consideration under that procurement program.

In addition, notwithstanding favorable findings regarding the safety and efficacy of BioThrax by the FDA in its final ruling in December 2005, the U.S. Government Accountability Office reiterated concerns regarding BioThrax in Congressional testimony in May 2006 that it had previously identified beginning in 1999. These concerns include the need for a six-dose

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regimen and annual booster doses, questions about the long-term and short-term safety of the vaccine, including how safety is affected by gender differences, and uncertainty about the vaccine s efficacy.

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

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

- the prevalence and severity of any side effects;
- the efficacy and potential advantages over alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- 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 filed a citizen s petition with the FDA and various lawsuits seeking the revocation of the license for BioThrax and the termination of the DoD program for the mandatory administration of BioThrax to military personnel. In October 2004, a federal court ruled that the FDA, as part of its review of all biological products approved prior to 1972, had not properly issued a final order determining that BioThrax is safe and effective and not misbranded. As a result, the court issued an injunction prohibiting the DoD from administering BioThrax to military personnel on a mandatory basis without informed consent of the recipient or a Presidential waiver. Although the FDA issued a final order in December 2005 determining that BioThrax is safe and effective and not misbranded and, as a result, an appellate court ruled in February 2006 that the injunction was dissolved, these actions created negative publicity about BioThrax. 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 2007, the government moved to dismiss the case. These and other lawsuits or publicity campaigns could limit 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.

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

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

The development and commercialization of new immunobiotics is highly competitive. We face competition with respect to BioThrax, our current product candidates and any products we may seek to develop or commercialize in the future from major pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. We believe that our most significant competitors in the area of immunobiotics are a number of pharmaceutical companies that have vaccine programs, including GlaxoSmithKline, Sanofi-Aventis, Wyeth, Merck and Novartis, as well as smaller more focused companies engaged in immunobiotic development, such as 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, we face significant competition for the supply of this vaccine to the U.S. government. We also face significant competition for our biodefense immunobiotic product candidates. HHS has awarded SNS supply contracts to Cangene for an anthrax immune globulin and Human Genome Sciences for a monoclonal antibody to Bacillus anthracis as a post-exposure therapeutic for anthrax infection. HHS has advised us that it is supplying Cangene with BioThrax doses that we delivered to HHS for placement into the SNS in order that Cangene can immunize donors and obtain plasma for its anthrax immune globulin product candidate. Several companies have botulinum vaccines in early clinical or preclinical development, and HHS is procuring a botulinum immune globulin derived from equine plasma for the SNS.

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

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scientific and management personnel, as well as in acquiring products, product candidates and technologies complementary to, or necessary for, our programs or advantageous to our business.

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

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

The 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. The declaration is meant to provide general immunity from all claims under state or federal law for loss arising out of the administration or use of a covered countermeasure. Manufacturers are not entitled to this protection in cases of willful misconduct.

Upon a declaration by the Secretary, a compensation fund is created to provide timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure. The covered injuries to which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer only after they have exhausted their remedies under the compensation program. However, a willful misconduct action could be brought against us if any individuals exhausted their remedies under the compensation program and thereby expose us to liability. Although we may petition the Secretary to make such a declaration with respect to anthrax generally and BioThrax specifically, we do not know if any such petition would be successful or that, if successful, the Act will provide adequate coverage or survive anticipated legal challenges to its validity.

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

In addition, although our existing and prior contracts with the DoD and HHS provide that the government will indemnify us for any damages resulting from product liability claims, we cannot be certain that we will be able to continue to negotiate similar rights in future contracts or that the U.S. government will honor this obligation. For example, although we have notified the DoD of the lawsuits filed against us by current and former members of the U.S. military claiming damages as the result of personal injuries allegedly suffered from vaccination with BioThrax, the DoD has not yet acted on our claim for indemnification pending resolution of our claims under our product liability insurance.

In addition, members of Congress have proposed and may in the future propose legislation that reduces or eliminates these and other liability protections for manufacturers of biodefense countermeasures.

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

We face an inherent risk of product liability exposure related to the sale of BioThrax and any other products that we successfully develop and the testing of our product candidates in clinical trials. In late 2005 and early 2006, we were named as a defendant in three federal lawsuits filed on behalf of three 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 plaintiff in each of these three lawsuits claimed different injuries and sought varying amounts of damages. The first plaintiff alleged that the vaccine caused erosive rheumatoid arthritis and requested damages in excess of $1 million. The second plaintiff alleged that the vaccine caused Bell s palsy and other related conditions and requested damages in excess of $75,000. The third plaintiff 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.

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, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

We have product liability insurance for coverage up to a $10 million annual aggregate limit with a deductible of $75,000 per claim. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. For example, from 2002 through February 2006, we were unable to obtain product liability insurance for sales of BioThrax on commercially reasonable terms. We do not believe that the amount of insurance we have been able to obtain for BioThrax is sufficient to manage the risk associated with the potential deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on contractual indemnification provisions and statutory protections to limit our liability for BioThrax.

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

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

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

Obtaining a determination that a product is covered is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to gain coverage. Even when a payor determines that a product is covered, the payor may impose limitations that preclude payment for some uses that are approved by the FDA or comparable authorities but are determined by the payor to not be medically reasonable and necessary. Moreover, eligibility for coverage does not imply that any product will be covered in all cases or that reimbursement will be available at a rate that permits the health care provider to cover its costs of using the product. We expect that the success of some of our commercial vaccine candidates for which we obtain marketing approval will depend on inclusion of those product candidates in government immunization programs.

Most non-pediatric commercial vaccines are purchased and paid for, or reimbursed by, managed care organizations, other private health plans or public insurers or paid for directly by patients. In the United States, pediatric vaccines are funded by a variety of federal entitlements and grants, as well as state appropriations. Foreign governments also commonly fund pediatric vaccination programs through national health programs. In addition, with respect to some diseases affecting the public health generally, particularly in developing countries, public health authorities or nongovernmental, charitable or philanthropic organizations fund the cost of vaccines.

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

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

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

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

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

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

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

Our success depends on our continued ability to attract, retain and motivate highly qualified managerial and key scientific personnel. We consider Fuad El-Hibri, our president, chief executive officer and chairman of our board of directors, Edward J. Arcuri, our executive vice president and chief operating officer, and Robert G. Kramer, president and chief executive officer of Emergent BioDefense Operations, and Daniel J. Abdun-Nabi, senior vice president corporate affairs, to be key to our BioThrax operations and our efforts to develop and commercialize our product candidates. All 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. This litigation was brought against us under a provision of the False Claims Act that allows a private citizen to file a suit in the name of the U.S. government charging fraud by government contractors and other entities who receive or use government funds and share in any money recovered. Although a federal district court dismissed the litigation, and a federal appeals court subsequently upheld that decision, we spent significant time and money defending the litigation.

The states, many municipalities and foreign governments typically also have laws and regulations governing contracts with their respective agencies. These domestic and foreign laws and regulations affect how we and our customers can do business and, in some instances, impose added costs on our business. Any changes in applicable laws and regulations could restrict our ability to maintain our existing contracts and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our revenues and results of operations.

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

Our BioThrax supply contract with the DoD grants us the right to use property and equipment owned by the DoD in the manufacture of BioThrax. This property and equipment, referred to as government furnished equipment, is in service at our Lansing site. Some of this government furnished equipment is important to our business. We pay the DoD a small usage fee for the government furnished equipment based on the number of doses of BioThrax that we produce for sale to customers other than the U.S. government. We have the option to purchase all or part of the government furnished equipment at any time during the contract period for approximately $21 million. If the DoD modifies the terms under which we use the government furnished equipment in a manner unfavorable to us, including raising the usage fee, our business could be harmed. If DoD terminated our contract, we could be required to rent or purchase all or a part of the government furnished equipment to continue production of BioThrax in our current facility.

Risks Related to Regulatory Approvals

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

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

In the United States, BioThrax, our biodefense product candidates and our commercial product candidates are regulated by the FDA as biologics. To obtain approval from the FDA to market these product candidates, other than biodefense products purchased by HHS for the 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 believe that, according to the FDA s current BLA requirements for biologics that cannot be ethically or feasibly tested in humans in Phase III efficacy trials, we may instead be able to obtain BLA approval based on clinical data from Phase II and Phase III trials in healthy subjects that demonstrate adequate safety and immune response and effectiveness data from studies in animals. Specifically, we intend to pursue FDA approval of BioThrax as a post-exposure prophylaxis, our immune globulin candidates, our recombinant bivalent botulinum vaccine candidate and a next generation anthrax vaccine under the FDA animal rule. Under the animal rule, if human efficacy trials are not ethical or feasible, the FDA can approve drugs or biologics used to treat or prevent serious or life threatening conditions caused by exposure to lethal or permanently disabling toxic chemical, biological, radiological or nuclear substances based on human clinical data demonstrating safety and immunogenicity and evidence of efficacy from appropriate non-clinical animal studies and any additional supporting data. Products approved under the animal rule are subject to additional regulation not normally required of other products. Additional regulation may include post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

We have applied to the FDA to reduce the number of required doses of BioThrax for pre-exposure prophylaxis from six to five, with an annual booster dose thereafter. Our application is based on an interim analysis of data from an ongoing clinical trial being conducted by the CDC to evaluate whether as few as three doses of BioThrax, administered over six months, 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 are being further analyzed, and we plan to submit an amendment to our application when this analysis is completed. If the FDA does not find our response to be adequate, we might be required to conduct additional independent testing to continue to pursue the development of this dosing regimen. Responding to the FDA s complete response letter will delay potential approval of our application. If we are unable ultimately to respond satisfactorily to the FDA, our application will not be approved.

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

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

Any immunobiotic product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and

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review by the FDA and other regulatory bodies, including through inspections of our facilities. As an approved product, BioThrax is subject to these requirements and ongoing review. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. The FDA enforces its cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect manufacturing facilities without a warrant at reasonable times and in a reasonable manner.

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

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug or biologic for that time period for the same indication. Orphan drug exclusivity in Europe lasts for ten years, but can be reduced to six years if a drug or biologic no longer meets the criteria for orphan drug designation or if the drug or biologic is sufficiently profitable so that market exclusivity is no longer justified. If a competitor obtains orphan drug exclusivity for an indication for a product that competes with one of the indications for one of our product candidates before we obtain orphan drug designation,

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and if the competitor s product is the same drug as ours, the FDA would be prohibited from approving our product candidate for the same orphan indication unless we demonstrate that our product is clinically superior. None of our products or product candidates have been designated as orphan drugs. Even if we obtain orphan drug exclusivity for one or more indications for one of our product candidates, we may not be able to maintain it. For example, if a competitive product that is the same drug or biologic as our product is shown to be clinically superior to our product, any orphan drug exclusivity we 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.

If a drug or biologic is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation. 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 would prevent us from marketing our products abroad.

We intend to have our products marketed outside the United States. To market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. With respect to some of our product candidates, we expect that a future collaborator will have responsibility to obtain regulatory approvals outside the United States, and we will depend on our collaborators to obtain these approvals. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We and our collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Risks Related to Our Dependence on Third Parties

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

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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 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 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.

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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 are aware of and are monitoring ongoing 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. We have licensed from the Bavarian State Ministry of the Environment, Public Health and Consumer Protection rights to materials and technology related to MVA. Our MVA platform technology, which is based on these licensed rights, could potentially be used as a viral vector for delivery of several vaccine antigens for different disease-causing organisms, including influenza, using recombinant technology. As a result, our licensed rights and our ability to use our MVA platform technology could be negatively affected by the outcome of this ongoing litigation. It also is possible that we could be named as a defendant in future similar litigation relating to MVA. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference and reexamination proceedings declared by the United States Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. For example, we have filed an opposition in the European Patent Office against Bavarian Nordic s patent covering certain aspects of the MVA technology. We may also become a party to trademark invalidation and interference proceedings in foreign trademark offices. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Risks Related to Our Acquisition Strategy

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

We have pursued an acquisition strategy since our inception to build our business of developing, manufacturing and commercializing immunobiotics. We commenced operations in September 1998 through an acquisition of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how from the Michigan Biologic Products Institute. We acquired our pipeline of commercial vaccine candidates through our acquisition of 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, our president, 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 March 15, 2007, Mr. El-Hibri was the beneficial owner of approximately 80% 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 our company that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring

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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% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of our company.

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

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 our company and to provide our board of directors with adequate time to evaluate unsolicited offers. The rights plan may have anti-takeover effects. The rights plan will cause substantial dilution to a person or group that attempts to acquire us on terms that our board of directors does not believe are in our best interests and those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

If 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 March 15, 2007, our common stock has traded as high as $17.75 per share and as low as $9.75 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. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

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

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

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

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

Sales of a substantial number of shares of our common stock in the public market 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 22.3 million shares of our common stock outstanding as of March 15, 2007 have the right to require us to register these shares of common stock under specified circumstances, subject to lock-up agreements signed in connection with our initial public offering.

In addition, as of March 15, 2007, options exercisable for approximately 1,644,038 shares of our common stock will expire if not exercised prior to July 1, 2007. Because these options have exercise prices ranging from $0.09 to $2.74 per share, which is less than the current market price of our common stock, we expect that the holders of these options will exercise the options prior to their expiration date and then promptly sell a substantial portion of the shares of our common stock issued upon exercise of the options. We have filed with the SEC a registration statement on Form S-8 registering the sale of all the shares of our common stock subject to outstanding options and options and other awards issuable pursuant to our equity incentive plans. Shares registered under this registration statement on Form S-8 are available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements signed in connection with our initial public offering that are applicable to these shares.

