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	**14-1902018**
(State or Other Jurisdiction of Organization)	(IRS Employer Identification No.)
2273 Research Boulevard, Suite 400	
Rockville, Maryland	**20850**
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

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

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

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

INDEX

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K and the documents incorporated by reference herein contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. All statements, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words anticipate, believe, estimate, expect, intend, may, plan, predict, project, will, would and similar exp to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

- our 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,

4

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.

5

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

10

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

11

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

12

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

13

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.

14

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

15

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

16

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

17

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.

18

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.

20

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

22

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

24

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.

25

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

26

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

28

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

30

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

33

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;

34

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

37

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 be