Emergent BioSolutions Inc.
Form 10-K
March 09, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2011

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001-33137

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

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

Registrant's Telephone Number, Including Area Code: (301) 795 - 1800
Securities registered pursuant to Section 12(b) of the Act:

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨

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

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

Large accelerated filer ¨ Accelerated filer ý Non-accelerated filer ¨ Smaller reporting company ¨

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2011 was approximately $492 million based on the price at which the registrant's common stock was last sold on that date as reported on the New York Stock Exchange.

As of February 29, 2012, the registrant had 36,014,773 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2012 annual meeting of stockholders scheduled to be held on May 17, 2012, 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, 2011, 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 2012 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®, NuThrax™, PreviThrax™, Anthrivig™, Thravixa™, MVAtor™, SMIP™, SCORPIONTM, TRU-ADhanCeTM and Typhella™ the registrant's trademarks. Each of the other trademarks, trade names or service marks appearing in this annual report on Form 10-K are the property of their respective owners.

EMERGENT BIOSOLUTIONS INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2011
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

- our ability to perform under our contracts with the U.S. government related to BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, including the timing of deliveries;
- our plans for future sales of BioThrax, including our ability to obtain funding for existing procurement contracts with the U.S. government;
- our plans to pursue label expansions and other improvements for BioThrax;
- our ability to perform under our development contract with the U.S. government for our product candidate PreviThraxTM (Recombinant Protective Antigen Anthrax Vaccine, Purified);
- our ability to perform under our contract with the U.S. government to develop and obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55, our large-scale vaccine manufacturing facility in Lansing, Michigan;
- our plans to expand our manufacturing facilities and capabilities;
- the rate and degree of market acceptance of our products and product candidates;
- the success of ongoing and planned development programs, preclinical studies and clinical trials of our product candidates and post-approval clinical utility of our products;
- our ability to identify and acquire or in-license products and product candidates that satisfy our selection criteria;
- our ability to successfully integrate and develop the products or product candidates, programs, operations and personnel of any entities or businesses that we acquire;
- the timing of and our ability to obtain and maintain regulatory approvals for our products and 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 in Item 1A of this annual report on Form 10-K, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

PART I

ITEM 1. BUSINESS

Overview.

We are a biopharmaceutical company focused on protecting and enhancing life by developing and manufacturing vaccines and therapeutics that are supplied to healthcare providers and purchasers for use in preventing and treating disease. We have two operating divisions: our Biodefense Division and our Biosciences Division. For financial reporting purposes, we operate in two business segments that correspond to these two operating divisions. For information for each of our business segments, see Note 24 to our Consolidated Financial Statements included in Item 8 of this annual report on Form 10-K.

Our Biodefense Division is directed to government-sponsored development and supply of countermeasures against potential agents of bioterror or biowarfare and targets the infectious disease anthrax. Our programs in this division include a pipeline of investigational product candidates and one marketed product, BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax disease. Operations in this division include biologics manufacturing, regulatory and quality affairs in support of BioThrax and a product development infrastructure in support of our investigational product candidates.

Our Biosciences Division is directed to commercial opportunities and targets oncology indications, including B-cell malignancies chronic lymphocytic leukemia, or CLL, and non-Hodgkin's lymphoma, or NHL, as well as T-cell malignancies cutaneous T-cell lymphoma, or CTCL, and peripheral T-cell lymphoma, or PTCL; autoimmune and inflammatory disorders, or AIID, including rheumatoid arthritis, or RA, and systemic lupus erythematosus, or SLE; and infectious diseases such as tuberculosis, or TB. Our programs in this division include clinical and preclinical stage investigational product candidates and development programs for our platform technologies. Operations in this division include product development in support of our investigational product candidates, and manufacturing and related infrastructure initiatives in support of our technology platforms.

We fund our product development efforts through a variety of sources. The primary source is reinvestment of internally generated cash flows, which are primarily a result of product sales of BioThrax to the U.S. government. A second source is financing from external sources, which offsets our development costs. In our Biodefense Division, our anthrax programs generally are substantially supported by funding from governmental agencies. In our Biosciences Division, our tuberculosis and influenza programs are supported in part by funding from governmental and non-governmental agencies and philanthropic organizations, and our most advanced AIID product candidate is being developed and commercialized by a large pharmaceutical company partner.

We have derived substantially all of our product revenues from sales of BioThrax to the U.S. Department of Health and Human Services, or HHS. We expect for the foreseeable future to continue to derive substantially all of our product revenues from the sale of BioThrax to U.S. government customers. Product revenues were $202.4 million in 2011, $251.4 million in 2010 and $217.2 million in 2009. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other international and domestic customers and pursuing ongoing BioThrax enhancements, including initiatives to secure a second label indication for post-exposure prophylaxis, or PEP, to extend the shelf life to five years and to optimize the general use prophylaxis, or GUP, schedule to a three dose primary series with boosters thereafter.

Contracts and grants revenues reflect development funds received through funding arrangements with governmental and non-governmental agencies and philanthropic organizations and from third party collaborators. Revenues from contracts and grants were $71.0 in 2011, $34.8 million in 2010 and $17.6 million in 2009. We continue to actively

pursue additional government-sponsored development contracts and grants for our anthrax programs, and additional governmental and non-governmental agency and philanthropic organizational support for our tuberculosis and influenza programs.

We were incorporated as BioPort Corporation, or BioPort, under the laws of Michigan in May 1998 and commenced operations as BioPort in September 1998 through an acquisition from the Michigan Biologic Products Institute of rights to the marketed product, BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how. In December 2003, we began a corporate reorganization in which we formed a new corporate parent, Emergent BioSolutions Inc., or Emergent, a Delaware corporation. In June 2004, we completed a corporate reorganization whereby Emergent 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 which we subsequently converted to Emergent Biodefense Operations Lansing LLC. We have established additional subsidiaries, each primarily consisting of an operational component of our business, including, among others, manufacturing in Baltimore, Maryland, product development in Gaithersburg, Maryland, the United Kingdom, Germany and Singapore and research and product development in Seattle, Washington.

Scientific Background

Vaccines

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

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

Monoclonal antibodies and antibody-like proteins

Traditional monoclonal antibodies. A monoclonal antibody, or mAb, is a therapeutic that provides an immediate protective effect. However, unlike immune globulins that can recognize and bind to multiple antigens, monoclonal antibodies are specific to a single antigen and are generally produced in cell culture rather than collected from humans. Monoclonal antibodies can be administered either intravenously or subcutaneously by intramuscular injection to patients. Similar to an immune globulin, use of a mAb is a form of passive immunization.

Antibody-like proteins. Similar to traditional monoclonal antibodies, antibody-like protein molecules target specific antigens or proteins that may be on the surface of a cell or to a soluble antigen that may be circulating in the vasculature. When a therapeutic targeted to a particular cell surface antigen binds to its target protein, it can elicit particular biological effects that can include particular forms of cell killing or cell death or other effects just like a

traditional monoclonal antibody.

B-cells. B-cells are a specific subset of lymphocytes and are important to the basic functioning of the body's immune system by, among other things, producing antibodies that attack and kill bacteria and viruses circulating within the body, and helping recruit and coordinate other types of immune system cells to perform specialized functions in the body's fight against disease and infection. When B-cells fail to appropriately distinguish between the body's own cells, tissues or organs and foreign pathogens or proteins, the B-cells can mistakenly initiate an immune response against healthy cells that results in an autoimmune disorder that can lead to progressive disability, such as RA, SLE, multiple sclerosis, type 1 diabetes or Graves' disease. In addition, when B-cells become malignant or otherwise multiply uncontrollably, they can result in cancers such as lymphomas, leukemias and myelomas. Our antibody-like therapeutic product candidates are designed to treat specific forms of cancer and AIID. Our therapeutic product candidates are designed to treat these conditions by selecting, targeting and binding to B-cells, which are then removed by the immune system by cell killing or cell death.

T-cells. T-cells are another specific subset of lymphocytes and play an integral role in the immune system by directly killing cells that have been infected or by regulating the activity of other lymphoyctes. When certain types of T-cells decrease, opportunistic infections may occur and when other subsets of T-cells are dysfunctional, autoimmune and inflammatory disorders may occur. When T-cells become malignant, PTCL or CTCL results. One of our clinical stage therapeutic candidates targets PTCL and CTCL, while other preclinical candidates target autoimmune and inflammatory disorders secondary to T-cell dysfunction.

Immune Globulins

Polyclonal antibodies, including immune globulins, can be used as therapeutics that provide an immediate protective effect. Immune globulin therapeutics are normally made by collecting plasma from individuals who have contracted a particular disease or who have been vaccinated against a particular disease and whose plasma contains a mixture of protective antibodies. This mixture can be composed of antibodies that recognize and bind to different pathogen antigens or to different sites on a single antigen. These polyclonal antibodies are isolated by fractionation of the plasma, purified and then administered either intravenously or by intramuscular injection to patients. Because it normally takes several weeks for the immune system 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. This use of immune globulins is therefore considered passive immunization.