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	16,000	Leases expire 2016

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

In February 2006, we began construction of a new 50,000 square foot manufacturing facility on our Lansing campus. We expect the construction of the facility to cost approximately $75 million, including approximately $55 million for the building and associated capital equipment, with the balance related to validation and qualification activities required for regulatory approval and initiation of manufacturing. We are constructing this new facility as a large scale commercial manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures. Subject to regulatory approval, we expect that the new manufacturing facility will serve as our primary BioThrax manufacturing facility. We anticipate that we will initiate large scale manufacturing of BioThrax for commercial sale at the new facility in 2008. 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 facility will be delayed and we will incur additional unanticipated costs.

We are constructing this facility to accommodate production of up to 40 million doses of BioThrax per year on a single production line, which we could expand for production of up to 80 million doses per year through the addition of a second production line. In comparison, our current facility has a maximum production capacity of approximately nine million doses of BioThrax per year. In addition to construction of a new manufacturing facility, we recently commissioned a pilot plant on our Lansing campus. Our Lansing facilities and substantially all of the other assets of our wholly owned subsidiary, Emergent BioDefense Operations Lansing Inc., other than accounts receivable under our DoD and HHS contracts, serve as collateral for our financing obligations for our facility expansion in Lansing.

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 and 2009. These plans also contemplate that we will build out commercial manufacturing operations

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two to three years after establishing initial product launch capabilities. We may elect to lease all or a substantial portion of 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. We conduct product development programs at this site for both our biodefense and commercial product candidates. Our facility in Wokingham, England of approximately 16,000 square feet contains a combination of laboratory and office space. We conduct product development programs at this site primarily for our commercial product candidates. Our facility in Rockville, Maryland contains approximately 23,000 square feet of office space, including our executive offices.

ITEM 3. LEGAL PROCEEDINGS

BioThrax product liability litigation. On October 14, 2005, January 9, 2006 and January 17, 2006, we were named as a defendant in three federal lawsuits filed on behalf of three 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 each of these three lawsuits claimed different injuries and sought varying amounts of damages. The first plaintiff alleged that the vaccine caused erosive rheumatoid arthritis and requested damages in excess of $1 million. The second plaintiff alleged that the vaccine caused Bell s palsy and other related conditions and requested damages in excess of $75,000. The third plaintiff 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.

We moved to dismiss these three lawsuits for lack of personal jurisdiction, or in the alternative, to transfer the lawsuits to federal court in Michigan. On October 27, 2006, one of these lawsuits was transferred to the U.S. District Court for the Western District of Michigan. Although this order was entered, the case has not been transferred to date. On October 31, 2006, another of these lawsuits was dismissed for lack of personal jurisdiction. The plaintiff in this lawsuit appealed that decision to the United States Court of Appeals for the Ninth Circuit. The appeal has not yet been briefed and oral argument is not scheduled. The court has not yet ruled on our motion in the third lawsuit. These lawsuits are in the preliminary stages of litigation, and we believe that we are entitled to indemnification under our contract with the DoD for legal fees and any damages that may result from these claims.

In April 2006, the U.S. District Court for the Western District of Michigan entered summary judgment in our favor in four other consolidated lawsuits asserting similar claims brought by approximately 120 individuals. The District Court s ruling in the four 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. We intend to rely on similar defenses with respect to the substantive claims asserted in our pending lawsuits. We also expect to rely on contractual indemnification provisions with the DoD and statutory protections to limit our potential liability resulting from the pending lawsuits.

Insurance coverage litigation. On December 26, 2006, we were named as a defendant in a lawsuit brought by Evanston Insurance Company in the United States 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. On October 27, 2004, the District Court enjoined the DoD from administering BioThrax to military personnel on a mandatory basis without their informed consent or a Presidential waiver. This ruling was based in part on the District Court s finding that the FDA, as part of its review of all biological products approved prior to 1972, had not properly issued a final order determining that BioThrax is safe and effective and not misbranded.

In December 2005, the FDA issued a final order determining that BioThrax is safe and effective and not misbranded. On February 9, 2006, the U.S. Court of Appeals for the District of Columbia, on appeal of the injunction by the government, ruled that the injunction had dissolved by its own terms as a result of the FDA s final order. 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. On December 14, 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 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. On February 26, 2007, the government moved to dismiss the case. Although we are not a party to either of the Milvax lawsuits, if the District Court were to grant all or part of the requested relief, the amount of future purchases of BioThrax 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 is currently a named defendant in 41 lawsuits pending in two jurisdictions: four in California and 37 in Illinois. The products at issue in these lawsuits are pediatric vaccines and immune globulins. Because we are not currently and have not historically been in the business of manufacturing or selling pediatric vaccines, we do not believe that we manufactured the pediatric vaccines at issue in the lawsuits. Under a contractual obligation to the State of Michigan, we manufactured one batch of vaccine suitable for pediatric use. However, the contract required the State to use the vaccine solely for Michigan public health purposes. One plaintiff in a thimerosal lawsuit alleges that he was injured by immune globulin containing thimerosal. We previously manufactured human immune globulin that contained thimerosal. We no longer manufacture any products that contain thimerosal. We 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

In October 2006, in connection with our initial public offering, we solicited the written consent of our stockholders to the following matters pursuant to Section 228 of the General Corporation Law of the State of Delaware:

- the amendment of our amended and restated certificate of incorporation to reclassify our previously outstanding class A common stock as common stock, increase the number of authorized shares of common stock and adjust the par value of our authorized and undesignated preferred stock;
- the approval of our restated certificate of incorporation that became effective upon the closing of our initial public offering;
- the approval of our amended and restated by-laws that became effective upon the closing of our initial public offering;
- the approval of our 2006 stock incentive plan;
- the approval of the rights agreement, dated November 14, 2006, with American Stock Transfer & Trust Company, as rights agent, providing for the implementation of our stockholder rights plan;
- the termination of the stockholders agreements that we had entered into with the holders of our previously outstanding class B common stock;
- the waiver of any and all prior notice requirements and any rights with respect to the registration of our securities in connection with, or arising from, the transactions contemplated by our initial public offering;
- the waiver of any right of first refusal and/or pre-emptive rights in connection with, or arising from, the transactions contemplated our initial public offering;
- the election of Fuad El-Hibri, Jerome M. Hauer and Ronald B. Richard as Class I directors;
- the election of Zsolt Harsanyi and Louis W. Sullivan as Class II directors;

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the election of Shahzad Malik and Joe M. Allbaugh as Class III directors; and

the ratification of Ernst & Young LLP as our independent registered public accounting firm.

We received the requisite consents of our stockholders on October 27, 2006. The written consent with respect to all such matters was adopted by holders of 506,454 of the 7,792,714 shares of our common stock issued and outstanding as of October 27, 2006, consisting of 5,075,054 of the 7,752,001 shares of our previously outstanding class A common stock and 21,400 of the 40,715 shares of our previously outstanding class B common stock.

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. For the period from November 15, 2006 to December 31, 2006, our common stock had a high sales price of $12.72 per share and a low sales price of $9.75 per share.

As of March 15, 2007, we had 57 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

During the period from January 1, 2006 to December 8, 2006, when we filed a registration statement on Form S-8 to register all of the shares subject to outstanding stock options and options and other awards issuable pursuant to our employee stock option plan and 2006 stock incentive plan, we granted options to employees to purchase an aggregate of 172,621 shares of our common stock at a weighted average exercise price of $11.89 per share. In addition, during the same period, we issued to directors an aggregate of 86,312 shares of our common stock upon the exercise of options at a weighted average exercise price of $10.28 per share.

These stock options and shares of common stock were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption provided by Section 3(b) of the Securities Act and Rule 701 promulgated thereunder. All recipients either received adequate information about us or had access, through employment or other relationships, to such information. All certificates representing the issued shares of common stock included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

Use of Proceeds

On November 20, 2006, we completed an initial public offering of 5,000,000 shares of our common stock at a price of $12.50 per share for an aggregate offering price of $62.5 million. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-136622), which was declared effective by the SEC on November 14, 2006. J.P. Morgan Securities Inc., Cowen and Company, LLC and HSBC Securities (USA) Inc. were the managing underwriters of the offering. The offering commenced on November 14, 2006 and did not terminate until the sale of all of the shares offered. Each share of common stock sold in the offering includes one series A junior

participating preferred stock purchase right pursuant to a rights agreement that establishes our stockholder rights plan. The series A junior participating preferred stock purchase rights initially trade together with the common stock.

We registered a total of 5,750,000 shares of common stock in connection with the initial public offering, including 750,000 shares that the underwriters had the option to purchase to cover over-allotments. The over-allotment option to purchase up to 480,000 shares of common stock from selling stockholders and up to 270,000 additional shares of common stock from us expired un-exercised on December 14, 2006.

We received net proceeds from the offering of approximately $54.2 million, after deducting underwriting discounts and commissions of approximately $4.4 million and other offering expenses of approximately $3.9 million. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any affiliates of ours.

Through December 31, 2006, we have used approximately $350,000 of the net proceeds from the offering to fund development of our biodefense product candidates, comprised of approximately $150,000 for label expansions and improvements for BioThrax, approximately $100,000 for a next generation anthrax vaccine candidate and approximately $100,000 for our anthrax immune globulin candidate; and approximately $2.4 million of the net proceeds to fund a portion of the construction, validation and qualification costs for our new manufacturing facility in Lansing, Michigan. 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, 2004, 2005 and 2006 and the consolidated balance sheet data as of December 31, 2005 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, 2002 and 2003 and the consolidated balance sheet data as of December 31, 2002, 2003 and 2004 from our audited consolidated financial statements, which are not included in this annual report on Form 10-K. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,				
(in thousands, except share and per share data)	**2002**	**2003**	**2004**	**2005**	**2006**
Statements of operations data:					
Revenues:					
Product sales	$ 61,253	$ 55,536	$ 81,014	$ 127,271	$ 147,995
Contracts and grants	17,288	233	2,480	3,417	4,737
Total revenues	78,541	55,769	83,494	130,688	152,732
Operating expenses (income):					
Cost of product sales	24,569	22,342	30,102	31,603	24,125
Research and development	2,808	6,327	10,117	18,381	45,501
Selling, general & administrative	13,397	19,547	30,323	42,793	44,601
Purchased in-process research and development	-	1,824	-	26,575	477
Settlement of State of Michigan Obligation	-	-	(3,819)	-	-
Litigation settlement	-	-	-	(10,000)	-
Total operating expenses	40,774	50,040	66,723	109,352	114,704
Income (loss) from operations	37,767	5,729	16,771	21,336	38,028
Other income (expense):					
Interest income	80	100	65	485	846
Interest expense	(451)	(293)	(241)	(767)	(1,152)
Other income (expense), net	(271)	168	6	55	293
Total other income (expense)	(642)	(25)	(170)	(227)	(13)
Income before provision for income taxes	37,125	5,704	16,601	21,109	38,015
Provision for income taxes	733	1,250	5,129	5,325	15,222
Net income	$ 36,392	$ 4,454	$ 11,472	$ 15,784	$ 22,793
Earnings per share basic	$ 1.97	$ 0.24	$ 0.61	$ 0.77	$ 0.99
Earnings per share diluted	$ 1.75	$ 0.22	$ 0.56	$ 0.69	$ 0.93

Weighted average number of shares	basic	18,441,235	18,904,992	18,919,850	20,533,471	23,039,794
Weighted average number of shares	diluted	20,752,243	20,316,752	20,439,252	22,751,733	24,567,302

(in thousands)	As of December 31, 2002	2003	2004	2005	2006
Balance Sheet Data:					
Cash and cash equivalents	$ 4,891	$ 7,119	$ 6,821	$ 36,294	$ 76,418
Working capital	1,130	(3,147)	7,509	29,023	82,990
Total assets	22,790	37,127	69,056	100,332	238,255
Total long-term liabilities	4,592	1,228	11,921	10,502	35,436
Total stockholders equity	4,155	8,448	22,949	59,737	138,472

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 section 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 biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics. We operate in two business segments: biodefense and commercial. We commenced operations as BioPort Corporation in September 1998 through an acquisition from the Michigan Biologic Products Institute of rights to our marketed product, BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how. Following this acquisition, we completed renovations at the Lansing facilities that had been initiated by the State of Michigan. In December 2001, the FDA approved a supplement to our manufacturing facility license for the manufacture of BioThrax at the renovated facilities.

In June 2004, we completed a corporate reorganization in which we:

- issued 18,666,479 shares of class A common stock in exchange for 18,017,994 shares of BioPort class A common stock and 648,485 shares of BioPort class B common stock;
- repurchased and retired all other issued and outstanding shares of BioPort class B common stock; and
- assumed all outstanding stock options to purchase BioPort class B common stock and granted option holders replacement stock options to purchase an equal number of shares of our class B common stock.

As a result of the reorganization, BioPort became a wholly owned subsidiary of Emergent. We subsequently renamed BioPort as Emergent BioDefense Operations Lansing Inc. We acquired our portfolio of commercial vaccine candidates through our acquisition of Microscience in a share exchange in June 2005 and our acquisition for cash of substantially all of the assets of Antex in May 2003 and Vivacs in July 2006. We subsequently renamed Microscience as Emergent Product Development UK Limited. We expect to continue to seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties.

Our biodefense business has generated net income for each of the last three fiscal years. However, in our commercial business, we have not received approval to market any of our product candidates and, to date, have received no product sales revenues. Our only sources of revenue in our commercial business are development grant funding and an upfront license fee and additional payments for development work under a collaboration agreement with Sanofi Pasteur. As a result, our commercial business has incurred a net loss for each of the last three fiscal years.

