Emergent BioSolutions Inc.
Form 10-K/A
March 13, 2008

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K/A
Amendment No. 1

(Mark One)

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

OR

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

Commission file number: **001-33137**

EMERGENT BIOSOLUTIONS INC.

(Exact Name of Registrant as Specified in Its Charter)

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

Registrant s Telephone Number, Including Area Code**(301) 795-1800**

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

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

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

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

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

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

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

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement for its 2008 annual meeting of stockholders scheduled to be held on May 21, 2008, which is expected to be filed with the Securities and Exchange Commission not later than 120 days after the end of the registrant s fiscal year ended December 31, 2007, are incorporated by reference into Part III of this annual report on Form 10-K. With the exception of the portions of the registrant s definitive proxy statement for its 2008 annual meeting of stockholders that are expressly incorporated by reference into this annual report on Form 10-K, such proxy statement shall not be deemed filed as part of this annual report on Form 10-K.

BioThrax® and *spi*-VEC are our trademarks. Each of the other trademarks, trade names or service marks appearing in this annual report on Form 10-K are the property of their respective owners.

We are filing this Amendment No. 1 on Form 10-K/A to our annual report on Form 10-K for the fiscal year ended December 31, 2007, as originally filed with the Securities and Exchange Commission on March 10, 2007, for the sole purpose of refiling certifications in accordance with Rule 13a-14(a) under the Securities Exchange Act of 1934 to include the conformed signatures of our Chief Executive Officer and our Chief Financial Officer, which were unintentionally omitted from the certifications filed as exhibits with the original filing. This Amendment No. 1 does not change the previously reported financial statements or any of the other disclosure contained in the original filing, other than to update the Exhibit Index that is incorporated by reference into Part IV of this Amendment No. 1. Except as noted above, this Amendment No. 1 includes the full text of the original filing. Also filed as exhibits with this Amendment No. 1 are new certifications in accordance with Rule 13a-14(b) of the Exchange Act.

EMERGENT BIOSOLUTIONS INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2007

INDEX

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

PART I

ITEM 1. BUSINESS

Overview

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

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

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

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

Our product candidates in advanced stages of development are:

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

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

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

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

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

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

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

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

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

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

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

Our Strategy

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

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

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

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

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

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

Market Opportunity

Vaccines have long been recognized as a safe and cost-effective method for preventing infection caused by various bacteria and viruses. Because of an increased emphasis on preventative medicine in industrialized countries, vaccines are now well recognized as an important part of effective public health management. According to a 2006 report issued by Frost & Sullivan, a market research organization, from 2002 to 2005, annual worldwide vaccine sales increased from $6.7 billion to $9.9 billion, a compound annual growth rate of approximately 14%. In this same report it is estimated that the worldwide sales of vaccines will grow at a compound annual rate of approximately 10.5% from 2005 through 2012. New vaccine technologies, coupled with a greater understanding of how infectious microorganisms, or pathogens, cause disease are leading to the introduction of new vaccine products. Moreover, while existing marketed vaccines generally are designed to prevent infections, new vaccine technologies have also led to a focus on the development of vaccines for therapeutic purposes. Potential therapeutic vaccines extend beyond infectious diseases to cancer, autoimmune diseases and allergies.

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

The market for biodefense countermeasures, including vaccines and therapeutics, has grown dramatically as a result of the increased awareness of the threat of global terror activity in the wake of the September 11, 2001 terrorist attacks and the October 2001 anthrax letter attacks. The U.S. government is the principal source of worldwide biodefense spending. Most U.S. government spending on biodefense programs results from development funding awarded by NIAID, BARDA and the DoD, and procurement of countermeasures by HHS, the CDC and the DoD. The U.S. government is now the largest source of development and procurement funding for academic institutions and biotechnology companies conducting biodefense research or developing vaccines and immunotherapies directed at potential agents of bioterror or biowarfare.

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

The DoD procures biodefense countermeasures that it administers primarily through the Military Vaccine Agency, or MilVax. MilVax administers various vaccination programs for military personnel, including vaccines for common infectious diseases, such as influenza, and vaccines to protect against specific bioterrorism threats, such as anthrax and smallpox. The level of spending by the DoD for MilVax is a function of the size of the U.S. military and the DoD s protocols with respect to vaccine stockpile management and active immunization. The DoD provides development funding for biodefense vaccines through its Joint Vaccine Acquisition Program, or JVAP. We believe that in the future the DoD will procure additional doses of BioThrax directly from HHS to satisfy ongoing requirements for its active immunization program and that these purchases may result in HHS procuring additional doses from us.

In addition to the U.S. government, we believe that other potential additional markets for the sale of biodefense countermeasures include:

state and local governments, which we expect may be interested in these products to protect emergency responders, such as police, fire and emergency medical personnel;

foreign governments, including both defense and public health agencies;

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

health care providers, including hospitals and clinics.

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

Scientific Background

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

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

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

Products

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

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

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

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

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

BioThrax (Anthrax Vaccine Adsorbed)

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

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

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

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

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

infection as an emergency public health intervention.

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

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

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

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

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

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

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

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

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

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

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

Expand label indication to include post-exposure prophylaxis. We plan to seek approval of BioThrax in combination with antibiotic therapy as a post-exposure prophylaxis for anthrax infection. In October 2007, we completed a human clinical trial of BioThrax for the post-exposure indication using the anticipated dosing schedule of three doses of BioThrax given two weeks apart. The purpose of this trial was to collect data that, in combination with data from our non-clinical studies, will be used to design our pivotal human clinical trial for this indication. We are currently conducting non-clinical studies for the post-exposure indication pursuant to the FDA animal rule. In these studies, we are evaluating the effect of a humanized dose of BioThrax in combination with antibiotics compared to antibiotics alone in rabbits exposed by inhalation to anthrax spores. We also plan to conduct one or more pivotal studies in non-human primates. The timing of such studies depends on the development of a non-human primate model by NIAID. In 2005, NIAID completed a proof-of-concept study in which rabbits infected with anthrax were treated with the antibiotic levofloxacin or with levofloxacin in combination with two doses of BioThrax in one of three dose amounts. One of the dose amounts tested was a dilution of BioThrax designed to elicit an immune response that is proportional to the effect of an undiluted dose in humans. This is referred to as a humanized dose. Only 44% of the rabbits treated with antibiotics alone survived, while 100% of the rabbits treated with either humanized doses or undiluted doses of BioThrax in combination with levofloxacin survived. In the trial, there were statistically significant increases in survival rates for rabbits treated with all dose amounts of BioThrax in combination with the antibiotic compared to rabbits treated with levofloxacin alone. These results were consistent with an earlier animal test conducted by the U.S. Army Medical Research Institute of Infectious Diseases, or USAMRIID, involving the administration of BioThrax in combination with an antibiotic to non-human primates infected with anthrax. We believe that the data from our rabbit and non-human primate efficacy studies, together with the human immunogenicity data, if favorable, will be sufficient to support the filing with the FDA of a BLA supplement for marketing approval of BioThrax for the post-exposure indication. In February 2007, the FDA granted Fast Track designation for BioThrax as a post-exposure prophylaxis for anthrax infection. In September 2007, BARDA awarded us up to $11.5 million in development funding for this indication, $8.8 million of which was paid in the fourth quarter of 2007.

Next Generation Anthrax Vaccine

We have established a program to develop additional