Platform Technologies

SMIP™ (mono-specific humanized protein therapeutic). Our Small Modular ImmunoPharmaceutical, or SMIP, humanized fusion protein therapeutics are mono-specific, single-chain antibody-like proteins that bind to specific protein targets such as surface proteins on B-cells. Our current clinical stage SMIP product candidates target either CD20 or CD37, two proteins found on B-cells. SMIP therapeutics are made up of an effector domain, a hinge domain and a binding domain. The effector domain can be designed to elicit a specific biological activity, the hinge domain can be varied to tune the strength of the response, and the binding domain recognizes and attaches to the specific antigen target. Using proprietary technology, we custom assemble SMIP proteins through the selection of binding domains that meet predetermined therapeutic criteria for specific diseases, along with hinge and effector domains selected to amplify desired activity. Although they function in the same manner as antibodies, SMIP proteins have some different characteristics. In particular, SMIP therapeutics are significantly smaller than whole antibodies. In addition, when engaging cell surface targets, SMIP proteins are capable of bringing together cell surface molecules with binding domains that are closer together than typically possible with monoclonal antibodies. The structural format of SMIP proteins also permits them to be engineered with a range of distances between the binding domains. We believe these molecules may have therapeutic applications in AIID, oncology and other high unmet needed areas.

SCORPION™ (multi-specific protein therapeutic). Like SMIP proteins, SCORPION molecules are protein therapeutics that we custom assemble using either single or dual chain proteins, and consist of an effector domain, a hinge domain and a binding domain. However, SCORPION therapeutics are different from SMIP proteins in that they have a second binding domain, which enables them to bind to multiple targets simultaneously. We believe this multi-specific feature could allow SCORPION therapeutics to generate multiple synergistic biological activities. We believe these molecules may have therapeutic applications in AIID, oncology, infectious diseases and other high unmet need areas.

TRU-ADhanCe™ (manufacturing technology). Antibody-dependent cellular cytotoxicity, or ADCC, is an important mechanism of cell killing in certain oncology and AIID indications. We believe TRU-ADhanCe technology can potentially enhance the ADCC potency of immunopharmaceutical product candidates by greater than an order of magnitude. In contrast to existing ADCC enhancement approaches that impose product development challenges, TRU-ADhanCe is a simple proprietary manufacturing methodology that is designed to achieve a desired change in glycosylation structures, which are the carbohydrate chains attached to proteins that affect protein function. We believe use of this technology may increase a product's biological activity while requiring no change to its amino acid sequence and no change to its manufacturing cell line.

MVAtor™ (modified vaccinia virus Ankara vector). Our modified vaccinia Ankara, or MVA, platform technology is based on rights to use MVA to develop and produce viruses and virus products, including recombinant viral vectors, that we license from a third party. We believe MVAtor 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 MVAtor.

Products

Our Biodefense segment focuses on vaccines and antibody therapies for use against the infectious disease anthrax. Our Biosciences segment focuses on vaccines and antibody therapies for use against infectious diseases and protein therapies to treat certain types of autoimmune and inflammatory disorders and cancer.

The following table summarizes key information about BioThrax and our clinical stage product candidates for which we currently are pursuing development. We currently hold commercial rights to BioThrax and each of the product candidates listed below.

Disease	Product or Product Candidate	Description	Development Stage
Infectious Diseases:			
Anthrax	BioThrax	Only FDA-approved vaccine for pre-exposure prevention of anthrax disease	Marketed
	BioThrax PEP	BioThrax as a post-exposure prophylaxis	Phase III
	NuThrax*	Pre-exposure prophylactic vaccine	Phase I
	PreviThrax*	Pre/post-exposure prophylactic vaccine	Phase II
	Anthrivig*	Human immune globulin therapeutic	Phase II
	Thravixa*	Fully human monoclonal antibody therapeutic	Phase I
Tuberculosis	MVA-85A	Prophylactic recombinant TB vaccine	Phase II
AIID:			
Rheumatoid Arthritis	SBI-087	Humanized anti-CD20 SMIP therapeutic	Phase II
Systemic Lupus Erythematosus	SBI-087	Humanized anti-CD20 SMIP therapeutic	Phase I
Cancer:			
Chronic Lymphocytic Leukemia	TRU-016	Humanized anti-CD37 SMIP therapeutic	Phase II
	TRU-016	Humanized anti-CD37 SMIP therapeutic	Phase I

Non-Hodgkin's Lymphoma			
Peripheral T-cell Lymphoma	Zanolimumab	Humanized anti-CD4 monoclonal antibody therapeutic	Phase I
Cutaneous T-cell Lymphoma	Zanolimumab	Humanized anti-CD4 monoclonal antibody therapeutic	Phase II

* We currently intend to rely on the FDA animal rule in seeking marketing approval for these programs. 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”, in this Item 1.

We are also developing preclinical product candidates including an influenza vaccine and additional protein therapeutics in our SMIP and SCORPION pipelines. In August 2010, we formed a joint venture with a Singaporean entity to develop, manufacture, and commercialize a multivalent, cross-protective human vaccine to protect against influenza caused by a broad range of circulating H5 influenza strains. Our SMIP and SCORPION protein therapeutics in preclinical development include ES301 (anti-CD3 SMIP protein), X2 (anti-CD86 x IL-10 SCORPION protein) and T-Scorp molecules targeted for solid organ transplant, inflammatory bowel disease, solid tumors and RA.

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

The results of a clinical trial are statistically significant if they are unlikely to have occurred by chance. We determined the statistical significance of clinical trial results based on a widely used, conventional statistical method that establishes the p value of the results. Under this method, a p value of 0.05 or less represents statistical significance in most trials. Statistical significance is required of trials for both vaccine and therapeutic products.

For vaccines, the immune responses observed in a group of vaccine trial participants can be compared with those observed in other groups of trial participants or with an assumed response rate. Immunogenicity alone does not establish efficacy for purposes of regulatory approval. Immunogenicity data only provide indications of potential efficacy and may not be required nor sufficient to enable a product candidate to proceed to Phase II or later stages of clinical development. Phase I clinical trials may be required to establish the safety of a product candidate, not its immunogenicity, before Phase II clinical trials may begin.

For AIID therapeutic products, response based on composite scores has typically been acceptable for Phase III clinical trials and regulatory approval. For oncology therapeutic products, the primary clinical endpoint is frequently the overall response rate in early phase trials. Later stage trials require progression and overall survival as clinical endpoints.

Infectious Diseases

Anthrax

Disease overview. Anthrax is a potentially fatal disease caused by the spore forming bacterium Bacillus anthracis. Anthrax bacteria are naturally occurring, and spores are found in soil throughout the world. Anthrax spores can withstand extreme heat, cold and drought for long periods. Anthrax infections occur if the spores enter the body through a cut, abrasion or open sore, or by ingestion or inhalation. Once inside the body, anthrax spores germinate into

anthrax bacteria that then multiply. Anthrax bacteria secrete three proteins: protective antigen, lethal factor and edema factor. Each of these proteins individually is non-toxic, but if allowed to interact on the surface of human or animal cells, they can form the highly potent toxins known as lethal toxin (protective antigen and lethal factor) or edema toxin (protective antigen and edema factor).

Cutaneous anthrax, although rare in the United States, is the most common type of naturally acquired anthrax. Cutaneous anthrax is typically acquired through contact with contaminated animals and animal products. The fatality rate for untreated cases of cutaneous anthrax is estimated to be approximately 5% - 20% and less than 1% with antibiotic treatment.

Gastrointestinal anthrax is a rare form of anthrax. Gastrointestinal anthrax is generally acquired through the consumption of meat and other food products contaminated with anthrax spores. The fatality rate of gastrointestinal anthrax is unknown, but is estimated to be 25% - 60%.

Inhalational anthrax is the most lethal form of anthrax. We believe that aerosolized anthrax spores are the most likely method to be used in a potential anthrax bioterrorism attack. Inhalational anthrax has been reported to occur from one to 43 days after exposure to aerosolized spores. Initial symptoms of inhalational anthrax are non-specific and may include sore throat, mild fever, cough, malaise, or weakness, lasting up to a few days. After a brief period of improvement, the release of anthrax toxins may cause an abrupt deterioration in the health of the infected person, with the sudden onset of symptoms, including fever, shock and respiratory failure as the lungs fill with fluids. Hemorrhagic meningitis is common. Death often occurs within 24-36 hours of the onset of advanced respiratory complications. Prior to 2001, the fatality rate for untreated inhalational anthrax was estimated to be between 85% and 97%. With antibiotics the fatality rate is estimated to be 75%. The fatality rate for inhalational anthrax cases in 2001, with intensive therapy, was 45%.

Market opportunity and current treatments. To date, the principal customer for anthrax medical countermeasures has been the U.S. government, specifically HHS and the U.S. Department of Defense, or DoD. Most U.S. government spending on biodefense programs is in the form of development funding from the National Institute of Allergy and Infectious Disease, or NIAID, the Biomedical Advanced Research and Development Authority, or BARDA, and the DoD (including the Defense Advanced Research Projects Agency, or DARPA), and procurement of countermeasures by BARDA, the Centers for Disease Control, or CDC, and the DoD. The U.S. government is the largest source of funding for academic institutions and biotechnology companies conducting biodefense research or developing vaccines and therapeutics directed at potential agents of bioterror or biowarfare.

The Project BioShield Act of 2004, or Project BioShield, authorizes expedited procurement of biomedical countermeasures against chemical, biological, radiological and nuclear attacks and related products. Project BioShield initially provided appropriations of $5.6 billion to be expended over ten years into a special reserve fund for procurement of countermeasures for the Strategic National Stockpile, or SNS. BARDA is one of the government agencies responsible for awarding procurement contracts for biomedical countermeasures. BARDA also provides development funding for advanced research and development in the biodefense arena. Appropriation funding for BARDA has been provided by annual appropriations by Congress. Congress also has appropriated 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 has been in addition to amounts available under Project BioShield for chemical, biological, radiological and nuclear countermeasures, and provides funding for activities related to public health emergencies and infectious diseases.