Biodefense

In our biodefense business, we develop and commercialize immunobiotics for use against biological agents that are potential weapons of bioterrorism or biowarfare. Our marketed product, BioThrax, is the only vaccine approved by the FDA for the prevention of anthrax infection. The DoD and HHS have been the principal customers for BioThrax. In addition, we have

supplied small amounts of BioThrax directly to several foreign governments. Since 1998, we have been a party to two supply agreements for BioThrax with the DoD. Pursuant to these contracts, we have supplied over nine million doses of BioThrax through December 2006 for immunization of military personnel. Our most recent contract with the DoD, which was amended in October 2006, provides for the supply of a minimum of approximately 1.5 million doses of BioThrax to the DoD through September 2007. We delivered to the DoD approximately 480,000 of these doses in December 2006, and we expect to deliver the balance by September 2007. The DoD s right to order additional doses of BioThrax under this contract expired in February 2007. Since May 2005, we have supplied 10 million doses of BioThrax to HHS for inclusion in the SNS. In May 2005, we entered into an agreement to supply five million doses of BioThrax for the strategic national stockpile, or SNS, for a fixed price of $123 million. We completed delivery of all five million doses by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax for the SNS by May 2007 for a fixed price of $120 million. We delivered approximately four million of those doses in 2006 and the balance in February 2007, more than two months earlier than required.

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales of BioThrax. Our total revenues from BioThrax sales were $81.0 million in 2004, $127.3 million in 2005 and $148.0 million in 2006. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers and pursuing label expansions and improvements for BioThrax.

In addition to BioThrax, our biodefense product portfolio includes three biodefense product candidates in preclinical development. We are independently developing an anthrax immune globulin candidate, in part with funding from NIAID. We are collaborating with HPA in the development of a recombinant bivalent botulinum vaccine candidate and a new botulinum toxoid vaccine that we plan to use as the basis for a botulinum immune globulin candidate. We are actively pursuing additional government sponsored development grants and working with various government agencies to encourage them to conduct studies relating to BioThrax and our other biodefense product candidates.

Commercial

In our commercial business, we are developing a range of immunobiotic product candidates that are designed to address significant unmet or underserved public health needs caused by infectious diseases. Our commercial product portfolio includes a typhoid vaccine candidate and a hepatitis B therapeutic vaccine candidate, both of which are in Phase II clinical development, a group B streptococcus vaccine candidate in Phase I clinical development and a chlamydia vaccine candidate and a meningitis B vaccine candidate, both of which are in preclinical development. In May 2006, we entered into a license and co-development agreement with Sanofi Pasteur under which we granted Sanofi Pasteur an exclusive, worldwide license under our proprietary technology to develop and commercialize a meningitis B vaccine candidate.

We plan to encourage government entities and non-government and philanthropic organizations to provide development funding for, or to conduct clinical studies of, one or more of our commercial product candidates. For example, the Wellcome Trust provided funding for our Phase I clinical trial of our typhoid vaccine candidate in Vietnam and is providing funding for our Phase II clinical trial of this vaccine candidate in Vietnam. In addition, the NIAID agreed to sponsor Phase I clinical development of our group B streptococcus vaccine candidate.

Manufacturing Infrastructure

To augment our existing manufacturing capabilities, we are constructing a new 50,000 square foot manufacturing facility on our Lansing, Michigan campus. We expect the construction of the facility to cost approximately $75 million, including approximately $55 million for the building and associated capital equipment, with the balance related to validation and qualification activities required for regulatory approval and initiation of manufacturing. We incurred costs of approximately $37 million for these purposes through 2006. We substantially completed construction of this facility in 2006, and expect to conduct installation, validation and qualification activities required for regulatory approval during 2007 and 2008. We are constructing this new facility as a large scale manufacturing plant that we can use to produce multiple vaccine products, subject to complying with appropriate change-over procedures. We anticipate that we will initiate large scale manufacturing of BioThrax for commercial sale at the new facility in 2008. 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 for commercial sale at our new facility will be delayed and we will incur additional unanticipated costs.

We also own two buildings in Frederick, Maryland that are available to support our future manufacturing requirements. We incurred costs of approximately $1 million related to initial engineering design and preliminary utility build out of these facilities during 2006. Because we are in

the preliminary planning stages of our Frederick build out, we cannot reasonably estimate the

timing and costs that will be necessary to complete this project. If we proceed with this project, we expect the costs to be substantial and to likely require external sources of funds to finance the project. We may elect to lease all or a substantial portion of 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 valuation of stock related to stock-based compensation and income taxes. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

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

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

We cannot sell BioThrax to our customers without written FDA approval for each lot that we manufacture. As part of the FDA review process, we submit a detailed lot protocol for each BioThrax lot that we produce for sale. We also are required to submit product samples to the FDA for testing. Although we generally submit lot protocols and product samples promptly following the satisfactory completion of internal testing, we are permitted to submit product samples in advance of the lot protocols. The length of the FDA review process is approximately four to six weeks. However, individual lots may be released sooner or later depending on factors such as reviewer questions, license supplement approval, reviewer availability and whether our internal testing of product samples is completed before or concurrently with FDA testing. During the period covered by our financial statements included in this annual report, the FDA has not denied the sale of any BioThrax lots that we have submitted for approval.

We have generated BioThrax sales revenues under U.S. government contracts with the DoD and HHS. Under our DoD contract, we invoice the DoD for progress payments upon reaching contractually specified stages in the manufacture of BioThrax. We record as deferred revenue the full amount of each progress payment invoice that we submit to the DoD. Title to the product passes to the DoD upon submission of the first invoice. The earnings process is complete upon FDA release of the product for sale and distribution. Following FDA release of the product, we segregate the product for later shipment and recognize as period revenue all deferred revenue related to the released product in accordance with the bill and hold sale requirements under SAB 104. At that time, we also invoice the DoD for the final progress payment and recognize the amount of that invoice as period revenue. Our contract with HHS does not provide for progress payments. We invoice HHS and recognize the related revenue upon delivery of the product to the government carrier, at which time title to the product passes to HHS. We do not record allowances for sales returns, rebates or special promotional programs for sales of BioThrax or provisions for sales made in prior periods.

Under the collaboration agreement that we entered into with Sanofi Pasteur in May 2006 for our meningitis B vaccine candidate, we received an upfront license fee and are entitled to additional payments for development work under the collaboration and upon achieving contractually defined development and commercialization milestones. We evaluate the various components of a collaboration in accordance with Emerging Issues Task Force, or EITF, Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, or EITF No. 00-21, which addresses whether, for revenue recognition purposes, there is one or several elements in an arrangement. We concluded that under EITF No. 00-21, the upfront license fee, the development work and the milestone payments under our agreement with Sanofi Pasteur should be accounted for as a single

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unit of accounting. We recognize amounts received under this agreement over the estimated development period as we perform services. We recorded the amount of the upfront license fee as deferred revenue. We are recognizing this revenue over the estimated development period under the contract, currently estimated at seven years, as adjusted from time to time for any delays or acceleration in the development of the product candidate. Under the collaboration agreement, we are entitled to payments up to specified levels for development work we perform for Sanofi Pasteur. We invoice Sanofi Pasteur in advance of each quarter for the estimated work to occur in the upcoming quarter. We record the invoice amount as deferred revenue. As services are completed, we recognize the amount of the related deferred revenue as period revenue. Under the collaboration agreement, we also will be entitled to royalty payments on any future net sales of this product candidate.

From time to time, we are awarded 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 revenue and the associated costs as research and development expense. We issue invoices under these contracts after we incur the reimbursable costs. We recognize revenue upon invoicing the sponsoring organization.

Accounts Receivable

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

Inventories

Inventories are stated at the lower of cost or market, with cost being determined using a standard cost method, which approximates average cost. Average cost consists primarily of material, labor and manufacturing overhead expenses and includes the services and products of third party suppliers. We analyze our inventory levels quarterly and write down in the applicable period inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand. We also write off in the applicable period the costs related to expired inventory. We capitalize the costs associated with the manufacture of BioThrax as inventory from the initiation of the manufacturing process through the completion of manufacturing, labeling and packaging.

Accrued Expenses

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

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

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

Purchased In-process Research and Development

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

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

Stock-based Compensation

Through December 31, 2005, in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, we elected to account for our employee stock-based compensation using the intrinsic value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees, and related interpretations*, or APB No. 25, rather than the alternative fair value accounting method provided for under SFAS No. 123. Accordingly, we did not record compensation expense on employee stock options granted in fixed amounts and with fixed exercise prices when the exercise prices of the options were equal to the fair value of the underlying common stock on the date of grant. Pro forma information regarding net loss and loss per share is required by SFAS No. 123 and has been determined as if we had accounted for employee stock option grants under the fair value method prescribed by that statement. We provide this pro forma disclosure in our financial statements. We account for transactions in which services are received in exchange for equity instruments based on the fair value of the services received from non-employees or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS No. 123 and EITF Issue No. 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring*, *or in Conjunction with Selling, Goods or Services*, or EITF No. 96-18. In accordance with EITF No. 96-18, we periodically remeasure stock-based compensation for options granted to non-employees as the underlying options vest. As of December 31, 2006, we had no outstanding options that had been granted to non-employees other than our directors.

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 fair values. Pro forma disclosure is no longer an alternative. We will continue to value our share-based payment transactions using a Black-Scholes valuation model. Under the modified prospective method, we recognize compensation cost in our financial statements for all awards granted after January 1, 2006 and for all awards outstanding as of January 1, 2006 for which the requisite service had not been rendered as of the date of adoption. Prior period operating results have not been restated. We measure the amount of compensation cost based on the fair value of the underlying common stock on the date of grant. We recognize compensation cost over the period that an employee provides service in exchange for the award.

As a result of our adoption of SFAS No. 123(R) effective January 1, 2006, we recorded stock-based compensation expense of $513,000 in 2006 related to stock options that were outstanding and had not completely vested as of January 1, 2006. During 2006, we granted 1,289,433 stock options. We recorded additional stock-based compensation expense of $210,000 related to these options in 2006. Both basic and diluted net income per share for 2006 are $0.02 less than if we had continued to account for stock-based compensation under APB No. 25. The effect of adopting SFAS No. 123(R) on net loss and net loss per share is not necessarily representative of the effects in future years due to, among other things, the vesting period of the stock options and the fair value of additional stock option grants in future years. Based on options granted to employees as of December 31, 2006, total compensation expense not yet recognized related to unvested options is approximately $3.1 million, after tax. We expect to recognize that expense over a weighted average period of 2.9 years. Based on options granted to employees as of December 31, 2006, we expect to recognize amortization of stock-based compensation, after tax, of $1.3 million in 2007, $1.0 million in 2008 and $815,000 in 2009.

Income Taxes

We account for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes*. 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 and in some foreign jurisdictions, primarily the United Kingdom. The amount of the deferred tax assets on our balance sheet reflects our expectations regarding our ability to use our net operating losses to offset future taxable income. The applicable tax rules in particular jurisdictions limit our ability to use net operating losses as a result of ownership changes. In particular, we believe that these rules will significantly limit our ability to use net operating losses generated by Microscience and Antex prior to our acquisition of Microscience in June 2005 and our acquisition of substantially all of the assets of Antex in May 2003.

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

Financial Operations Overview

Revenues

We have generated substantially all of our revenues from sales of BioThrax. We delivered approximately 5.2 million and 6.1 million total doses of BioThrax in 2005 and 2006, respectively, representing 97% of our total revenues in both years. The DoD and HHS have been the principal customers for BioThrax. We also have had limited sales of BioThrax to foreign governments and private industry. In addition, we periodically realize revenues from grants from government entities and non-government and philanthropic organizations and from licensing fees, milestone payments and development reimbursement payments. These items accounted for 3% of our total revenues in each of 2005 and 2006. If our ongoing development efforts are successful, we would expect to generate revenues from sales of additional products and milestone payments, development payments and royalties on sales of products that we license to third parties.

In May 2005, we entered into an agreement to supply five million doses of BioThrax to HHS for the SNS for a fixed price of $123 million. We completed delivery of all five million doses by February 2006, seven months earlier than required. In May 2006, we entered into a contract modification with HHS for the delivery of an additional five million doses of BioThrax for the SNS by May 2007 for a fixed price of $120 million. We delivered approximately four million of these doses in December 2006 and the balance in February 2007, more than two months earlier than required.

In January 2004, we entered into our current contract with the DoD for the delivery of a minimum number of doses of BioThrax over one base contract year plus two option periods for a minimum fixed price of approximately $91 million. Under the original terms of this contract, we were required to deliver a minimum of approximately 3.8 million total doses through September 2006. We delivered approximately 4.9 million total doses under this contract from 2004 through September 30, 2006 pursuant to DoD purchase orders. Our current contract with the DoD was amended to provide for the supply of a minimum of approximately 1.5 million additional doses of BioThrax to the DoD through September 2007. We delivered to the DoD approximately 480,000 of these doses in December 2006, and we expect to deliver the balance by September 2007. We have invoiced the DoD, as contemplated under this contract, for progress payments as doses of BioThrax are manufactured for sale to the DoD. In accordance with our revenue recognition policy, we record deferred revenue for invoiced amounts until the FDA releases the product for sale and delivery. As of December 31, 2006, we had no deferred revenue for DoD sales. In April 2006, the DoD issued a notice that it intends to negotiate a sole source fixed price contract for the purchase of up to an additional 11 million doses of BioThrax over one base year plus four option years. The DoD has not issued a formal request for proposals for such a contract and we have not yet entered into an agreement with the DoD for this procurement.

In May 2006, we entered into a collaboration agreement with Sanofi Pasteur relating to the development and commercialization of our meningitis B vaccine candidate and received a $3.8 million upfront license fee. This agreement also provides for a series of milestone payments upon the achievement of specified development and commercialization objectives, payments for development work under the collaboration and royalties on net sales of this product. We deferred the upfront license fee, milestone payments and development reimbursement payments under this agreement, and will record revenue in accordance with our revenue recognition policies.