The DoD, primarily through the Military Vaccine Agency, or MilVax, administers various vaccination programs for military personnel, and vaccines to protect against specific bioterrorism threats. The level of spending by the DoD for MilVax is a function of the size of the U.S. military and the DoD’s protocols with respect to vaccine stockpile management and active immunization. The DoD provides development funding for biodefense vaccines through its Joint Vaccine Acquisition Program, or JVAP. The DoD procures doses of BioThrax from HHS, rather than from us

directly, to satisfy ongoing requirements for its active immunization program in accordance with an October 2007 Presidential Directive that outlines the U.S. government's objective to enhance coordination and cooperation among federal agencies with respect to countermeasure procurement and stockpile management.

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

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

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

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

BioThrax and BioThrax Related Programs

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

As with any pharmaceutical product, the use of vaccines carries a risk of adverse health effects that must be weighed against the expected health benefit of the product. The adverse reactions that have been associated with the administration of BioThrax are similar to those observed following the administration of other adult vaccines and include local reactions, such as redness, swelling and limitation of motion in the inoculated arm, and systemic reactions, such as headache, fever, chills, nausea and general body aches. In addition, some serious adverse events have been reported to the vaccine adverse event reporting system, or VAERS, database maintained by the CDC and the FDA with respect to BioThrax. The report of any such adverse event to the VAERS database is not proof that the

vaccine caused such an event. These putative serious adverse events, including diabetes, heart attacks, autoimmune disorders, Guillain-Barre syndrome, lupus, multiple sclerosis, lymphoma and death, have not been causally linked to the administration of BioThrax.

BioThrax Related Programs

§ Extended expiry dating. In June 2009, we received approval from the FDA of our supplemental biologics license application, or sBLA, to extend the expiry dating of BioThrax from three years to four years, which will allow BioThrax to be stockpiled for a longer period of time. In follow up to that, in December 2010, we submitted to the FDA a new sBLA to extend the expiry dating of BioThrax from four year to five years, which would further extend the length of time BioThrax may be stockpiled. In February 2011, the FDA issued a complete response letter indicating that the submitted data are not adequate to support a five year expiry. We are currently evaluating our response to the FDA.

§ Optimized dosing schedule for general use prophylaxis (GUP). In February 2010, we submitted a BLA efficacy supplement to the FDA to change the BioThrax dosing schedule from the current 0-, 1-, 6-, 12- and 18-month schedule with annual boosters to a 0-, 1- and 6-month schedule with triennial boosters. The BLA supplement was primarily based on data from a clinical trial completed by the CDC in December 2009 to evaluate whether as few as three doses of BioThrax administered over six months, with booster doses up to three years apart, would confer an adequate immune response

According to the statistical analysis plan of the trial, a switch in the dosing schedule would be justified by demonstrated non-inferiority of immune response of groups with a modified vaccination schedule as compared to the original approved schedule. The primary endpoints for comparison to determine non-inferiority were (1) geometric mean antibody titer, or GMT, (2) geometric mean antibody concentration, or GMC, and (3) the proportion of subjects achieving 4-fold increase in antibody titer after vaccination. Non-inferiority had to be demonstrated for all primary endpoints in order to support the use of specific regimens. In accordance with applicable regulatory guidance and the FDA's recommendations to the CDC on trial design, all non-inferiority tests were done at the 0.025 significance level to insure that results were not due to random variation. A conclusion of non-inferiority, to be accepted by the FDA, required that the upper limits of 95% confidence intervals be less than 1.5 for GMT and GMC ratios and less than 0.1 for differences in proportions of subjects achieving 4-fold increase in antibody titer.

In this trial, the immunogenicity for groups with a modified vaccination schedule were all non-inferior to the group with the original approved schedule for all primary endpoints. Additionally, the intramuscular route of administration resulted in significantly fewer adverse events when compared to the subcutaneous route for six of the eight solicited local (injection site) adverse events: warmth, tenderness, erythema, swelling, bruising and itching. Intramuscular administration resulted in a shorter duration of the adverse event than subcutaneous administration for the same six solicited adverse events. Few statistically significant differences were detected in the occurrence of systemic adverse events between the intramuscular treatment groups and the subcutaneous treatment group.

In November 2010, the FDA sent us a complete response letter to our BLA efficacy supplement stating that it could not be approved on the basis of the BLA efficacy supplement as submitted. We had an informal meeting with the FDA in July 2011 to discuss steps necessary for approval. Based on the discussion, in November 2011, we submitted a complete response to the FDA's letter, supporting a three dose primary vaccination series followed by boosters thereafter.

§ Second label indication to include PEP. We plan to seek approval of BioThrax as a PEP against anthrax disease, to be administered in combination with the approved course of antimicrobial therapy in persons 18 to 65 years of age. In February 2007, the FDA granted Fast Track designation for BioThrax as PEP against anthrax disease. In October 2007, we completed a human clinical trial of BioThrax for the PEP indication using the anticipated dosing schedule of three doses of BioThrax given two weeks apart. The data from that trial, in combination with data from

our non-clinical studies, were used to design our anticipated pivotal human clinical trial. We submitted our proposal for this trial to the FDA in May 2008. Based on an initial meeting with the FDA, we conducted additional studies employing the FDA animal rule to demonstrate efficacy of BioThrax in an anthrax post-exposure setting. These additional non-clinical studies included a confirmatory study in non-human primates for pre-exposure general-use prophylaxis, or GUP, which we completed in September 2009. We conducted these non-clinical studies to determine the immune correlate of protection and proof-of-concept that BioThrax is protective in a post-exposure setting. Previously completed proof-of-concept PEP model studies conducted by NIAID and the U.S. Army Medical Research Institute of Infectious Diseases, or USAMRIID, also demonstrated the efficacy of BioThrax by establishing statistically significant increases in survival rates for rabbits treated with all dose amounts of BioThrax in combination with antibiotics compared to rabbits treated with antibiotics alone.

In November 2010, a Vaccines and Related Biological Products Advisory Committee, or VRBPAC, was convened to discuss the pathway to licensure for protective antigen-based anthrax vaccines for a PEP indication (for the prevention of disease caused by residual B. anthracis spores in exposed individuals who have received full course antibiotics) using the animal rule. The VRBPAC agreed with an FDA-proposed strategy for bridging animal protection data to humans for protective antigen-based anthrax vaccines for a PEP indication using appropriately designed GUP studies. In November 2011, we initiated a pivotal immunogenicity and safety study to evaluate a three-dose vaccination schedule of BioThrax for the PEP indication. We believe that the data from our non-clinical efficacy studies such as our GUP studies and proof-of-concept PEP studies, together with pivotal data on human immunogenicity and noninterference of the vaccine with antimicrobials, will be sufficient to support the filing of a BLA supplement with the FDA for marketing approval of BioThrax for the PEP indication. Our development efforts to obtain approval of BioThrax as a PEP are supported in part with funding from BARDA. In December 2011, we entered into an extension of our contract with BARDA through June 2012. BARDA is reviewing a proposal to extend the contract through PEP licensure.

§ NuThrax™ (Anthrax Vaccine Adsorbed containing CPG 7909 Adjuvant). We are developing NuThrax, a product candidate based on BioThrax combined with CPG 7909, an adjuvant that we license from Pfizer Inc., or Pfizer, in part with funding from NIAID and BARDA. We anticipate that NuThrax will, among other things, require fewer doses to produce a sufficient protective immune response, or elicit an enhanced immune response. We obtained additional U.S. government funding through a NIAID award in August 2010 to supplement the further development of NuThrax, including activities related to manufacturing and stability studies of Phase II clinical trial lots, process characterization and assay validation, and clinical trial preparation. The award also contains additional optional funding from NIAID for milestone-based activities for continued stability testing of Phase II clinical trial lots, non-clinical studies and a Phase II clinical trial to evaluate safety and immunogenicity of this product candidate, which we expect to begin in 2012.

In collaboration with us, Coley Pharmaceuticals, the owner of CPG 7909 before its sale to Pfizer, conducted a double-blind Phase I clinical trial of BioThrax combined with CPG 7909 that was funded by DARPA. That trial, which was completed in 2005 and involved 69 healthy volunteers, was designed to evaluate the safety and immunogenicity of this product candidate compared to BioThrax alone and to CPG 7909 alone. In this Phase I trial, the product candidate was administered in three doses by intramuscular injection at two week intervals and elicited an enhanced immune response. The immunogenicity parameters for this trial were the mean peak antibody concentration and the median time to achieve mean peak immune response in trial participants who received BioThrax combined with CPG 7909 as compared to trial participants who received BioThrax alone. In this trial, the mean peak concentration of antibodies to anthrax protective antigen in participants who received the product candidate was approximately 6.3 times higher than in participants who received BioThrax alone. This result was statistically significant, with a p value of less than 0.001. Participants who received BioThrax alone achieved a mean peak geometric anti-PA IgG concentration approximately 42.5 days after first injection. Participants who received BioThrax combined with CPG 7909 achieved this same mean antibody concentration 21 days after the first injection. This result was statistically significant, with a p value of less than 0.001. In this trial, there was a higher frequency of moderate injection site reactions and systemic adverse events in the volunteers who received the product candidate as

compared to volunteers who received BioThrax alone or CPG 7909 alone. One volunteer withdrew from this trial because of an adverse event. There were no serious adverse events reported that the trial investigators considered related to the product candidate, to BioThrax or to CPG 7909.

In August 2010, we obtained additional U.S. government funding through a NIAID award to supplement the further development of NuThrax, including activities related to manufacturing and stability studies of Phase II clinical trial lots, process characterization and assay validation, and clinical trial preparation. The award also contains additional optional funding from NIAID for milestone-based activities for continued stability testing of Phase II clinical trial lots, non-clinical studies and a Phase II clinical trial to evaluate safety and immunogenicity of this product candidate, which we expect to begin in the first quarter of 2012.

In December 2010, we initiated a parallel arm dose-ranging Phase I clinical trial designed to evaluate the safety, tolerability and immunogenicity of NuThrax. The trial was conducted in multiple sites within the United States and involves 105 healthy volunteers. Preliminary data from this study confirmed previous data which indicate superiority of NuThrax over BioThrax. We are currently preparing the clinical study report.

Additional Anthrax Product Candidates

§ PreviThrax™ (Recombinant Protective Antigen Anthrax Vaccine, Purified). We are developing a recombinant anthrax vaccine, based on original development work at USAMRIID. This vaccine, PreviThrax, contains purified recombinant protective antigen, or rPA, formulated with an aluminum hydroxide adjuvant and is designed to induce antibodies that neutralize anthrax toxins in a manner similar to BioThrax. PreviThrax has been evaluated in one Phase II clinical trial, but this trial did not achieve statistically significant results due to product stability issues. We believe that future trials will not be adversely affected by similar stability concerns. In September 2010, BARDA awarded us a contract valued at up to approximately $187 million to fund development activities related to process characterization and assay validation, as well as formulation and stability studies, with potential milestone-based options for completion of a Phase II clinical trial and non-clinical efficacy studies, process validation and consistency lot manufacture. We have completed several formulation studies and have initiated additional studies designed to determine the optimal dose presentation for PreviThrax.

§ Anthrivig™ (Human Anthrax Immune globulin). We are developing Anthrivig, a human anthrax immune globulin, or AIG, therapeutic product candidate, which is a polyclonal antibody therapeutic, designed as a treatment for patients who have been exposed to anthrax spores and who present with symptoms of anthrax disease. We expect that, if approved, Anthrivig would be prescribed as an intravenous infusion in conjunction with a regimen of antibiotics. We are developing Anthrivig using plasma produced by healthy donors who have been immunized with BioThrax.

NIAID has previously provided us grant and contract funding for a combination of initiatives, including studies designed to assess the tolerability, pharmacokinetics and efficacy of this product candidate in non-clinical studies, the development and validation of product assays, and a human clinical trial to evaluate safety and pharmacokinetics. In March 2009, we commenced a Phase I/II dose-escalation trial to evaluate the safety and pharmacokinetics of Anthrivig in 125 healthy human volunteers. We completed dosing in July 2010 and completed subject follow-up in October 2010. The final clinical study report was completed in April 2011 and filed with the FDA in June 2011. The study findings indicated that Anthrivig was safe and that exposure was proportional to dose. All activities under the NIAID contract have been completed. In November 2010, BARDA requested that we submit a full proposal for late-stage development of Anthrivig, including all development activities through license. We submitted our proposal in January 2011 and BARDA has since indicated that it is evaluating its funding priorities. We are currently evaluating our future development efforts for this product candidate.

§ Thravixa™ (Fully Human Anthrax Monoclonal Antibody). We are developing Thravixa, a human monoclonal antibody therapeutic product candidate as an intravenous treatment for patients who present with symptoms of inhalational anthrax disease. Thravixa's development has been funded in part by BARDA and NIAID to support

efficacy testing in non-clinical studies, the establishment of a current good manufacturing practices, or cGMP, manufacturing process and initial clinical evaluation. In August 2010, we commenced a randomized, double-blind, placebo-controlled, dose escalation Phase I clinical trial involving 50 healthy volunteers, designed to evaluate the safety and pharmacokinetics of Thravixa. Dosing was completed in the first quarter of 2011 and subject follow-up was completed in the second quarter of 2011. We are currently preparing the final clinical study report. We are currently evaluating our future development efforts for this product candidate.

Tuberculosis

Disease overview. Tuberculosis, or TB, is an infection caused by Mycobacterium tuberculosis, which manifests primarily as an illness of the respiratory system and is spread by coughing, sneezing and associated respiratory actions. According to the World Health Organization, or WHO, TB is the world's second leading cause of death from infectious disease in adults, after HIV/AIDS.

Prevalence, market opportunity and current treatment. According to the WHO, approximately one third of the world's population is currently infected with tuberculosis. One of ten people infected will develop the active form of the disease during their lifetime. A majority of TB cases occur in individuals between the ages of 25 to 54 years. Between 1.2 million and 1.5 million people die annually worldwide with between 8.5 and 9 million new cases developing each year. The economic impact of TB in high-disease burden countries is significant. Bacille Calmette Guerin, or BCG, introduced in 1921, is currently the only available vaccine against tuberculosis. BCG is administered to infants throughout the developing world and in certain countries in the developed world. However, BCG provides only variable protection against tuberculosis and is not sufficiently effective in adults. According to a 2006 BioVentures for Global Health Report, the global tuberculosis vaccine market is expected to equal approximately $800 million annually by 2021.

Standard TB treatment involves a six to nine month treatment regimen with a combination of three or four antibiotic agents. These drugs are reasonably effective but poorly tolerated. Low patient compliance has contributed to the emergence of multi-drug resistant TB strains, or MDR-TB, and extensively-drug resistant strains, or XDR-TB. MDR-TB does not respond to the standard treatment using first-line drugs, such as isoniazid and rifampicin. Treatment of MDR-TB can last up to two years with drugs that produce more side effects and are more expensive than first-line drugs. According to the WHO, each year up to an estimated 290,000 new MDR-TB cases occur, with an annual prevalence of 650,000 MDR-TB cases and an estimated 150,000 deaths recorded worldwide as a result of MDR-TB infections. XDR-TB is caused by bacteria resistant to most of the effective drugs used to treat TB, including, for example, isoniazid, rifampicin, fluoroquinolone, and any of the second-line anti-TB injectable drugs, such as amikacin, kanamycin or capreomycin. As a result, XDR-TB is extremely difficult to treat. There are an estimated 25,000 new XDR-TB cases annually worldwide. By March 2010, XDR-TB cases had been confirmed in more than 58 countries and in all regions of the world. XDR-TB cases resistant to all commonly used TB drugs have been confirmed in India, Italy and Iran. The mortality rates associated with these strains can approach 100%. The emergence of MDR-TB and XDR-TB strains of Mycobacterium tuberculosis complicates treating the infection, indicating that a vaccine may be the most appropriate countermeasure for controlling TB.

Tuberculosis vaccine. Our tuberculosis vaccine product candidate, designated as MVA85A, uses the attenuated, or weakened, MVA virus, as a vaccine platform. MVA is an attenuated strain of vaccinia virus, the small pox vaccine, which does not replicate in mammalian cells. MVA is used as a vector, or carrier, to present antigen 85A to the immune system. Antigen 85A is a major antigen from Mycobacterium tuberculosis, which forms part of the antigen 85 complex. Antigen 85A is highly conserved among all mycobacterial species and is present in all strains of BCG, suggesting that antigen 85A should elicit a strong immune response in individuals vaccinated with BCG.

The clinical development of MVA85A is focused on the production of an effective TB vaccine for use in infants, adolescents, and HIV-infected adults and is intended to boost the immunity induced by a previous BCG vaccination. We in-license the commercial rights to our tuberculosis vaccine from the Oxford-Emergent Tuberculosis

Consortium, or OETC.

To date, a total of fifteen Phase I and four Phase II clinical trials of MVA85A have been completed or are ongoing in the United Kingdom, South Africa, Senegal and Gambia. A total of 297 healthy adults, 12 adolescents, 24 children and 251 infants have been immunized in the completed trials and 68 adults (including subjects with TB and/or HIV) and 1,399 infants have been immunized in the ongoing studies. The trials have evaluated and are evaluating the safety and immunogenicity of various intradermal doses of MVA85A, first in healthy adults, both BCG-vaccinated and BCG-naive, and then also in special populations such as infants, adolescents and TB/HIV-infected adults. The key findings from these clinical trials to date are that the MVA85A vaccine is well tolerated, with no significant safety concerns, and previous vaccination with BCG does not affect the safety profile. Additionally, MVA85A is effective at increasing cellular immune responses to antigen 85A in individuals previously vaccinated with BCG.

A Phase IIb trial in infants commenced in South Africa in the first half of 2009. This trial is a double-blind, randomized placebo-controlled single site study to evaluate MVA85A for safety, immunogenicity and prevention of TB disease in BCG-vaccinated, HIV-negative infants. The primary endpoint is safety with secondary endpoints of efficacy and immunogenicity. This trial has enrolled 2,797 infants and is expected to report preliminary data in 2012.

A Phase IIb trial in HIV-infected adults commenced in the second half of 2011. This trial is a double-blind, randomized placebo controlled study to evaluate MVA85A for safety, immunogenicity and prevention of TB disease in 1,400 HIV positive adults with no evidence of active TB disease for prevention of TB disease. The primary endpoint is prevention of TB disease. The trial is being conducted in Senegal and South Africa and enrollment is underway.