Our revenue, operating results and profitability have varied, and we expect that they will continue to vary, on a quarterly basis primarily because of the timing of our fulfilling orders for BioThrax. We expect contracts and grant revenues to increase in 2007 compared to 2006 as we receive reimbursement for development expenses under our meningitis B collaboration with Sanofi

Pasteur, funding from the Wellcome Trust for costs associated with our completed Phase I clinical trial and initiated Phase II clinical trial of our typhoid vaccine candidate in Vietnam and funding from NIAID for costs associated with our animal efficacy studies for our anthrax immune globulin candidate.

Cost of Product Sales

The primary expense that we incur to deliver BioThrax to our customers is manufacturing costs, which are primarily fixed costs. These fixed manufacturing costs consist of attributable facilities, utilities and salaries and personnel related expenses for indirect manufacturing support staff. Variable manufacturing costs for BioThrax consist primarily of costs for materials, direct labor and contract filling operations. In 2005, we improved manufacturing efficiencies for BioThrax. As a result, the cost of product sales per dose of BioThrax decreased in 2006 compared to 2005, as well as in 2005 compared to 2004. We do not expect further significant improvements in manufacturing efficiencies for BioThrax until we complete our new manufacturing facility in Lansing, Michigan. We expect our manufacturing costs to remain relatively stable during 2007.

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

Research and Development Expenses

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

- salaries and related expenses for personnel;
- fees to professional service providers for, among other things, 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.

The successful development of our product candidates is highly uncertain. We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to be in a position to realize the potential of our product candidates. We cannot reasonably estimate or know the nature, timing and projected costs of the efforts that will be necessary to complete the remainder of the development for our product candidates, or the period, if any, in which material net cash inflows may commence from any of our product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our clinical trials and other research and development activities;
- our ability to obtain adequate supplies of our product candidates required for later stage clinical trials, including from third party manufacturers;
- the potential benefits of our product candidates over other products;
- our ability to market, commercialize and achieve market acceptance for any of our product candidates that we are developing or may develop in the future;
- future clinical trial results;
- the terms and timing of regulatory approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate.

We expect that development spending will increase for all of our biodefense product candidates as our product development activities continue and we prepare for regulatory submissions and other regulatory activities. We expect our development expenses in our commercial business to increase in connection with our ongoing activities, particularly as we conduct additional and later stage clinical trials for our product candidates.

We expect that the magnitude of any increase in our research and development spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, the size, structure and duration of any follow on clinical program that we may initiate, cost associated with manufacturing our product candidates on a large scale basis for later stage clinical trials, our ability to use data generated by government agencies, such as the ongoing CDC studies with BioThrax, and our ability to rely upon and utilize clinical and 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. Furthermore, if the FDA or other regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

Selling, General and Administrative Expenses

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 expect that our general and administrative expenses will increase as we add personnel to support the increased scale of our operations and become subject to the reporting obligations applicable to public companies. Our general and administrative expenses have increased as a result of preparing for our initial public offering and subsequently operating as a public company and supporting the overall growth of the company. We currently market and sell BioThrax directly to the DoD and HHS with a small, targeted marketing and sales group. As we seek to broaden the market for BioThrax and if we receive marketing approval for additional products, we expect that we will increase our spending for marketing and sales activities.

Total Other Income (Expense)

Total other income (expense) consists principally of interest income and interest expense. We earn interest on our cash, cash equivalents and short-term investments, and we incur interest expense on our indebtedness. Our interest income may increase in future periods as a result of the investment of the net proceeds from our initial public offering. Our net interest expense will increase in future periods as compared to prior periods as a result of the mortgage loan that we entered into in April 2006 and the term loan that we entered into in August 2006, as well as any borrowings under our revolving lines of credit. In addition, some of our existing debt arrangements provide for increasing amortization of principal payments in future periods. See Liquidity and Capital Resources Debt Financing for additional information.

Results of Operations

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 grant revenues increased by $1.3 million, or 39%, to $4.7 million in 2006 from $3.4 million in 2005. 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. Contracts and grant 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 Defense Advanced Research Projects Agency, or 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 approximately $13.1 million. The increase in the number of doses delivered resulted in an increase in costs of approximately $5.6 million.

Research and Development Expenses

Research and development expenses increased by $27.1 million to $45.5 million for 2006 from $18.4 million for 2005. This increase reflects increased expenses of $11.9 million in the biodefense segment and $15.9 million in the commercial segment, offset by a reduction of $633,000 in other research and development expense.

The increase in biodefense spending was attributable to increased efforts on all our biodefense programs as we completed various studies and began subsequent studies and trials. This increase primarily reflects additional personnel and contract service costs. The increase in spending for BioThrax enhancements is related to preparing for animal efficacy studies to support applications for marketing approval of these enhancements, which we expect to submit to the FDA in late 2008 or early 2009. The increase in spending for immune globulin development related primarily to costs associated with our plasma donor stimulation program for our anthrax immune globulin candidate. The increase in spending for the recombinant botulinum vaccine program, which is in preclinical development, resulted from advancing this program to the process development stage and the manufacture of clinical trial material. The increase in spending for the next generation anthrax vaccine program, which has product candidates in preclinical and Phase I clinical development, resulted from 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. This increase primarily reflects additional personnel and contract service costs. Research and development spending by Microscience prior to our acquisition of Microscience in June 2005 is not included in our results for 2005. The spending for our typhoid vaccine candidate resulted from ongoing work for the Phase I clinical trial in Vietnam that we recently completed and preparing for our Phase II clinical trial in Vietnam that we initiated in the fourth quarter of 2006. 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 that we recently completed 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 a each of the two components seperately and the two-proteins in combination in healthy human volunteers. Both our chlamydia vaccine and meningitis B vaccine candidates are in preclinical development.

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

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. Selling, general and administrative expenses related to our biodefense segment decreased by $508,000, or 1%, to $35.0 million for 2006 from $35.5

million for 2005. Selling, general and administrative expenses related to our commercial segment increased by $2.3 million, or 32%, to $9.6 million for 2006 from $7.3 million for 2005. The increase in the commercial segment

was primarily attributable to an increase in general and administrative expenses of approximately $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.

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, $0.9 million as fixed assets, $0.7 million as current liabilities and $26.6 million as the value attributable to development programs. Because we determined that the development programs had no future alternative use, we charged the value attributable to the development programs as purchased in-process research and development. We are amortizing this charge for tax purposes over 15 years.

In July 2006, we recorded a non-cash charge for purchased in-process research and development of $477,000 associated with our acquisition of ViVacs. 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. We are amortizing this charge for tax purposes over 15 years.

Litigation Settlement

In June 2005, we recorded a gain of $10.0 million relating to a settlement of a litigation matter that we initiated to resolve a contract and intellectual property dispute. There were no material settlements during 2006.

Total Other Income (Expense)

Total other expense decreased by $214,000 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 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.

Year Ended December 31, 2005 Compared to Year Ended December 31, 2004

Revenues

Product sales revenues increased by $46.3 million, or 57%, to $127.3 million for 2005 from $81.0 million for 2004. This increase in product sales revenues was primarily due to a 52% increase in the number of doses delivered. Product sales revenues in 2005 consisted of BioThrax sales

to HHS of $111.2 million, sales to the DoD of $14.5 million and aggregate international sales of $1.6 million. Product sales revenues in 2004 consisted of BioThrax sales to the DoD of $80.6 million and international sales of $360,000.

Contracts and grant revenues increased by $937,000, or 38%, to $3.4 million in 2005 from $2.5 million in 2004 primarily as a result of additional work that we performed on a project basis for DARPA to evaluate a new vaccine adjuvant for BioThrax.

Cost of Product Sales

Cost of product sales increased by $1.5 million, or 5%, to $31.6 million for 2005 from $30.1 million for 2004. This increase was attributable to the delivery of 1.8 million additional doses of BioThrax in 2005 and a decrease in production yield, resulting in a higher average manufacturing cost per dose in 2005, offset by improved utilization of our manufacturing capacity for BioThrax as a result of extending the hours of operation for our manufacturing facility. The increase in the number of doses delivered combined with the decrease in production yield resulted in additional costs of $6.6 million. Manufacturing efficiencies resulted in a cost savings of $5.1 million.

Research and Development Expenses

Research and development expenses increased by $8.3 million, or 82%, to $18.4 million for 2005 from $10.1 million for 2004. This increase reflects increased expenses of $4.0 million in the biodefense segment and $5.8 million in the commercial segment, offset by a reduction of $1.6 million in other research and development expenses.

The increase in spending in the biodefense segment resulted from costs associated with our plasma collection program for our anthrax immune globulin candidate, process development related to our recombinant botulinum vaccine candidate and evaluation of third party technology related to our next generation anthrax vaccine program for potential acquisition or in license, offset by decreased spending on BioThrax enhancements. In 2004, the immune globulin program was in initial development and we had not yet begun work on the recombinant botulinum vaccine and next generation anthrax vaccine candidates. The decrease in spending on BioThrax enhancements resulted from substantial completion during 2004 of research regarding manufacturing process development for BioThrax to improve the stability and consistency of production lots.

The increase in spending in the commercial segment was attributable to spending on the commercial programs listed in the table below following our acquisition of Microscience in June 2005. Research and development spending by Microscience is not included in our results prior to the acquisition date. The commercial spending in 2005 resulted from the Phase I clinical trial in Vietnam for our typhoid vaccine candidate, preparation for a planned Phase II clinical trial for our hepatitis B therapeutic vaccine candidate, including the manufacture of clinical trial material, preparation for one of three planned Phase I clinical trials related to one of the protein components of our group B streptococcus vaccine candidate and preclinical work for our chlamydia vaccine and meningitis B vaccine candidates.

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

Our principal research and development expenses for 2004 and 2005 are shown in the following table:

	Year ended December 31,	
	2004	**2005**
	(in thousands)	
Biodefense:		
BioThrax enhancements	$ 5,929	$ 2,883
Immune globulin development	350	5,309
Recombinant bivalent botulinum vaccine	-	1,708
Next generation anthrax vaccine	-	427
Total biodefense	6,279	10,327
Commercial:		
Typhoid vaccine	-	1,477
Hepatitis B therapeutic vaccine	-	1,884
Group B streptococcus vaccine	-	1,032
Chlamydia vaccine	1,136	837
Meningitis B vaccine	-	1,334
Total commercial	1,136	6,564
Other	2,702	1,490
Total	$ 10,117	$ 18,381

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $12.5 million, or 41%, to $42.8 million for 2005 from $30.3 million for 2004. Selling, general and administrative expenses related to our biodefense segment increased by $6.4 million to $35.5 million for 2005 from $29.0 million for 2004. Selling, general and administrative expenses related to our commercial segment increased by $6.0 million to $7.3 million for 2005 from $1.3 million for 2004. The increase in the biodefense segment was attributable to an increase in general and administrative expenses of $5.5 million resulting from additional personnel and

professional service providers for our headquarters organization who devoted time to the biodefense segment and an increase in sales and marketing expenses of $1.0 million resulting from the addition of sales personnel to investigate potential other markets for BioThrax. The increase in the commercial segment was attributable to an increase in general and administrative expenses of $5.3 million resulting from the addition of personnel for Emergent Product Development UK and legal expenses associated with reorganizing our corporate structure following our acquisition of Microscience in June 2005.

Purchased In-process Research and Development

In 2005, as described above, we recorded a non-cash charge of $26.6 million for purchased in-process research and development associated with our acquisition of Microscience.

Litigation Settlement

In 2005, we recorded a gain of $10.0 million relating to a settlement of a litigation matter that we initiated to resolve a contract and intellectual property dispute. There were no material settlements in 2004.

Total Other Income (Expense)

Total other expense increased by $57,000 to $227,000 for 2005 from $170,000 for 2004. This increase resulted primarily from an increase in interest expense associated with our financing of the acquisition costs for one building at our Frederick facility.

Income Taxes

Provision for income taxes increased by $196,000, or 4%, to $5.3 million for 2005 from $5.1 million for 2004. The provision for income taxes for 2005 resulted primarily from our income before provision for income taxes of $21.1 million and an effective annual tax rate of 25%. The provision for income taxes for 2004 resulted primarily from our income before provision for income taxes of $16.6 million and an effective annual tax rate of 31%. The provision for income taxes also reflects research and development tax credits of $474,000 for 2005 and $492,000 for 2004 and small amounts of permanent tax differences in each year.

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, 2006 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases, revenues under our collaboration agreement with Sanofi Pasteur, development funding from government entities and non-government and philanthropic organizations and, to a lesser extent, from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the years in the three year period ended December 31, 2006.

As of December 31, 2006, we had cash and cash equivalents of $76.4 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, 2004, 2005 and 2006.

	Year ended December 31,		
(in thousands)	**2004**	**2005**	**2006**
Net cash provided by (used in):			
Operating activities(1)	$ 9,196	$ 41,974	$ (4,258)
Investing activities	(18,175)	(5,841)	(41,638)
Financing activities	8,681	(6,660)	86,020
Total net cash provided (used)	$ (298)	$ 29,473	$ 40,124

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

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 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 reduction in inventory of $8.3 million reflecting product sales in December 2006.

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 provided by operating activities of $9.2 million in 2004 resulted principally from our net income of $11.5 million, a non-cash stock-based compensation charge that we incurred as a result of our issuance of new stock options in our corporate reorganization in June 2004, which reduced net income by $4.3 million, an increase in income taxes payable of $5.8 million related to the timing of payment of taxes and related deferred tax assets, and an increase in deferred revenue of $3.9 million, reflecting invoices to and payments from the DoD for progress in the manufacture of BioThrax lots, offset by an increase in accounts receivable of $15.7 million, reflecting invoices for amounts due from the DoD for progress in the manufacture of BioThrax lots, and a one-time non-cash gain of $3.8 million resulting from the satisfaction of an obligation to the State of Michigan for less than originally estimated.