Autoimmune and Inflammatory Disorders

Rheumatoid Arthritis

Disease overview. RA is an autoimmune disease characterized by inflammation of the joint lining, called the synovium. In RA, a person’s immune system attacks the synovium, resulting in the thickening of the normally thin membrane and degradation of the cartilage and bone at the joint. Though the primary symptoms of RA are pain, stiffness and swelling of joints, additional symptoms may include fatigue, weakness, muscle pain, and lumps of tissue under the skin. Tissue damage from the inflammation ultimately results in deformity and disability.

Prevalence, market opportunity and current treatment. According to a 2012 DecisionResources report, by 2020 RA is estimated to effect approximately 5.6 million people in the United States, Japan and the five major European markets. The same report estimated that sales in these seven major markets surpassed $10 billion in 2010 and will equal approximately $13 billion in 2020. Notwithstanding the administration of currently available treatments, approximately two-thirds of the RA patient population experiences pain, stiffness and fatigue on a daily basis. As a result, we believe that there is a large unmet medical need in the RA patient population for an effective drug therapy.

Initially, a patient presenting symptoms of RA is typically prescribed non-steroidal anti-inflammatory drugs, or NSAIDS. As the disease progresses, the RA patient may be prescribed a regimen of disease modifying anti-rheumatic drugs, or DMARDS, an anti-tumor necrosis factor, or anti-TNF, or other biologics. Most biologics currently on the market for RA attempt to block the activity of immune system cytokines, which are chemical messengers thought to be associated with the autoimmune reactions, joint inflammation and bone damage characteristic of RA. Biologics are typically administered to patients with moderate to severe RA who need therapy in addition to NSAIDS or DMARDS. There are a variety of biological agents approved for treatment of RA. These therapeutics are directed against a number of different targets. Anti-TNF biologics include Remicade® (Infliximab Injection), Enbrel® (Etanercept Injection), Humira® (Adalimumab) and Cimzia® (Certolizumab Pegol). Other biologics target IL-1, such as Kineret® (Anakinra), co-receptors on T-cells, such as, Orencia® (Abatacept), IL-6 such as Actemra® (Tocilizumab) and CD20, such as Rituxan® (Rituximab Injection).

SBI-087 for RA. SBI-087 is a humanized, CD20-directed SMIP product candidate for the treatment of RA and SLE. Preclinical trials conducted by Pfizer, our partner in the development of SBI-087, evaluated the pharmacokinetics and pharmacodynamics of SBI-087 following a single intravenous dose. Administration of SBI-087 in preclinical trials resulted in dose-dependent B-lymphocyte depletion in peripheral blood and lymphoid tissues that was greater and longer in duration in SBI-087-treated groups compared with Rituximab.

Under the terms of our agreement with Pfizer, Pfizer has commenced two clinical trials of SBI-087 for the treatment of RA. The first is a Phase II randomized, placebo-controlled, double-blind, parallel-group, 200 subject outpatient dose regimen-finding trial in which patient dosing commenced in December 2009, with final data anticipated in 2012. The second is an escalating, single dose Phase I trial of SBI-087 for RA to assess the pharmacokinetic and pharmacodynamic attributes of SBI-087 in the Japanese population. This trial is being conducted in preparation for potentially seeking regulatory approval of SBI-087 in Japan.

Systemic Lupus Erythematosus

Disease overview. SLE is a debilitating, chronic, inflammatory autoimmune disease characterized by the presence of auto-reactive antibodies. It can cause disease in the skin, internal organs and nervous system. Some of the most common symptoms include extreme fatigue, painful or swollen joints, fever, skin rashes, and kidney problems. SLE is a chronic condition with episodic periods of disease activity, known as flares, and periods of remission. Currently, there is no cure for SLE, and symptomatic treatment is used in an effort to prevent flares or treat them when they occur.

Prevalence, market opportunity and current treatment. According to a 2012 Decision Resources Report, drug sales for the treatment of SLE totaled approximately $300 million in 2010 across the United States, Japan and the five major European markets and are expected to exceed $2 billion across these seven major markets by 2020. The first new protein therapeutic drug to treat SLE in over 40 years was approved in 2011. We believe that there is a significant unmet medical need in the SLE patient population as SLE patients have a death rate three times higher than that of the general population despite the fact that most patients are young and middle-aged individuals. Current drug therapies are predominantly palliative in nature and are targeted to the patient’s specific symptoms. Different medications are used to treat specific manifestations of SLE. Treatments include acetaminophen and/or NSAIDs, immunosuppressants such as methotrexate and cylcophosphamide, corticosteroids such as methylprednisolone, and antimalarials such as hydroxychloroquine.

SBI-087 for SLE. Under the terms of our agreement with Pfizer, Pfizer is conducting a 30 subject Phase I clinical trial of SBI-087 for SLE. This trial is an escalating, single dose pharmacokinetics study and pharmacodynamics trial evaluating intravenous and subcutaneous dosing of SBI-087. Patient dosing is completed and follow-up is ongoing.

Oncology

B-cell Malignancies: Chronic Lymphocytic Leukemia and Non-Hodgkin’s Lymphoma

Disease overview. B cells and T cells are the two major types of lymphocytes responsible for defending the body against infection. Lymphocytic malignancies arise when these cells multiply uncontrollably. CLL is a type of cancer affecting the blood and bone marrow. It is a slowly progressing disease and in most patients the abnormal proliferating lymphocytes are clonal B cells arrested in the differentiation pathway between pre B cells and mature B cells. NHL is a diverse group of lymphocytic malignancies, approximately 85% of which are B-cell malignancies.

Prevalence, market opportunity and current treatment. According to a 2011 Decision Resources report, CLL is estimated to afflict approximately 101,000 people in the United States. Approximately 19,000 new cases of CLL are diagnosed each year in the United States according to Decision Resources. About 59,000 people in the United States

are expected to be newly diagnosed with NHL in 2012 according to the Decision Resources. Total reported worldwide sales of Rituxan®, one of the most commonly used biologics in the treatment of CLL and NHL, surpassed $967 million for CLL and $4.1 billion for NHL in 2010.

While available CLL and NHL therapies include chemotherapy, radiation therapy, surgery and bone and stem cell transplantation, biologics have become the standard of care to treat these cancers. For the treatment of CLL, there are a number of chemotherapeutics and monoclonal antibodies. Campath® is a CD52-targeted antibody indicated for CLL. Treanda®, a cytotoxic, is also indicated for CLL. Depending upon the nature of the patient's tumor, the chemotherapeutic agent fludarabine in combination with Rituxan®, or the combination of fludarabine, the chemotherapeutic agent cyclophosphamide and Rituxan® are currently the most effective combinations for the treatment of CLL. Biologic therapies for NHL include antibodies such as Rituxan®/Mabthera, Bexxar®, Zevalin® and Arzerra®. These therapies all target CD20 on B-cells.

TRU-016 for treatment of B-cell malignancies. Our TRU-016 program is focused on the development of a novel therapy for B-cell malignancies such as CLL and NHL. Specifically, TRU-016 is a SMIP directed at the CD37 antigen on the surface of both normal and malignant B-cells. CD37 is found at high levels on B-cells and at lower levels on a subpopulation of T-cells and myeloid cells, which could potentially avoid off-target toxicity. Experiments suggest that CD37 plays an important role in B-cell regulation. TRU-016 uses a different mechanism of action than CD20-directed therapies and targets a different cell surface receptor. As a result, we believe its novel design may provide patients with improved therapeutic options and enhanced efficacy when used alone or in combination with chemotherapy or other CD20-directed therapeutics. Preclinical data have demonstrated that TRU-016 induced potent ADCC, a form of cell death mediated by antibodies, and potent apoptosis, or direct programmed cell death, in in vitro studies with primary CLL cells. In addition, combination therapy with a CD37-directed SMIP, a close analogue of TRU-016, and Rituxan® has shown greater preclinical efficacy in decreasing tumor size and prolonging survival than either therapy alone. In August 2009, Trubion Pharmaceuticals, Inc., or Trubion, predecessor to Emergent, and Facet Biotech Corp., predecessor to Abbott Biotherapeutics Corp., an affiliate of Abbott Laboratories, or Abbott, entered into a collaboration agreement for the joint development and commercialization of TRU-016 and other protein therapeutics that bind to the CD37 antigen. In December 2011, Abbott notified us of its decision to terminate the collaboration agreement as a result of Abbott's portfolio prioritization process. Upon the termination of the collaboration agreement, effective March 20, 2012, we will retain worldwide rights for the development and commercialization of TRU-016.

A TRU-016 Phase I clinical trial for patients with CLL is nearing completion with approximately 90 patients enrolled. The open label clinical trial is composed of two parts: a dose escalation study designed to evaluate the safety, tolerability and pharmacokinetics of TRU-016 (Phase 1) and an expansion cohort designed to further evaluate safety and to estimate clinical activity of TRU-016 in patients with previously treated CLL or small lymphocytic leukemia (Phase Ib). We have amended our study protocol to include treatment of patients with treatment naïve NHL and relapsed/refractory NHL, and patient dosing has been completed.

In December 2010, we announced positive data following preliminary analysis from our Phase I trial of TRU-016 in patients with relapsed and refractory CLL. Evidence of TRU-016 biological activity in reducing malignant lymphocytes was seen beginning with patients dosed at the 0.3 mg/kg dose level, including in high-risk patients. Partial response of greater than or equal to 50% reduction in tumor burden was observed. The maximum tolerated dose was not reached.

In December 2011, we announced positive data following preliminary analysis from our Phase 1b trial of TRU-016 in patients with treatment naïve CLL and relapsed/refractory NHL. Evidence of biological activity was observed and a maximum tolerated dose was not reached.