Net cash used in investing activities for the years ended December 31, 2004, 2005 and 2006 resulted principally from the purchase of property, plant and equipment. Capital expenditures in 2004 include infrastructure investments of $4.7 million, $3.8 million for an enterprise resource planning system and $8.5 million for the purchase of our first facility in Frederick, Maryland. Capital expenditures in 2005 were primarily attributable to investments in information technology upgrades and miscellaneous facility enhancements. 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 $5.0 million in infrastructure investments and other equipment.

Net cash provided by financing activities of $86.0 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 $6.7 million in 2005 resulted principally from the payment of a special dividend of $5.4 million from a portion of the proceeds of a litigation settlement and the repayment of notes payable to employees.

Net cash provided by financing activities of $8.7 million in 2004 resulted principally from an increase in notes payable as a result of $11.0 million of total debt incurred to finance the purchase of our first facility in Frederick, Maryland and to finance the purchase of an enterprise resource planning system, offset by the repayment of non-recurring royalty and product supply obligations to the State of Michigan of $2.4 million.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2006.

	Payments due by period						
(in thousands)	**Total**	**2007**	**2008**	**2009**	**2010**	**2011**	**After 2011**
Contractual obligations:							
Short and long-term debt(1)	$ 52,413	$ 13,956	$ 5,049	$ 4,831	$ 4,626	$ 21,451	$ 2,500
Operating lease obligations	9,178	1,726	1,866	634	651	669	3,632
Contractual settlement liabilities	200	150	50	-	-	-	-
Total contractual obligations	$ 61,791	$ 15,832	$ 6,965	$ 5,465	$ 5,277	$ 22,120	$ 6,132

(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. Based on our current development plans, we estimate that the maximum amount of these contingent contractual milestone payments under our existing contracts would be approximately $11 million. We are not obligated to pay any minimum royalties under our existing contracts.

Debt Financing

As of December 31, 2006, we had $42.8 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;
- $7.0 million outstanding under a mortgage loan from Mercantile Potomac Bank used to finance the remaining portion of the purchase price for the Frederick facility;
- $8.4 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance the purchase price for the second facility on the Frederick site;
- $1.0 million outstanding under a term loan from Fifth Third Bank used to finance the purchase of an enterprise resource planning system;
- $8.9 million outstanding under a $10.0 million revolving line of credit with Fifth Third Bank;
- $10.0 million outstanding under a term loan from HSBC Realty Credit Corporation used to finance a portion of the costs of our facility expansion in Lansing, Michigan; and
- $5.0 million outstanding under a $5.0 million revolving line of credit with HSBC Realty Credit Corporation.

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

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

- Under our 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 Mercantile Potomac Bank for our Frederick facility, we are required to maintain at all times a minimum tangible net worth of not less than $5.0 million. In addition, we are required to maintain at all times a ratio of earnings before interest, taxes, depreciation and amortization to the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable within the following 12 months, of not less than 1.1 to 1.0.
- Under our 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.
- Under our term loan and revolving credit loan with HSBC Realty Credit Corporation, we are required to maintain on an annual basis a minimum tangible net worth of not less than the sum of 85% of our tangible net worth for the most recently completed fiscal year plus 25% of current net operating profit after taxes. In addition, we are required to maintain on a quarterly basis a ratio of earnings before interest, taxes, depreciation and amortization for the most recent four quarters to the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable for the following four quarters, of not less than 1.25 to 1.00.

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

Our term loan and revolving line of credit with HSBC Realty Credit Corporation has various limitations on our ability to incur indebtedness and liens and enter into mergers or similar transactions among others. 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 Mercantile Potomac Bank, the State of Maryland, HSBC Realty Credit Corporation and Fifth Third Bank serve as collateral for these loans. Our line of credit with Fifth Third Bank is secured by accounts receivable under our DoD and HHS contracts. Our term loan and revolving line of credit with HSBC Realty Credit Corporation are secured by substantially all of Emergent BioDefense Operations assets, other than accounts receivable under our DoD and HHS contracts. The covenants under our existing debt instruments and the pledge of our existing assets as collateral limit our ability to obtain additional debt financing.

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

Under our revolving line of credit with Fifth Third Bank, any outstanding principal is due upon maturity in May 2007. 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 $8.9 million of outstanding principal under the line of credit in January 2007. Interest is payable monthly and accrues at an annual rate equal to 0.375% less than the prime rate of interest established from time to time by Fifth Third Bank.

Under our term loan with HSBC Realty Credit Corporation, we are required to make monthly principal payments beginning in April 2007. A residual principal payment of approximately $5.6 million is due upon maturity in August 2011. Upon our request, the term loan is subject to an extension term in the sole discretion of HSBC Realty Credit Corporation for five additional years until August 2016 for an extension fee of 1.00% of the principal balance of the loan. If the term of the loan were extended, we would be required to continue to make monthly principal payments through maturity in August 2016 in lieu of the residual principal payment otherwise due in August 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.75%.

Under our revolving line of credit with HSBC Realty Credit Corporation, we are not required to repay outstanding principal until October 2007. In October 2007, the outstanding principal under the revolving line of credit will convert to a term loan with required monthly principal payments through maturity in August 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.75%. We also are required to pay a fee on a quarterly basis equal to 0.50% of the average daily difference between $5.0 million and the amount outstanding under the revolving line of credit. As of December 31, 2006, $5.0 million was outstanding under the revolving line of credit.

Tax Benefits

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

Funding Requirements

We 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 of up to $20 million to fund our facility expansion in Lansing, Michigan and to provide additional financial flexibility. In addition to purchase obligations and orders under our contract with the DoD for BioThrax sales, our only committed external sources of funds are 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, including for animal efficacy studies of our anthrax immune globulin candidate, and funding from the Wellcome Trust for our Phase II clinical trial of our typhoid vaccine candidate in Vietnam. Our ability to borrow additional amounts under our loan agreements is subject to our satisfaction of specified conditions. Our future capital requirements will depend on many factors, including:

- the level and timing of BioThrax product sales and cost of product sales;
- the timing of, and the costs involved in, constructing our new manufacturing facility in Lansing, Michigan and the build out of our manufacturing 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 June 2006, the FASB issued FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109, Accounting for Income Taxes* (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes. FIN 48 prescribes a recognition

threshold and measurement attribute for the financial statement recognition and measurement of

a tax position taken or expected to be taken in a tax return. FIN 48 requires that the Company recognize in its financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006,

We will adopt FIN 48 as of January 1, 2007, as required. The cumulative effect of adopting FIN 48 will be recorded as an adjustment to beginning retained earnings and other accounts as applicable. Although we have not made a final determination of the effect the adoption of FIN 48 will have on our financial position and results of operations, it is expected that the cumulative adjustment to retained earnings will not have a material effect on our financial statements. The adoption of FIN 48 will impact the amount of, and balance sheet classification of, deferred tax assets and liabilities, and other accounts as applicable, and result in greater volatility in the effective tax rate.

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* (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 have not yet determined the impact of the adoption of this statement on our financial statements.

In September 2006, the SEC issued Staff Accounting Bulletin (SAB 108), *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*. SAB 108 requires that registrants quantify errors using both a balance sheet and statement of operations approach and evaluate whether either approach results in a misstated amount that, when all relevant quantitative and qualitative factors are considered, is material. SAB 108 became effective during the fourth quarter of 2006. The Company has determined that adoption of this statement had no impact on the financial statements.

In September 2006, the FASB issued SFAS 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. We have not yet determined the impact of the adoption of this statement 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 have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. and Subsidiaries as of December 31, 2005 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, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's

internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Emergent BioSolutions Inc. and Subsidiaries at December 31, 2005 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, 2006, in conformity with U.S. generally accepted accounting principles.

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

McLean, Virginia

March 21, 2007

Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2005	2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 36,294	$ 76,418
Accounts receivable	2,530	43,331
Inventories	16,441	24,721
Income taxes receivable	763	869
Deferred tax assets	1,989	295
Prepaid expenses and other current assets	1,099	1,703
Total current assets	59,116	147,337
Property, plant and equipment, net	30,645	78,174
Deferred tax assets, net of current	9,981	11,477
Other assets	590	1,267
Total assets	$ 100,332	$ 238,255
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 10,425	$ 27,366
Accrued expenses and other current liabilities	2,609	3,253
Accrued compensation	6,177	7,190
Indebtedness under lines of credit	-	8,930
Long-term indebtedness, current portion	902	2,456
Notes payable to employees, current portion	506	17
Income taxes payable	2,134	13,703
Deferred revenue, current portion	7,340	1,432
Total current liabilities	30,093	64,347
Long-term indebtedness, net of current portion	10,471	31,368
Notes payable to employees, net of current portion	31	-
Deferred revenue, net of current portion	-	2,997
Other liabilities	-	1,071
Total liabilities	40,595	99,783
Commitments and contingencies	-	-
Stockholders equity:		
Preferred Stock $0.001 par value; 3,000,000 and 15,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2005 and 2006, respectively	-	-
Common Stock, Class A, $0.001 par value; 100,000,000 shares authorized, 22,303,280 issued and outstanding at December 31, 2005; 0 shares authorized, issued and outstanding at December 31, 2006	22	-
Common Stock, Class B, $0.01 par value; 2,000,000 shares authorized, 21,283 issued and outstanding at December 31, 2005; 0 shares authorized, issued and outstanding at December 31, 2006	-	-
Common Stock, $0.001 par value; 0 shares authorized, issued and outstanding at December 31, 2005; 100,000,000 shares authorized, 27,596,249 shares issued and outstanding at December 31, 2006	-	28
Additional paid-in capital	34,595	90,920
Accumulated other comprehensive loss	(276)	(473)
Retained earnings	25,396	47,997
Total stockholders equity	59,737	138,472
Total liabilities and stockholders equity	$ 100,332	$ 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)

	2004	2005	2006
Revenues:			
Product sales	$ 81,014	$ 127,271	$ 147,995
Contracts and grants	2,480	3,417	4,737
Total revenues	83,494	130,688	152,732
Operating expense (income):			
Cost of product sales	30,102	31,603	24,125
Research and development	10,117	18,381	45,501
Selling, general and administrative	30,323	42,793	44,601
Purchased in-process research and development	-	26,575	477
Settlement of State of Michigan obligation	(3,819)	-	-
Litigation settlement	-	(10,000)	-
Income from operations	16,771	21,336	38,028
Other income (expense):			
Interest income	65	485	846
Interest expense	(241)	(767)	(1,152)
Other income (expense), net	6	55	293
Total other income (expense)	(170)	(227)	(13)
Income before provision for income taxes	16,601	21,109	38,015
Provision for income taxes	5,129	5,325	15,222
Net income	$ 11,472	$ 15,784	$ 22,793
Earnings per share - basic	$ 0.61	$ 0.77	$ 0.99
Earnings per share - diluted	$ 0.56	$ 0.69	$ 0.93
Weighted-average number of shares - basic	18,919,850	20,533,471	23,039,794
Weighted-average number of shares - diluted	20,439,252	22,751,733	24,567,302
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,		
	2004	**2005**	**2006**
Cash flows from operating activities:			
Net income	$ 11,472	$ 15,784	$ 22,793
Adjustments to reconcile net income to net cash provided by (used in) operating activities (net of effects of acquisitions):			
Stock-based compensation expense (credit)	4,310	(17)	723
Non-cash gain on settlement	(3,819)	-	-
Depreciation and amortization	1,867	3,549	4,715
Deferred income taxes	(418)	(10,968)	987
Other obligations	200	-	-
Loss on disposal of property and equipment	43	32	27
Purchased in-process research and development	-	26,575	477
Excess tax benefit from stock based compensation	-	-	(789)
Changes in operating assets and liabilities:			
Accounts receivable	(15,664)	16,107	(40,801)
Inventories	(1,609)	(3,189)	(8,280)
Income taxes	5,794	(2,390)	11,463
Prepaid expenses and other assets	50	(865)	(792)
Accounts payable	2,472	5,463	5,801
Accrued compensation	585	2,466	1,013
Accrued expenses and other liabilities	44	619	1,513
Deferred revenue	3,869	(10,916)	(2,911)
Net cash provided by (used in) operating activities	9,196	42,250	(4,061)
Cash flows from investing activities:			
Purchases of property, plant and equipment	(17,072)	(6,532)	(41,228)
Acquisitions, net of cash received	-	(559)	(218)
Restricted cash deposits	(1,250)	1,250	(192)
Proceeds from investment maturities	147	-	-
Net cash used in investing activities	(18,175)	(5,841)	(41,638)
Cash flows from financing activities:			
Proceeds from borrowings on long term indebtedness and lines of credit	10,992	31	32,430
Proceeds from notes payable to employees	947	123	-
Repayments on product supply and royalty obligations	(2,351)	-	-
Issuance of common stock in initial public offering (net of issuance cost)	-	-	54,229
Issuance of common stock subject to exercise of stock options	12	33	590
Redemption of Class B common stock	(665)	(337)	(192)
Principal payments on long term indebtedness, notes payable to employees, and lines of credits	(184)	(1,110)	(1,569)
Proceeds from excess tax benefits	-	-	789
Debt issuance costs	(70)	-	(257)
Payment of dividend	-	(5,400)	-
Net cash provided by (used in) financing activities	8,681	(6,660)	86,020
Effect of exchange rate changes on cash and cash equivalents	-	(276)	(197)
Net increase (decrease) in cash and cash equivalents	(298)	29,473	40,124
Cash and cash equivalents at beginning of year	7,119	6,821	36,294
Cash and cash equivalents at end of year	6,821	36,294	76,418
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ 170	$ 696	$ 1,681
Cash paid during the year for income taxes	$ -	$ 17,985	$ 2,788
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	$ -	$ -	$ 11,140