In January 2011, we initiated a Phase Ib/II clinical trial of TRU-016 for CLL. The open-label, multi-center, active-controlled trial is expected to enroll up to 114 bendamustine naïve patients with a confirmed diagnosis of

relapsed CLL and who have failed up to three previous treatments. The Phase Ib portion of the trial is designed to determine a safe and tolerable dose of TRU-016 in combination with bendamustine in up to 14 patients with relapsed CLL. The primary endpoint for the Phase Ib portion is the incidence of dose-limiting toxicities. The Phase II portion of the trial will evaluate the safety and efficacy of TRU-016 in combination with bendamustine compared with bendamustine alone in a total of 60-100 randomized patients. The primary endpoint for the Phase II portion of the trial is an overall response rate as defined by 2008 International Workshop on Chronic Lymphocytic Leukemia, or IWCLL, criteria. Secondary endpoints include complete and partial response rates as defined by the 2008 IWCLL and the 1996 National Cancer Institute criteria, progression-free survival, duration of response, and improvement in quality of life and disease symptoms. The pharmacokinetics and pharmacodynamics of TRU-016 will be studied in both phases of the study. Enrollment in the Phase Ib portion of the study has been completed and enrollment in the Phase II portion of the study is ongoing.

A Phase Ib/II study of TRU-016 combined with rituximab and bendamustine in patients with relapsed indolent NHL was initiated in May 2011. This open-label, multi-center, active controlled trial is expected to enroll up to 88 patients with a confirmed diagnosis of indolent NHL who have relapsed after at least one prior treatment. The Phase Ib portion of the trial is designed to determine a safe and tolerable dose of TRU-016 in combination with rituximab and bendamustine in up to 12 patients with indolent NHL. The primary endpoint for the Phase Ib portion of the trial is the incidence of dose-limiting toxicities. The Phase II portion of the trial will evaluate the safety and efficacy of TRU-016 in combination with rituximab and bendamustine compared with rituximab and bendamustine alone in up to 76 patients with indolent NHL. The primary endpoint for the Phase II portion of the trial is complete response rate as defined by the disappearance of all evidence of disease. Secondary endpoints include overall response rate, progression-free survival, overall survival, and duration of response. The pharmacokinetics and pharmacodynamics of TRU-016 will be studied in both phases of the study. Enrollment in the Phase Ib portion of the study has been completed.

T-cell Malignancies: Cutaneous T-cell Lymphoma and Peripheral T-cell Lymphoma

Disease overview. B cells and T cells are the two major types of lymphocytes responsible for defending the body against infection. Lymphocytic malignancies arise when these cells multiply uncontrollably. Both CTCL and PTCL are sub-types of non-Hodgkin's lymphoma. CTCL is a type of cancer that affects T-cells and results in leukemic cell infiltration of the skin. The disease is initially indolent and can be treated with topical agents. Later it can become more aggressive and require systemic therapy. PTCL is an aggressive sub-type of non-Hodgkin's lymphoma and grows uncontrollably in the lymph nodes, requiring systemic therapy.

Prevalence, market opportunity and current treatment. According to the Lymphoma Research Foundation, CTCL is one of the most common T-cell lymphomas, estimated to occur in approximately 16,000 to 20,000 people in the U.S. and PTCL comprises a group of rare and usually aggressive lymphomas that are diagnosed in approximately 5,000 patients in the U.S. per year. Worldwide sales of drugs currently sold to treat CTCL and PTCL are approximately $175 million. Therapeutics currently marketed for the treatment of CTCL or PTCL include Ontak® and Targretin® (Eisai), Istodax® (Celgene), Zolinza® (Merck), Folotyn® (Allos Therapeutics), and Campath® (Bayer Schering AG).

Zanolimumab for treatment of T-cell malignancies. Zanolimumab is a fully human monoclonal antibody against CD4. CD4 is a cell surface protein strongly expressed on a subset of T-cells and weakly expressed on monocytes. The function of CD4 is to enhance T-cell activation by stabilizing the adhesion between antigen presenting cells and the T-cell, and by enhancing signal transduction. Zanolimumab has demonstrated efficient depletion of CD4+ T-cells in preclinical and clinical studies. The depletion was time and dose dependent and CD4+ T-cells recovered slowly after therapy. The potential mechanisms of action include antibody dependent cytotoxicity and inhibition of T-cell activation by interfering with the interaction between MHC class II and the CD4 molecule. In in vitro studies, zanolimumab did not cause significant complement dependent cytotoxicity or apoptosis.

In Phase I trials of zanolimumab in CTCL published in 2007, the overall response rate was 32% (15/47) and 56% (10/18) at the two highest doses of 560 mg and 980 mg. Efficacy was observed in a dose dependent fashion. Adverse events reported most frequently included low-grade infections and eczematous dermatitis. In a Phase I trial in PTCL published in 2010, the overall response rate was 24% (5/21) with two of the patients having a complete response. The most frequently reported adverse events were rash and pyrexia. A Phase II/III trial was initiated in 2005 after a special protocol assessment by the FDA in CTCL. The trial was placed on hold in 2010 by TenX BioPharma, Inc., the entity then developing zanolimumab, due to funding difficulties. We have evaluated the preliminary results of this trial, concluded that the trial would not be sufficient to support a BLA and have closed the study. We are currently evaluating potential future studies relating to this product candidate.

Manufacturing

We manufacture BioThrax at our facilities in Lansing, Michigan using well-established vaccine manufacturing procedures. In 2009, we completed construction of Building 55, our 50,000 square foot vaccine manufacturing facility at our Lansing campus, and in July 2010 we entered into a contract with BARDA valued at up to approximately $107 million to develop and obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55. The contract award was based on a technical proposal provided to BARDA that projects an annual large-scale manufacturing capacity of approximately 25 million doses of BioThrax in Building 55 and provides funding for activities related to process validation, assay validation, fill/finish, non-clinical studies and, if required, clinical studies as well as regulatory activities in support of the submission to the FDA of a sBLA for BioThrax at the expanded scale.

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

We currently rely on contract manufacturers and other third parties to manufacture some of the supplies we require for preclinical studies and clinical trials and for supplies and raw materials used for the production of BioThrax and our product candidates. We typically acquire these supplies and raw materials on a purchase order basis in quantities adequate to meet our needs. We obtain Alhydrogel, the adjuvant used in the manufacture of BioThrax, from a single-source supplier for which we have no alternative source of supply. However, we maintain stored supplies of this adjuvant sufficient to meet our expected manufacturing needs for BioThrax for approximately one year. We believe that there are adequate alternative sources of supply available for most of our raw materials if any of our current suppliers were unable to meet our needs. We anticipate that we may use our existing facilities to support continued process development and manufacture of clinical supplies of some of our product candidates. However, we also expect that we will continue to use third parties for production of preclinical and clinical supplies including the manufacture of bulk drug substance to support some of our product candidates, and for all filling services we require.

Hollister-Stier Laboratories LLC, or Hollister-Stier, performs contract filling for BioThrax at its FDA-licensed 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 and to accommodate fill requests in excess of our annual estimate, subject to its available production capacity. Under the agreement we executed with Hollister-Stier in December 2010, Hollister-Stier will provide filling services for BioThrax during an initial five-year period that commenced January 1, 2011, which we may extend in our discretion for two additional two-year renewal periods. Additionally, we are obligated to utilize Hollister-Stier for 75% of our BioThrax filling requirements during the term of the agreement, subject to certain exceptions. We have also entered into an agreement for contract filling operations with a second vendor, JHP Pharmaceuticals, LLC, which was licensed by the FDA in November 2011 for the filling of BioThrax.

We are a party to an agreement with Talecris Biotherapeutics, Inc. that provides for plasma fractionation and purification and contract filling of Anthrivig at Talecris' FDA-licensed facilities located in Melville, New York and Clayton, North Carolina. Talecris was acquired by Grifols, S.A. in June 2011 and now operates under the name Grifols Therapeutics Inc., or Grifols. Under our agreement with Grifols, in the event that we request Grifols to produce any quantities of Anthrivig, we and Grifols would be required to negotiate in good faith as to the timing, price, quantity and support, among other terms, of such production, subject to Grifols' right to delay or refuse such request. Subject to limited exceptions, the agreement also provides for us to obtain all manufacturing requirements for Anthrivig exclusively at Grifols. While our agreement with Grifols remains in effect, Grifols has agreed not to market, sell or acquire any competing product that contains anthrax immune globulin as an active ingredient. We have agreed to pay Grifols mid-single digit royalties on net sales on a country-by-country basis for commercial product manufactured by Grifols. Our contract with Grifols expires July 31, 2016, and we have the option to extend the term for an additional five-year period upon notice to Grifols at least 12 months prior to the expiration of the initial term. In the event we are not able to reach an agreement with Grifols on satisfactory product supply terms, we would be required to explore other options for our anthrax immune globulin program, which would result in significant costs and project delay and the need for additional clinical trials. Under the existing agreement, after three years following initiation of commercial manufacturing, either party may terminate the contract upon two years' advance notice. We have the right to terminate the contract, under specified circumstances, including if we discontinue our production of anthrax immune globulin source plasma or the development of Anthrivig.

We also expect that we will rely on third parties for some or all of the manufacturing process for commercial supplies of other product candidates that we successfully develop, including but not limited to fermentation for some of our vaccine product candidates and contract fill and finish operations.

Marketing and Sales

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

We have established marketing and sales capability targeting 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, Europe and several countries in Southeast Asia, and anticipate engaging additional representatives as interest in biopreparedness grows.