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

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

	Class A No-Par Common Stock		Class B No-Par Common Stock		Class A $0.001 Par Value Common Stock		Class B $0.01 Par Value Common Stock		$0.001 Par Value Common Stock		Additional Paid-In Capital	Accumulated Other Comp-rehensive Loss	Ret Ear
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2003	18,017,994	$ 2,940	1,099,223	$ 101	-	$ -	-	$ -	-	$ -	$ -	$ -	$ 5,
Redemption of common stock	-	-	(573,322)	(53)	-	-	-	-	-	-	-	-	(1,5
Issuance of common stock	-	-	122,584	12	-	-	-	-	-	-	-	-	-
Conversion of class A no-par common stock to class A $.001 par value common stock	(18,017,994)	(2,940)	-	-	18,017,994	18	-	-	-	-	2,922	-	-
Conversion of class B no-par common stock to class A $.01 par value common stock	-	-	(648,485)	(60)	648,485	1	-	-	-	-	59	-	-
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	4,310	-	-
Tax benefit related to the disqualifying disposition	-	-	-	-	-	-	-	-	-	-	319	-	-
Net Income	-	-	-	-	-	-	-	-	-	-	-	-	11,4
Balance at December 31, 2004	-	-	-	-	18,666,479	19	-	-	-	-	7,610	-	15,3
Issuance of common stock to acquire Microscience Limited	-	-	-	-	3,636,801	3	-	-	-	-	26,998	-	-
Exercise of stock options	-	-	-	-	-	-	133,451	1	-	-	32	-	-
Redemption of common stock	-	-	-	-	-	-	(112,168)	(1)	-	-	(28)	-	(308
Forfeiture of stock options	-	-	-	-	-	-	-	-	-	-	(17)	-	-
Payment of dividend	-	-	-	-	-	-	-	-	-	-	-	-	(5,4
Net income	-	-	-	-	-	-	-	-	-	-	-	-	15,7
Foreign currency translation	-	-	-	-	-	-	-	-	-	-	-	(276)	-
Comprehensive income	-	-	-	-	-	-	-	-	-	-	-	-	-
Balance at December 31, 2005	-	$ -	-	$ -	22,303,280	$ 22	21,283	$ -	-	$ -	$ 34,595	$ (276)	$ 25
Exercise of stock options	-	-	-	-	-	-	95,858	1	175,828	-	589	-	-
Redemption of common stock	-	-	-	-	-	-	-	-	-	-	-	-	(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	-	-
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	723	-	-
Excess tax benefits from exercises of non-qualified stock options	-	-	-	-	-	-	-	-	-	-	789	-	-
Net income	-	-	-	-	-	-	-	-	-	-	-	-	22,7
Foreign currency translation	-	-	-	-	-	-	-	-	-	-	-	(197)	-
Comprehensive income	-	-	-	-	-	-	-	-	-	-	-	-	-
Balance at December 31, 2006	-	$ -	-	$ -	-	$ -	-	$ -	27,596,249	$ 28	$ 90,920	$ (473)	$ 47

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

Emergent BioSolutions Inc. and Subsidiaries

Notes to consolidated financial statements

(dollars in thousands, except per share data)

1. Nature of the business and organization

Emergent Biosolutions Inc. (the Company or Emergent) is a biopharmaceutical company focused on the development, manufacture and commercialization of immunobiotics. The Company operates in two business segments: biodefense and commercial. The Company commenced operations as BioPort Corporation (BioPort) in September 1998 through an acquisition from the Michigan Biologic Products Institute of rights to the marketed product, BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how. Following this acquisition, the Company completed renovations at the Lansing facilities that had been initiated by the State of Michigan. In December 2001, the U.S. Food and Drug Administration (FDA) approved a supplement to the Company s manufacturing facility license for the manufacture of BioThrax at the renovated facilities. In June 2004, the Company completed a corporate reorganization (Reorganization) in which:

- Emergent issued 18,666,479 shares of Class A Common Stock in exchange for 18,017,994 shares of BioPort class A common stock and 648,485 shares of BioPort class B common stock;
- all other issued and outstanding shares of BioPort class B common stock were repurchased and retired; and
- all outstanding stock options to purchase BioPort class B common stock were assumed by Emergent and option holders were granted replacement stock options to purchase an equal number of shares of Class B Common Stock of Emergent.

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

Fair value of financial instruments

The carrying amounts of the Company s short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair values due to their short maturities. The 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 $11,910 and $11,497, respectively, at December 31, 2005 and $33,841 and $33,233, respectively, at December 31, 2006.

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Restricted cash

Restricted cash at December 31, 2006 consists of a certificate of deposit held by a bank as collateral for a letter of credit acting as a security deposit on a loan. As of December 31, 2005 and 2006 the Company had restricted cash of $0 and $192, respectively.

Significant customers and accounts receivable

The Company s primary customers are the U.S. Department of Defense (DoD) and U.S. Department of Health and Human Services (HHS). For the years ended December 31, 2004, 2005 and 2006, sales of BioThrax to the DoD and HHS comprised 99%, 96% and 97% of total revenues, respectively. As of December 31, 2005 and 2006, the Company s receivable balances were comprised of 38% and 100%, respectively, from these customers. The balance of the receivables in 2005 was attributable to government funding for NIAID. Unbilled accounts receivable, included in accounts receivable, totaling $1,418 and $26 as of December 31, 2005 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, 2005 and 2006, an allowance for doubtful accounts was not recorded, as the prior collection history from these customers indicates collection is likely.

Concentrations of credit risk

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

Inventories

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

Property, plant and equipment

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

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

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

Under the provisions of the Statement of Position No. 98-1, *Accounting for the Costs of Computer Software Developed or Obtained for Internal Use*, the Company capitalizes costs associated with software developed or obtained for internal use when the preliminary project stage is completed. Capitalized costs include only: (1) external direct costs of materials and services consumed in developing or obtaining internal use software and (2) payroll and payroll-related costs for employees who are directly associated with and who devote time to the internal use software project during the development stage. Capitalization of such costs ceases before training and other post implementation software activities occur. Computer software maintenance costs related to software development are expensed as incurred.

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

In December 2005, the Securities and Exchange Commission released an interpretation with respect to the accounting for sales of vaccines and bioterror countermeasures to the federal government for placement into the Strategic National Stockpile (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. This interpretation is applicable to the Company s contracts with HHS, but because the Company recognizes revenue upon delivery of product to HHS, the Company has not applied this guidance.

Collaborative research and development agreements can provide for one or more 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 No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144), the Company assesses the recoverability of its long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If an impairment is indicated, the Company measures the amount of such impairment by comparing the fair value to the carrying value. The Company has recorded no impairment losses for the years ended December 31, 2004, 2005 and 2006.

Research and development

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

Purchased in-process research and development

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

Comprehensive income

Statement of Financial Accounting Standards No. 130, *Reporting Comprehensive Income* (SFAS No. 130), 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).

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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 based on the cost of major ongoing capital projects which have not yet been placed in service. For the years ended December 31, 2004, 2005 and 2006, the Company capitalized $0, $0 and $759 of interest, 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 contracts do not necessarily increase the likelihood that it will secure future comparable contracts with the U.S. government. The Company expects that a significant portion of the business that it will seek in the near future, in particular for BioThrax, will be under government contracts that present a number of risks that are not typically present in the commercial contracting process. U.S. government contracts for BioThrax require annual funding decisions by the government and are subject to unilateral termination or modification by the government. The Company may fail to achieve significant sales of BioThrax to customers in addition to the U.S. government, which would harm its growth opportunities. The Company may not be able to sustain or increase profitability. The Company is spending significant amounts for the expansion of its manufacturing facilities. The Company may not be able to manufacture BioThrax consistently in accordance with FDA specifications. Other than BioThrax, all of the Company s product candidates are undergoing clinical trials or are in early stages of development, and failure is common and can occur at any stage of development. None of the Company s product candidates other than BioThrax has received regulatory approval.

Earnings per share

Basic net income 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:

	Year Ended December 31,		
	2004	**2005**	**2006**
Numerator:			
Net Income	$ 11,472	$ 15,784	$ 22,793
Denominator:			
Weighted-average number of shares basic	18,919,850	20,533,471	23,039,794
Dilutive securities stock options	1,519,402	2,218,262	1,527,508
Weighted-average number of shares diluted	20,439,252	22,751,733	24,567,302
Earnings per share-basic	$ 0.61	$ 0.77	$ 0.99
Earnings per share-diluted	$ 0.56	$ 0.69	$ 0.93

For the years ending December 31, 2004, 2005 and 2006, outstanding stock options to purchase approximately 0, 21,000 and 160,000 shares, respectively, of common stock are not considered in the diluted earnings per share calculation because the exercise price of these options is greater than the average per share closing price during the year.

The Company has taken into consideration the disclosure required by the Participating Securities and the Two-Class Method under FASB Statement No. 128 (EITF No. 03-6).

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Accounting for stock-based compensation

As of December 31, 2006, 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 (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25) and has 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. 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,* (EITF No. 96-18).

Effective January 1, 2006, the Company adopted the fair value provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123(R)), using the modified prospective method. Under the fair value recognition provisions of SFAS No. 123(R), the Company recognizes stock-based compensation net of an estimated forfeiture rate.

Under the modified prospective method, compensation cost recognized in 2006 includes: (1) compensation cost for all share-based payments granted prior to but not yet vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, and (2) compensation cost for all share-based payments granted 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). As a result of adopting SFAS No. 123(R) on January 1, 2006, the Company s income before income taxes and net income for the year ended December 31, 2006 are approximately $723 and $470 lower, respectively, than if it had continued to account for share-based compensation under APB No. 25.

Both basic and diluted income per share for the year ended December 31, 2006 are $0.02 lower than if the Company had continued to account for share-based compensation under APB No. 25. Results for prior periods have not been restated. Based on options granted to employees as of December 31, 2006, total compensation expense not yet recognized related to unvested options is approximately $3,119, after tax. The Company expects to recognize that expense over a weighted average period of 2.9 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,		
	2004	**2005**	**2006**
Expected dividend yield	0%	0%	0%
Expected volatility	52%	50%	50%
Risk-free interest rate	2.93%	3.33-4.32%	4.58-5.21%
Expected average life of options	2.5 years	2.9 years	3.0 years

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

Expected volatility Volatility is a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company analyzed the 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 average U.S. Treasury rate with a term that most closely resembles the expected life of the option for the quarter in which the option was granted.

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

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

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 years ended December 31, 2004 and 2005.

	Year Ended December 31,	
	2004	**2005**
Net income, as reported	$ 11,472	$ 15,784
Add: Stock-based compensation in reported net income, net of taxes	2,801	-
Deduct: Total stock-based compensation expense determined under the fair value based method for all awards, net of taxes	(3,185)	(258)
Pro forma net income	$ 11,088	$ 15,526
Net income per common share basic	$ 0.61	$ 0.77
Net income per common share diluted	$ 0.56	$ 0.69
Pro forma net income per common share basic	$ 0.59	$ 0.76
Pro forma net income per common share diluted	$ 0.54	$ 0.68

Recent accounting pronouncements

In June 2006, the FASB issued FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109, Accounting for Income Taxes (FIN 48)*. FIN 48 clarifies the accounting for uncertainty in income taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 requires that the Company recognize in its financial statements, the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006.

The Company will adopt FIN 48 as of January 1, 2007, as required. The cumulative effect of adopting FIN 48 will be recorded as an adjustment to beginning retained earnings and other accounts as applicable. Although the Company has not made a final determination of the effect the adoption of FIN 48 will have on the Company s financial position and results of operations, it is expected that the cumulative adjustment to retained earnings will not have a material effect on its financial statements. The adoption of FIN 48 will impact the amount of, and balance sheet classification of, deferred tax assets and liabilities, and other accounts as applicable, and result in greater volatility in the effective tax rate.

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 has not yet determined the impact of adoption of this statement on its financial statements.

In September 2006, the SEC issued Staff Accounting Bulletin, or SAB, No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 requires that registrants quantify errors using both a balance sheet and statement of operations approach and evaluate whether either approach results in a misstated amount that, when all relevant quantitative and qualitative factors are considered, is material. SAB 108 became effective during the fourth quarter of 2006. The Company has determined that adoption of this statement had no impact on the 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 has not yet determined the impact of adoption of this statement 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 (ViVacs) 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 in cash on the closing date of the agreement and agreed to pay $50 on each of the first and second anniversaries of the closing date. The acquisition agreement also provides for a potential variable earn-out purchase price of up to $220, based on future payments from third party licensees of the technology. As of December 31, 2006, 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:

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:

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

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

Microscience Limited

On June 23, 2005, Emergent Europe, Inc., 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:

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

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

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

In connection with the transaction, the Company recorded a charge of $26,575 for acquired research projects associated with products in development for which, at the acquisition date, technological feasibility had not been established and, for accounting purposes, no alternative future use existed.

4. Accounts receivable

Accounts receivable consist of the following:

	December 31, 2005		2006
Billed	$	1,112	$ 43,305
Unbilled		1,418	26
Total	$	2,530	$ 43,331

5. Inventories

Inventories consist of the following:

	December 31, 2005		2006
Raw materials and supplies	$	2,229	$ 2,133
Work-in-process		9,547	22,239
Finished goods		4,665	349
Total inventories	$	16,441	$ 24,721

6. Property, plant and equipment

Property, plant and equipment consist of the following:

	December 31, 2005		2006
Land and improvements	$	2,995	$ $ 5,173
Buildings and leasehold improvements		14,143	25,074
Furniture and equipment		12,520	15,963
Software		3,937	3,937
Construction-in-progress		6,197	41,563
		39,792	91,710
Less: Accumulated depreciation and amortization		(9,147)	(13,536)
Total Property, plant and equipment, net	$	30,645	$ 78,174

Depreciation and amortization expense was $1,867, $3,549 and $4,715 for the years ended December 31, 2004, 2005 and 2006, respectively. For the years ended December 31, 2004, 2005 and 2006, depreciation and amortization expense included approximately $209, $1,257 and $1,257 respectively, related to the amortization of internal-use software. As of December 31, 2005 and 2006, un-amortized software cost was $2,471 and $1,214, respectively.

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7. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31, 2005	2006
Contract costs	$ 445	$ 1,218
Professional fees	1,390	1,115
Interest payable	146	222
Property taxes and other	628	698
	$ 2,609	$ 3,253

8. Long-term debt and related party notes payable

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

	December 31, 2005	2006
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 October 2004; 6.625%, due October 2011	7,000	6,955
Forgivable Loan dated October 2004; 3.0%, due March 2013	2,500	2,500
ERP Term Loan; Prime less 0.375%, due September 2007	1,760	960
Term Loan dated April 2006; Libor plus 3%, due April 2011	-	8,383
Employee notes payable for stock redemption; 6%, due 2006	537	17
Other	113	26
Total long-term indebtedness and related party notes payable	11,910	33,841
Less current portion of long-term indebtedness and related party notes payable	(1,408)	(2,473)
Noncurrent portion of long-term indebtedness and related party notes payable	$ $ 10,502	$ $ 31,368

In August 2006, the Company entered into a term loan for $10,000 and a revolving credit loan that provides for borrowings up to $5,000. Under the term loan, the Company is required to make monthly principal payments beginning in April 2007. A residual principal payment of approximately $5,600 is due upon maturity in August 2011. At the Company s request, the term loan is subject to an extension term at the sole discretion of the lender for five additional years until August 2016 for an extension fee of 1.00% of the principal balance of the loan. If the term of the loan were extended, the Company would be required to continue to make monthly principal payments through maturity in August 2016 in lieu of the residual principal payment otherwise due in August 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.75% (9.11% as of December 31, 2006).

Under the revolving credit loan, the Company is not required to repay outstanding principal until October 2007. In October 2007, the outstanding principal under the revolving credit loan will convert to a term loan with required monthly principal payments through maturity in August 2011. Interest is payable monthly and accrues at an annual rate equal to LIBOR plus 3.75% (9.11% as of December 31, 2006). The Company also is required to pay a fee on a quarterly basis equal to 0.50% of the average daily difference between $5,000 and the amount outstanding under the revolving credit loan.

The term loan and revolving credit loan are secured by substantially all of Emergent BioDefense Operations assets, other than accounts receivable under BioThrax supply contracts with the DoD and HHS. The Company is required to maintain on an annual basis a minimum tangible net worth of not less than the sum of 85% of tangible net worth for the most recently completed fiscal year plus 25% of current net operating profit after taxes. In addition, the Company is required to maintain on a quarterly basis a ratio of earnings before interest, taxes, depreciation and amortization for the most recent four quarters to the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable for the following four quarters, of not less than 1.25 to 1.00. The Company is in compliance with these covenants as of December 31, 2006.

In April 2006, the Company completed the acquisition of a 145,000 square foot facility in Frederick, Maryland for $9,750. This facility was previously under a lease which contained an option to purchase the facility. The Company paid $1,250 in cash and financed the remaining balance with a bank loan in the amount of $8,500. This loan requires monthly principal and interest payments from May 2006 through April 2011 of $72 with a balloon payment for the remaining unpaid principal and interest due in April 2011. The interest rate is a floating rate based on the three month LIBOR plus 3% (8.36% as of December 31, 2006). 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, 2006.

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In October 2004, the Company entered into a Secured Conditional Loan with the Maryland Economic Development Assistance Fund for $2,500. The proceeds of the loan were used to reimburse the Company for eligible costs it incurred to purchase a building in Frederick, Maryland. The loan is secured by a $1,250 letter of credit and a security interest in the building. The Company is required to pay an annual fee of 1% to maintain the letter of credit. The borrowing bears interest at 3% per annum, and the term of the loan ends March 31, 2013. The principal and related accrued interest may be forgiven if specified employment levels are achieved and maintained through December 2012, at least $42,900 in project costs are expended prior to December 2009, and the Company occupies the building through December 2012. 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 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 first building in Frederick, Maryland discussed above, the Company entered into a loan agreement for $7,000 with a bank to finance the remaining portion of the purchase price. The borrowing 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, 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 $5,000 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, 2006. This loan is guaranteed by all of the subsidiaries of the Company.

During 2004, the Company implemented an Enterprise Resource Planning (ERP) system. The Company financed $2,280 of the costs through the issuance of a term loan. The loan bears interest at prime less 0.375% (7.88% as of December 31, 2006) and is due in September 2007. Monthly payments escalate from $40 to $106 over the term. The ERP system provides security for the loan.

In 2004, the Company issued notes as consideration for the repurchase of outstanding class B common stock of BioPort. These notes were issued to various current and past employees who were issued equity as a result of earlier stock option exercises. Amounts are payable in annual installments, through 2007, and bear interest at 6%.

Scheduled principal repayments and maturities on long-term debt as of December 31, 2006 are as follows:

2007	$	2,473
2008		2,624
2009		5,265
2010		2,916
2011		15,313
Thereafter		5,250
	$	33,841

9. Line of credit

On April 1, 2005, the Company, through Emergent BioDefense Operations, formerly BioPort, obtained a line of credit that provides for borrowings of up to $10,000. The line of credit is scheduled to expire on May 15, 2007. 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% (7.88% as of December 31, 2006). Emergent BioDefense Operations is subjected to certain covenants, including maintenance of specified equity levels on a quarterly basis. Emergent BioDefense Operations is currently in compliance with those covenants. A total of $8,930 was outstanding under this line of credit as of December 31, 2006. This amount was repaid in January 2007. No borrowings were outstanding under this line of credit as of December 31, 2005.

10. Stockholders equity

Preferred stock

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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, 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, or 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 $62,500. Issuance costs related to the offering were $8,271, resulting in net proceeds from the offering of $54,229. 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 $0.001 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, reclassifies the Class A Common Stock as $0.001 par value per share Common Stock, increases the number of authorized shares of Common Stock to 100,000,000 shares and adjusts 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 ratably dividends payable as and when declared by the Company s board of directors. On June 15, 2005, the Company s board of directors declared a special cash dividend to the holders of outstanding shares of Class A Common Stock and Class B Common Stock in an aggregate amount of $5,400. The Company s board of directors declared this special dividend in order to distribute the net proceeds of a payment received as a result of the settlement of litigation initiated in 2002 by the Company against Elan Pharmaceuticals, Inc., Athena Neurosciences, Inc. and Solstice Neurosciences, Inc. in an effort to clarify intellectual property rights, including the recovery of royalties and other costs and fees, to which the Company believed it was entitled under a series of agreements regarding the development of botulinum toxin products. The Company paid the special cash dividend on July 13, 2005 to stockholders of record as of June 15, 2005. No regular dividends have been declared or paid.

In June 2004, in connection with the Reorganization, the Company issued 18,666,479 shares of Class A Common Stock in exchange for 18,017,994 shares of BioPort Class A Common Stock and 648,485 shares of BioPort Class B Common Stock held by BioPharm, L.L.C. The Company repurchased and retired the remaining issued and outstanding shares of BioPort Class B Common Stock from former employees. Approximately 544,000 BioPort shares were repurchased at $2.74 per share and approximately 28,000 BioPort shares were repurchased at $4.12 per share. Shares were repurchased for $665 in cash and the issuance of $947 in notes payable. See Note 8 Long-term debt and related party notes payable, for additional information related to the former employee notes payable.

During the year ended December 31, 2005, the Company repurchased 112,168 shares of Class B Common Stock with an original weighted average cost of $0.26 per share, for $337.

Stock options

As of December 31, 2006, the Company has two stock-based employee compensation plans, the 2006 Plan and the 2004 Plan, 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 Company established the 2006 Plan in connection with its initial public offering in November 2006. Under the 2006 Plan, the Company may grant options for a total of 503,500 shares of Common Stock, plus the number of shares of Common Stock reserved for issuance under the 2004 Plan that remained available for grant immediately prior to the initial public

offering on November 14, 2006, of 585,961 shares. Accordingly, the 2006 Plan initially authorizes the issuance of up to 1,089,461 shares. In addition, the 2006 Plan contains an evergreen provision that allows for increases in the number of shares available for issuance under the 2006 Plan in the first and third quarter of each year from 2007 through 2009. 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 contractual life of no more than 10 years.

In conjunction with the establishment of the 2006 Plan, as noted above, the shares reserved for issuance under the 2004 Plan that remained available for grant became available for grant under the 2006 Plan. The exercise price of each incentive option granted under the 2004 Plan must be not less than 100% of the fair market value of the shares on the date of grant, except in the case of the incentive stock option being granted to a 10% stockholder, in which case the exercise price must be not less than 110% of the fair market value of the shares on the date of grant.

Prior to the Reorganization, BioPort had a separate stock option plan (BioPort plan) under which options were granted to purchase BioPort Class B Common Stock. The exercise price and vesting schedule for options were determined by BioPort s board of directors, or a committee thereof, which was established to administer the BioPort plan options.

As of June 30, 2004, options to purchase 1,948,892 shares of BioPort Class B Common Stock were outstanding under the BioPort plan. Pursuant to the Reorganization, all outstanding BioPort plan options were assumed by Emergent and option holders were granted replacement stock options to purchase an equal number of shares of Class B Common Stock of Emergent. The exercise period for the replacement options was extended to June 30, 2007. The BioPort options were scheduled to expire on June 30, 2004.

In connection with the Reorganization, the Company recorded stock-based compensation expense as a result of the issuance of the stock options to purchase Class B Common Stock. Based upon the guidance in APB No. 25, because the stock options granted for Class B Common Stock provided for an extended term over that of the cancelled BioPort plan options, a new measurement date was created and the Company recorded as stock-based compensation expense the excess of the intrinsic value of the modified options over the intrinsic value of the BioPort plan options when originally issued. This resulted in stock-based compensation expense of $4,310, or $2,801 net of taxes, for the year ended December 31, 2004.

Outside of the Reorganization, options to purchase an additional 322,235 shares of Class B common stock of Emergent under the 2004 Plan were granted during the year ended December 31, 2004.

The terms and conditions of stock options (including price, vesting schedule, term and number of shares) under the Emergent Plans are determined by the Company s compensation committee, which administers the Emergent Plans.

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:

	Emergent 2004 Plan			**Emergent 2006 Plan**			
	Number of Shares		**Weighted-Average Exercise Price**	**Number of Shares**		**Weighted-Average Exercise Price**	**Aggregate Intrinsic Value**
Outstanding at December 31, 2005	3,141,829	$	1.78	-	$	-	
Exercisable at December 31, 2005	2,452,483	$	1.22	-	$	-	
Granted	258,933		11.36	1,030,500		10.13	
Exercised	(271,686)		2.16	-		-	
Forfeited	(195,851)		2.63	-		-	
Outstanding at December 31, 2006	2,933,225	$	2.53	1,030,500	$	10.13	26,375,147
Exercisable at December 31, 2006	2,395,693	$	1.43	-	$	-	23,310,093

The weighted average remaining contractual term of options outstanding and exercisable as of December 31, 2005 and December 31, 2006 was 2.46 years and 3.18 years, and 2.12 years and 1.06 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2004, 2005 and 2006 was $0.95, $1.37 and $3.94, respectively. The total intrinsic value of options exercised during the years ended December 31, 2004, 2005 and 2006 was $325, $563 and $2,337, respectively. The total fair value of shares vested during 2006 was $434.

During 2006, the Company recognized pre-tax share-based compensation cost of $723. Of this amount, $623 is included in Selling, General and Administrative Expense, $97 is included in Research and Development Expense, and $3 is included in Cost of Product Sales.

A summary of the status of the Company s nonvested stock options at December 31, 2006 is presented below:

	Emergent 2004 Plan		Emergent 2006 Plan	
	Number of Shares	Weighted-Average Price	Number of Shares	Weighted-Average Price
Nonvested at December 31, 2005	684,551	$ 3.77	-	$ -
Granted	258,933	11.23	1,030,500	10.13
Exercised	-	-	-	-
Vested	(345,536)	1.28	-	
Forfeited	(60,416)	1.49	-	-
Nonvested at December 31, 2006	537,532	$ 9.21	1,030,500	$ 10.13

During the year ended December 31, 2006, the Company received a tax benefit from stock options exercised of approximately $1,300.

11. Income taxes

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

	Year Ended December 31,		
	2004	2005	2006
Current			
Federal	$ 5,547	$ 16,093	$ 14,212
State	-	200	812
Total Current	5,547	16,293	15,024
Deferred			
Federal	(372)	(9,769)	100
State	(46)	(1,199)	98
Total Deferred	(418)	(10,968)	198
Total Provision for Income Taxes	$ 5,129	$ 5,325	$ 15,222

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

	December 31,	
	2005	2006
Net operating loss carryforward	$ 2,242	$ 4,160
Research and development credit carryforward	721	549
Stock compensation	1,696	1,452
Foreign deferrals	27,797	32,534
Other	1,219	1,681
Deferred tax asset	33,675	40,376
Fixed assets	(1,387)	(888)
Other	(393)	(433)
Deferred tax liability	(1,780)	(1,321)
Valuation allowance	(19,925)	(27,283)
Net deferred tax asset	$ 11,970	$ 11,772

Net operating loss carryforwards consist of $91 million for state jurisdictions and $77 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:

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	Year ended December 31,		
	2004	2005	2006
US	$ 16,601	$ 54,259	$ 56,698
International	-	(33,150)	(18,683)
Earnings before taxes on income	16,601	21,109	38,015
Federal tax at statutory rates	5,863	$ 7,388	$ 13,305
State taxes, net of federal benefit	(714)	(2,329)	(395)
Impact of foreign operations	-	(17,982)	(6,050)
Change in valuation allowance	479	16,901	4,248
Effect of foreign rates	-	2,358	3,110
Tax credits	(492)	(474)	(759)
Other differences	11	(212)	1,043
Permanent differences	(18)	(325)	720
Provision for income taxes	$ 5,129	$ 5,325	$ 15,222

The estimated effective annual tax rate for the years ended December 31, 2005 and 2006 was 25% and 40%, respectively. The increase in the estimated 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 Company is the subject of an ongoing federal income tax audit for the tax years ended December 31, 2004 and 2005. The financial statement impact of the audit has been estimated at approximately $760. This amount has been accrued as of December 31, 2006.