We also expect to increase our sales and marketing resources to market and sell commercial products for which we retain commercialization rights. As we develop our internal sales and marketing capabilities we may expand our role with respect to certain products or product candidates. We anticipate that our internal marketing and sales organization will be complemented by selective co-promotion and other partnering arrangements with pharmaceutical and biotechnology companies and distributors, especially in situations in which a collaborator has particular expertise or resources for the commercialization of our products or product candidates or access to particular markets.

Competition

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

industry is concentrated with Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Novartis and Pfizer, generating over 86% of the total worldwide vaccine revenues in 2011. Smaller or more narrowly focused organizations 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.

Biodefense

Product candidates in our Biodefense Division face significant competition for U.S. government funding for both development and procurement of medical countermeasures for biological, chemical and nuclear threats, diagnostic testing systems and other emergency preparedness countermeasures. In addition, our products and product candidates must satisfy government procurement requirements for biodefense products.

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

§ BioThrax. Although BioThrax is the only product approved by the FDA for human use for the prevention of anthrax infection, we face potential future competition for the supply of anthrax vaccines to the U.S. government. Various agencies of the U.S. government are providing funding to our competitors for development of anthrax vaccines. In addition, the United Kingdom Health Protection Agency, or HPA, manufactures an anthrax vaccine for use by the government of the United Kingdom. Other countries may also have anthrax vaccines for use by or in development for their own internal purposes.
§ PreviThrax and NuThrax. PharmAthene, Vaxin and Pfenex are currently developing rPA based anthrax vaccines funded by BARDA.
§ Anthrivig and Thravixa. Cangene is currently developing an anthrax immune globulin therapeutic based on plasma collected from military personnel who have been vaccinated with BioThrax. In addition, three companies, Human Genome Sciences, Elusys Therapeutics and PharmAthene, are developing monoclonal antibodies to B. anthracis protective antigen. Human Genome Sciences is developing ABthrax™ as a therapeutic for anthrax. Elusys is developing Anthim™, for pre-exposure and PEP and as a therapeutic against anthrax. PharmAthene is developing Valortim™ as a PEP and as a therapeutic against anthrax. The FDA has granted Fast Track designation and orphan drug status for ABthrax and Valortim. HHS awarded development and procurement contracts to Human Genome Sciences and development contracts to Elusys and PharmAthene.

Biosciences

Vaccine product candidates in our Biosciences Division will face significant competition from companies that are developing competitive products for the same targeted markets or that treat the same indications. Our AIID and oncology therapeutic product candidates will also be subject to significant competition from companies utilizing alternative technologies. In addition, as the principles of our SMIP™ product candidates become more widely known and appreciated based on patent and scientific publications and regulatory filings, we expect the field to become even more highly competitive.

Infectious Diseases

The competition for our commercial vaccine product candidate includes the following:

§ Tuberculosis vaccine. The Aeras Global Tuberculosis Vaccine Foundation is developing or supporting the development of five tuberculosis vaccine product candidates, two of which are in a Phase II clinical trial, and the rest of which are either in Phase I clinical trials or close to commencing Phase I clinical trials. The Aeras Global Tuberculosis Vaccine Foundation is also the sponsor of the Phase IIb clinical trial of our tuberculosis vaccine

product candidate.

AIID and Oncology Therapeutics

The competition for our AIID and oncology product candidates includes the following:

- § SBI-087. If approved for the treatment of RA, we anticipate that SBI-087 would compete with other marketed protein therapeutics for the treatment of RA including: Rituxan® (Genentech, Roche and Biogen Idec), Enbrel® (Amgen and Pfizer), Remicade® (Johnson & Johnson and Schering-Plough), Humira® (Abbott), Orencia® (Bristol-Myers Squibb), Cimzia® (Union Chimique Belge), Simponi® (Johnson & Johnson and Schering-Plough) and Actemra® (Roche and Chugai). In addition, Pfizer is currently developing a small molecule Janus kinase inhibitor for the treatment of RA. If approved for the treatment of SLE, we anticipate that SBI-087 would compete with Benlysta® (Human Genome Sciences and GlaxoSmithKline) and other B-cell depleting therapies, including CD20-directed therapeutics.
- § TRU-016. If approved for the treatment of CLL, NHL, or other B-cell malignancies, we anticipate that TRU-016 would compete with other B-cell depleting therapies. Non-CD37-directed therapeutics marketed for the treatment of NHL or CLL or both include Rituxan® (Genentech), Zevalin® (Spectrum Pharmaceuticals, Inc. and Bayer Schering AG), Bexxar® (GlaxoSmithKline), Campath® (Genzyme and Bayer Schering AG), Treanda® (Cephalon Oncology) and Arzerra® (GlaxoSmithKline and Genmab). In addition, Boehringer Ingelheim and Immunogen recently announced their development of monoclonal antibodies directed to CD37 and Abbott is developing ABT-263, a Bcl-2 inhibitor, for treatment of CLL in collaboration with Genentech.
- § Zanolimumab. If approved for the treatment of CTCL and PTCL, we anticipate that zanolimumab would compete with other T-cell therapies and related therapeutics. Therapeutics marketed for the treatment of CTCL or PTCL include Ontak and Targretin (Eisai), Istodax ® (Celgene), Zolinza ® (Merck), Folotyn ® (Allos Therapeutics) and Campath ® (Bayer Schering AG). In addition, GlaxoSmithKline, Roche, Bristol-Myers Squibb, AstraZeneca and Spectrum Pharmaceuticals are developing therapies directed to CTCL or PTCL.

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. This term can sometimes be extended via patent term adjustments to make up for the time lost due to delay at the United States Patent and Trademark Office, and via patent term extensions to make up for time lost by biologics in the regulatory approval process. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. Our patent portfolio includes patents and patent applications with claims directed to compositions of matter, pharmaceutical formulations and methods of use.

We have applied, and are applying for, patents directed to our SMIP therapeutic product candidates including TRU-016, and SBI-087, SCORPION therapeutic product candidates and TRU-ADhanCe technology. Our SMIP patent portfolio includes three U.S. patents that will expire between 2023 and 2025 and 13 U.S. patent applications from which any patents, if granted, are expected to expire between 2022 and 2029, as well as 60 foreign patents that will expire between 2022 and 2029 and 118 foreign patent applications from which any patents, if granted, are expected to expire between 2022 and 2029. Our SCORPION patent portfolio includes four U.S. patent applications from which any patents, if granted, are expected to expire in 2027, as well as 31 foreign patent applications from which any patents, if granted, are expected to expire in 2027. Our TRU-ADhanCe patent portfolio includes one U.S. patent that will expire in 2027 and two U.S. patent applications from which any patents, if granted, are expected to expire in 2027, as well as 12 foreign patent applications from which any patents, if granted, are expected to expire in

2027. With respect to patent applications that are pending, we cannot predict the availability or length of any patent term adjustment by the U.S. Patent and Trademark Office, which could extend the term of any patent that is ultimately approved as a result of a pending application. Patent applications and any resulting patents with claims to TRU-016 and SBI-087 are out-licensed to Abbott and Pfizer under the terms of our agreements with them. Our out-license to Abbott will terminate when our collaboration with Abbott terminates on March 20, 2012.

We own two U.S. patents and three corresponding foreign applications that contain claims supporting Thravixa. Absent any patent term extension, these patents will expire in 2024.

We have exclusive licenses to patents and, in some instances, know-how, that we consider important for our vaccine and therapeutic product candidates in clinical development. We consider our exclusive license from USAMRIID to two U.S. patents relating to PreviThrax to be important. We also consider the patent rights that we have exclusively licensed from the University of Oxford relating to our tuberculosis vaccine product candidate through our stake in OETC to be important.

We also rely on trade secrets relating to manufacturing processes and product development to protect our business. Because we do not have patent protection for BioThrax or for the label expansions and improvements that we are pursuing for BioThrax, our only intellectual property protection for BioThrax, aside from the BioThrax trademark, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and biological starting materials. However, these types of trade secrets can be difficult to protect. We seek to protect this confidential information, in part, with agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

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

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

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

licensed product in that country and the expiration of the last-to-expire licensed patent in that country. In addition, we are required to pay USAMRIID a specified fee per dose for any sales by us to a U.S. government agency.

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

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

OETC agreement. In July 2008, we entered into a technology license agreement with OETC pursuant to which we obtained rights to develop, manufacture and commercialize product candidates containing MVA85A for the prevention or treatment of Mycobacterium tuberculosis in humans. Generally, our rights to manufacture the licensed product and to commercialize it in developed countries are exclusive. The licensed patent portfolio includes one issued U.S. patent that will expire in 2027, as well as 72 granted foreign patents and 14 pending foreign patent applications, which, if issued as patents, would expire in 2026.

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

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

The term of the license agreement lasts until the later of 20 years from the grant of the first marketing approval for a licensed product and the expiration of the last-to-expire valid claim of the licensed patent application. We may terminate the license agreement upon 30 days advance written notice; provided such notice is given within six months, following receipt of the final report from the Phase IIb clinical trial of the licensed product in infants, a bridging study and an age de-escalation study, whichever is later; or upon at least 30 days advance written notice if OETC terminates its underlying license agreement with Isis Innovation Limited for a material breach of that agreement. We may terminate the license agreement upon 60 days advance written notice if any clinical trial of the licensed product is suspended or terminated for safety reasons or upon 90 days advance written notice if a clinical trial for an infant indication within the development plan agreed upon by the parties does not meet predetermined criteria for success. We may terminate the license agreement upon 12 months advance written notice at any time after we receive the final results in writing from the Phase IIb clinical trial of the licensed product in infants, provided, that, unless otherwise agreed with OETC, we complete any ongoing, Emergent-sponsored clinical trial that is part of the development plan. We and OETC each have the right to terminate the license agreement following the occurrence of a

material uncured breach by the other party.