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, 2004, 2005 and 2006, the Company made matching contributions of approximately $452, $520 and $573, 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 on November 30, 2008.

The Company leases approximately 23,000 square feet of 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. The Company has a five year renewal option at the end of the initial term. For the years ended December 31, 2004, 2005 and 2006, total rent expense was $1,334, $2,526 and $2,386, respectively.

Future minimum payments under operating lease obligations as of December 31, 2006 are as follows:

2007	$ 1,726
2008	1,866
2009	634
2010	651
2011	669
2011 and beyond	3,633
Total minimum lease payments	$ 9,179

Vendor contracts

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In accordance with a recently signed research contract, the Company is committed to spending a minimum of $100 in research and development activities by September 2007. To date, the Company has incurred minimal expenditures under this contract.

Litigation

In June 2002, the Company initiated a lawsuit against Élan Pharmaceuticals and related entities in an effort to clarify intellectual property rights, including the recovery of royalties and other costs and fees, to which the Company believed it was entitled under a set of 1991 agreements and to clarify intellectual property rights associated with those agreements. The Company sought damages, injunctive relief and declaratory relief. On June 27, 2005, the Company obtained a settlement pursuant to which Élan and related entities agreed to pay the Company $10,000. Payment of such settlement was received by the Company in July 2005. The agreement also clarified the parties intellectual property rights. Upon receipt of the settlement from Élan Pharmaceuticals and related entities, the Company distributed a net settlement amount (total proceeds from the settlement less reserves for applicable federal and state income taxes, legal expenses related to the suit and other miscellaneous expenses) of $5,400 to all Company stockholders of record as of June 15, 2005.

In 1998, the Company recorded obligations related to the initial purchase agreement of Michigan Biologic Products Institute of $10,119. During 2004, the Company settled its entire remaining purchase obligations to the State of Michigan for $6,300, resulting in a gain of $3,819, which is reflected as a component of operations on the accompanying statement of operations.

From time to time, the Company is involved in product liability claims and other litigation considered normal in the nature of its business. The Company does not believe that any such proceedings would have a material, adverse effect on the results of its operations. For claims filed against the Company for use of BioThrax by the DoD, we expect 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

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, 2004, 2005 and 2006, the Company paid approximately $32,$34 and $13, respectively, for transportation on an as needed basis for business purposes. As of May 2006, this arrangement has been terminated.

The Company has entered into marketing and sales contracts with 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. A marketing arrangement with an entity affiliated with the Chief Executive Officer and his family requires a payment of 40% of gross sales in countries in the Middle East and North Africa, except Israel. No royalty payments under these agreements have been triggered for the years ended December 31, 2004, 2005 and 2006. The arrangement with the Chief Executive Officer s sister has been terminated.

For the years ended December 31, 2004, 2005 and 2006, the Company paid approximately $494, $794 and $419, respectively, in consulting, lease and transportation arrangements with various persons or entities affiliated with the Chief Executive Officer or two members of the board of directors. For the year ended December 31, 2005 and 2006, there was $22 and $17 respectively, in accounts payable for these services. The Company currently has an agreement with a director to perform corporate strategic issues consultation and directed project support to the marketing and communications group and an agreement with East West Resources Corporation, a company owned by the Chief Executive Officer, to provide transportation and logistical support.

15. Segment information

The Company operates in two business segments: biodefense and commercial. In the biodefense business, the Company develops, 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 with 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 business and includes costs of the centralized services departments, which are not allocated to the other segments. The assets in this segment consist of cash and fixed assets.

	Reportable Segments Biodefense	Commercial	All Other	Total
Year Ended December 31, 2006				
External revenue	$ 147,707	$ 5,025	$	$ 152,732
Inter-segment 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
Year Ended December 31, 2005				
External revenue	$ 128,219	$ 2,469	$ -	$ 130,688
Inter-segment revenue	-	-	-	-
Research and Development	10,327	6,962	1,092	18,381
Interest revenue	-	-	485	485
Interest expense	-	-	(767)	(767)
Depreciation and amortization	2,911	411	226	3,548
Net Income (Loss)	58,632	(40,325)	(2,523)	15,784
Assets	40,502	5,489	54,341	100,332
Expenditures for long-lived assets	$ 3,286	$ 3,052	$ 194	$ 6,532

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, 2005 and 2006 is presented in the following tables:

	March 31,	June 30,	September 30,	Three months ended December 31,
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
Fiscal year 2005				
Revenue	$ 15,261	$ 44,058	$ 27,581	$ 43,788
Income from operations	425	3,699	4,498	12,714
Net income	225	2,616	3,410	9,533
Net income per share, basic	0.01	0.14	0.15	0.43
Net income per share, diluted	0.01	0.12	0.13	0.38

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

Not applicable.

ITEM 9A. 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, 2006. 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

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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, 2006, 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.

No change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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 2007 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 2007 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 2007 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 2007 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 2007 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 2007 Annual Meeting of Stockholders. Such information is incorporated herein by reference. The Compensation Committee Report contained in the Proxy Statement for our 2007 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 MAT

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 2007 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 2007 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 2007 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, 2005 and 2006

Consolidated Statements of Operations for the years ended December 31, 2004, 2005 and 2006

Consolidated Statements of Cash Flows for the years ended December 31, 2004, 2005 and 2006

Consolidated Statement of Changes in Stockholders Equity for the years ended December 31, 2004, 2005 and 2006

Notes to Consolidated Financial Statements

Financial Statement Schedules

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

Exhibits

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

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

By: /s/Fuad El-Hibri
Fuad El-Hibri
President, Chief Executive Officer and Chairman of the Board of Directors
Date: March 27, 2007
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	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 27, 2007
/s/R. Don Elsey R. Don Elsey	Vice President Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 27, 2007
/s/Joe M. Allbaugh Joe M. Allbaugh	Director	March 27, 2007
/s/Zsolt Harsanyi, Ph.D. Zsolt Harsanyi, Ph.D.	Director	March 27, 2007
/s/Jerome M. Hauer Jerome M. Hauer	Director	March 27, 2007
/s/Shahzad Malik, M.D. Shahzad Malik, M.D.	Director	March 27, 2007
/s/Ronald B. Richard Ronald B. Richard	Director	March 27, 2007
/s/Louis W.Sullivan, M.D. Louis W.Sullivan, M.D.	Director	March 27, 2007

EXHIBIT INDEX

Exhibit Number	Description
3.1 (2)	Restated Certificate of Incorporation of the Registrant
3.2 (2)	Amended and Restated By-laws of the Registrant
4.1(1)	Specimen Certificate Evidencing Shares of Common Stock
4.2(1)	Registration Rights Agreement, dated June 23, 2005, between the Registrant and Microscience Investments Limited, formerly Microscience Holdings PLC
4.3(1)	Registration Rights Agreement, dated September 22, 2006, among the Registrant and the entities listed on Schedule 1 thereto
4.4(2)	Rights Agreement, dated November 14, 2006, between the Registrant and American Stock Transfer & Trust Company
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
9.1(1)	Voting and Right of First Refusal Agreement, dated October 21, 2005, between the William J. Crowe, Jr. Revocable Living Trust and Fuad El-Hibri
9.2(1)	Voting Agreement, dated June 30, 2004, between BioPharm, L.L.C. and Michigan Biologic Products, Inc.
9.3(1)	Voting Agreement, dated June 30, 2004, between BioPharm, L.L.C. and Biologika, L.L.C.
9.4(1)	Voting Agreement, dated June 30, 2004, by and among the stockholders named therein
9.5(1)	Voting Agreement, dated August 11, 2006, between BioPharm, L.L.C. and Microscience Investments Limited
9.6 #	Assignment and Assumption Agreement by and between Microscience Investments Limited, the Investors named therein and BioPharm, L.L.C., dated March 8, 2007, relating to the Voting Rights Agreement, dated August 11, 2006, between BioPharm, L.L.C. and Microscience Investments Limited
10.1(1)	Employee Stock Option Plan, as amended and restated
10.2(1)	Form of Director Stock Option Agreement
10.3(1)	2006 Stock Incentive Plan
10.4(1)	Form of Incentive Stock Option Agreement under 2006 Stock Incentive Plan
10.5(1)	Form of Nonstatutory Stock Option Agreement under 2006 Stock Incentive Plan
10.6(1)	Severance Plan and Termination Protection Program
10.7(1)	Form of Indemnity Agreement
10.8(1)	Contract No. W9113M-04-D-0002, dated January 3, 2004, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and U.S. Army Space and Missile Defense Command, as amended
10.9(1)	Contract No. 200-2005-11811, dated May 5, 2005, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Department of Health and Human Services, Office of Public Health Emergency Preparedness and Office of Research and Development Coordination, as amended
10.10(1)	Filling Services Agreement, dated March 18, 2002, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Hollister-Stier Laboratories LLC, as amended
10.11(1)	BT Vaccine License Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency
10.12(1)	BT Vaccine Development Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency
10.13(1)	rBot Vaccine License Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency
10.14(1)	rBot Vaccine Development Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency
10.15(1)	Exclusive Distribution Agreement, dated November 23, 2004, between the Registrant and the Health Protection Agency
10.16(1)	Investment Agreement relating to Microscience Holdings PLC, dated March 18, 2005, among the Wellcome Trust, Microscience Investments Limited, formerly Microscience Holdings PLC, and Emergent Product Development UK Limited, formerly Microscience Limited, as amended
10.17(1)	Standard Employment Contract, dated September 22, 2006, between Emergent Product Development UK Limited, formerly Emergent Europe Limited, and Steven N. Chatfield
10.18(1)	Letter Agreement, dated July 11, 2006, between the Registrant and Steven N. Chatfield
10.19(1)	Consulting Services Agreement, dated March 1, 2006, between the Registrant and The Hauer Group

10.20(1)	Amended and Restated Marketing Agreement, dated January 1, 2000, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Intergen N.V., as amended
10.21(1)	Lease, dated December 1, 1998, between ARE-QRS, Corp. and Antex Biologics Inc., as amended
10.22(1)	Lease (540 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire), dated December 13, 1996, between Slough Properties Limited and Azur Environmental Limited, as assigned to Emergent Product Development UK Limited, formerly Microscience Limited
10.23(1)	Lease (545 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire), dated December 13, 1996, between Slough Properties Limited and Azur Environmental Limited, as assigned to Emergent Product Development UK Limited, formerly Microscience Limited
10.24(1)	Lease Agreement, dated June 27, 2006, between Brandywine Research LLC and the Registrant
10.25(1)	Amended and Restated Loan Agreement, dated July 29, 2005, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Fifth Third Bank, as amended
10.26(1)	Loan and Security Agreement, dated October 14, 2004, among the Registrant, Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., Antex Biologics Inc., Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Mercantile Potomac Bank
10.27(1)	Promissory Note, dated October 14, 2004, from Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., to Mercantile Potomac Bank
10.28(1)	Loan Agreement, dated October 15, 2004, between Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., and the Department of Business and Economic Development
10.29(1)	Deed of Trust Note, dated October 14, 2004, between Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., and the Department of Business and Economic Development
10.30(1)	Term Note, dated August 10, 2004, from Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, to Fifth Third Bank
10.31(1)	Loan Agreement, dated April 25, 2006, among the Registrant, Emergent Frederick LLC and HSBC Realty Credit Corporation (USA)
10.32(1)	Bond Purchase Agreement, dated March 31, 2005, between the County Commissioners of Frederick County, Emergent Commercial Operations Frederick Inc., formerly Emergent Biologics Inc., and Mercantile Potomac Bank
10.33(1)	License and Co-development Agreement, dated May 6, 2006, between Emergent Product Development UK Limited, formerly Emergent Europe Limited, and Sanofi Pasteur, S.A
10.34(1)	Product Supply Agreement, dated June 12, 2006, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics, Inc.
10.35(1)	Election of Fuad El-Hibri to Participate in the Severance Plan and Termination Protection Program
10.36(1)	Services Agreement, dated August 1, 2006, between East West Resources Corporation and the Registrant
10.37(1)	Director Compensation Program
10.38(1)	Revolving Credit Note, dated July 29, 2005, from Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, to Fifth Third Bank
10.39(1)	Promissory Note, dated April 25, 2006, from Emergent Frederick LLC to HSBC Realty Credit Corporation (USA)
10.40(1)	Loan Agreement, dated August 25, 2006, among the Registrant, Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and HSBC Realty Credit Corporation (USA)
10.41(1)	Promissory Note (Term Note), dated August 25, 2006, from Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, to HSBC Realty Credit Corporation (USA)
10.42(1)	Promissory Note (Revolving Credit Loan), dated August 25, 2006, from Emergent BioDefense Operations Lansing Inc., formerly, BioPort Corporation to HSBC Realty Credit Corporation (USA)
10.43(1)	Agreement, dated June 16, 2005, between the Free State of Bavaria and Emergent Product Development UK, formerly ViVacs GmbH
10.44 #	Amendment to Consulting Services Agreement, effective March 30,2007, between the Registrant and The Hauer Group
10.45#	Fourth Amendement to Amended and Restated Loan Agreement, effective December 21, 2006, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Fifth Third Bank.
10.46#	Fifth Amendment to Amended and Restated Loan Agreement, effective February 15, 2007, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Fifth Third Bank.
21.1(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.