Pfizer license. We are a party to an exclusive out-licensing agreement with Pfizer that grants Pfizer an exclusive license to develop and commercialize SMIP therapeutics that bind to CD20, such as SBI-087. The agreement includes an option for us to co-promote with Pfizer, on customary terms to be agreed, CD20-directed therapies in the United States for niche indications. The agreement contains a non-compete clause which generally precludes both parties from developing human therapeutics against any CD20 until there has been a first commercial sale of a licensed product, but in May 2011, we entered into an amendment to the agreement which released certain restrictions on Pfizer related to the development and commercialization of biosimilar CD20 antibodies. Pfizer's financial obligations under the agreement include reimbursement of certain agreed-upon external research and development costs and patent costs. In addition, Pfizer is obligated to make payments to us of up to $250 million based on the achievement of specified regulatory and sales milestones for CD20-directed therapies. The agreement also provides for us to receive royalty payments in the event of future licensed product sales. Unless it is terminated earlier, our agreement with Pfizer will remain in effect on a product-by-product basis and on a country-by-country basis until the later of the date that any such product shall no longer be covered by a valid claim of a United States or foreign patent or application and, generally, ten years after the first commercial sale of any product licensed under the agreement. Pfizer may terminate the agreement without cause at any time upon 90 days' prior written notice.

Abbott collaboration. On August 27, 2009, Trubion and Facet Biotech Corporation, predecessor in interest to Abbott, entered into a collaboration and license agreement for the joint worldwide development and commercialization of TRU-016. Under the collaboration agreement, Abbott was granted an exclusive worldwide license under our patent rights and know-how relating to TRU-016 and any other CD37 directed molecules to research, develop and commercialize such collaboration products. Trubion received a non-refundable up-front payment of $20 million in 2009, and Emergent, as successor in interest to Trubion, was eligible to receive additional contingent payments upon the achievement of specified development, regulatory and sales milestone events. In addition, Emergent and Abbott were obligated to share equally the costs of all collaboration development, commercialization and promotional activities and global collaboration operating profits. As described above in the section entitled "Products – Oncology" in this Item 1, our collaboration agreement with Abbott will terminate on March 20, 2012.

Government Regulation

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

U.S. Government Regulation

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

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

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

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

Preclinical Studies and the IND

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

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

Clinical Trials

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

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

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

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

Marketing Approval

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

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

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

In addition, in certain circumstances the FDA may require additional testing and surveillance programs for approved products that have been commercialized. The FDA has the power to prevent or limit further marketing or distribution of a product based on the results of these post-marketing studies or programs.

Fast Track Designation

In February 2007, the FDA granted Fast Track designation for BioThrax as PEP against anthrax infection. Additionally, in September 2010, the FDA granted Fast Track designation for Thravixa for the treatment of inhalation anthrax, and in June 2011, Fast Track designation for NuThrax as a PEP against anthrax infection. The FDA's Fast Track designation program is designed to facilitate the development and review of new drugs, including biological products that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for the conditions. Fast Track designation applies to a combination of the product and the specific indication for which it is being studied. Thus, it is the development program for a specific drug for a specific indication that receives Fast Track designation. Certain of our other drug candidates also have received Fast Track designation from the FDA, including Anthrivig for the treatment of inhalation anthrax and zanolimumab for CTCL.

The sponsor of a product designated as being in a Fast Track drug development program may engage in early communication with the FDA, including timely meetings and early feedback on clinical trials, and may submit portions of an application on a rolling basis rather than waiting to submit a complete application. Products in Fast Track drug development programs also may receive priority review or accelerated approval. Under priority review, FDA's goal for review of an application is six months after a complete NDA or BLA is accepted for filing, rather than the current ten months for standard review. Under accelerated approval, sponsors may rely on a surrogate endpoint for approval, on the condition that post-marketing clinical trials verify the anticipated clinical benefit. The FDA may notify a sponsor that its program is no longer classified as a Fast Track development program if the Fast Track designation is no longer supported by emerging data or the designated drug development program is no longer being pursued.

Post-Marketing Regulation

Any products manufactured or distributed by us pursuant to FDA licenses or approvals are subject to pervasive and continuing regulation by the FDA, including, but not limited to:

- 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;
- labeling;
- distribution of samples;
- import and export;
- reporting of adverse experiences with the product; and
- advertising and promotion restrictions.

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

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

Drug manufacturers, distributors and their subcontractors are required to register their establishments with the FDA and state agencies. The cGMP requirements for biological products in particular are extensive and compliance with them requires considerable time, resources and ongoing investment. The regulations require manufacturers to establish validated systems to ensure that products meet high standards of sterility, purity and potency. The requirements apply to all stages of the manufacturing process, including the synthesis, processing, sterilization, packaging, labeling, storage and shipment of the biological product. For all drugs and biological products, the regulations require

investigation and correction of any deviations from cGMP requirements and impose documentation requirements upon us and any third party manufacturers that we may decide to use. Manufacturing establishments are subject to periodic unannounced inspections by the FDA and state agencies for compliance with all cGMP requirements. The FDA is authorized to inspect manufacturing facilities without a warrant at reasonable times and in a reasonable manner. We or our present or future suppliers may not be able to comply with cGMP and other FDA regulatory requirements.

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

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

BioThrax Lot Release and FDA Review

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

Regulation of Immune Globulin Products

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

Legislation and Regulation Related to Bioterrorism Counteragents and Pandemic Preparedness

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

described below.

Project BioShield

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

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

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

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

SAFETY Act

The Support Anti-Terrorism by Fostering Effective Technologies Act, or SAFTEY 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 DHS 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. 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 about known dangers arising from the use of the product. Although sales of BioThrax are subject to the protections of the SAFETY Act, our product candidates may not qualify for the protections of the SAFETY Act or the government contractor defense.

Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act, or PREP Act, enacted by Congress in 2005 provides immunity to manufacturers from all claims under state or federal law for “loss” arising out of the administration or use of a “covered countermeasure.” However, injured persons may still bring a suit for “willful misconduct” against the manufacturer under some circumstances. “Covered countermeasures” include security countermeasures and “qualified pandemic or epidemic products,” including products intended to diagnose or treat pandemic or epidemic disease, such

as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or "credible risk" of a future public health emergency. In October 2008, the Secretary of HHS issued a declaration that BioThrax and Anthrivig have been included as covered countermeasures under the PREP Act. We cannot predict whether the Secretary will renew that declaration when it expires, whether Congress will fund the relevant PREP Act compensation programs, or whether the necessary prerequisites for immunity would be triggered with respect to our product or product candidates.

Changing Legal and Regulatory Landscape

Periodically legislation is introduced in the U.S. Congress that could change the statutory provisions governing the approval, manufacturing and marketing of drugs, including biological products. For example, in 2010, Congress enacted comprehensive health reform legislation that, among other things, created a licensure pathway for biological products shown to be biosimilar to or interchangeable with previously licensed biologic products and permits litigation regarding certain relevant patents between innovative product sponsors and biosimilar manufacturers prior to market entry. This legislation, known as the Biologics Price Competition and Innovation Act of 2009, or BPCIA, gives FDA broad discretion in setting the application requirements for biosimilars. At this time, FDA has not approved any biosimiliars and has issued only general draft guidelines relating to the biosimiliar approval pathway. Until FDA finalizes these guidelines and begins approving biosimilars, it is difficult to predict the impact of the BCPIA on our business.

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

Foreign Regulation

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

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

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

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

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

Orphan Drugs

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

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

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

In the European Union, a product can be designated as an orphan drug if it is intended for either (i) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made; or (ii) a serious and chronic condition in the European Union for which, without incentives, it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the

necessary investment. In either case, the applicant must also demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition. The COMP assesses the orphan status at both the time of first designation and also in parallel with the review of every marketing authorization application for an orphan medicine.

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

Anthrivig and Thravixa have been granted orphan drug status in the United States and the European Union, and our tuberculosis vaccine product candidate has been granted orphan drug status in the European Union. Additionally, TRU-016 for treatment of CLL and zanolimumab for treatment of CTCL have also been granted orphan drug status in the United States.

Reimbursement and Pricing Controls

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

In the United States, there has been an increasing focus on drug and biologic pricing in recent years. There are currently no direct government price controls over private sector purchases in the United States. However, under the Veterans Health Care Act, or VHCA, manufacturers are required to offer certain drugs at a reduced price to a number of federal agencies including the U.S. Department of Veterans Affairs, or VA, the DoD, and the U.S. Public Health Service, or PHS, as well as certain private PHS-designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Also, legislative changes purport to extend VHCA discounts to additional DoD purchases for its TRICARE program via a rebate system. The rebate system is currently subject to legal challenge, but payments of rebates on certain past purchases may be required if such challenge ultimately is unsuccessful. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as entry into government procurement contracts governed by the FAR.

Under the Medicaid program, a joint federal/state program that provides medical coverage to certain low income families and individuals, pharmaceutical manufacturers must pay prescribed rebates on specified drugs, including biological products, to enable them to be eligible for reimbursement. Vaccines are generally exempt from these rebate requirements, and vaccines for Medicaid-eligible children are primarily provided through the Vaccines for Children Program. Medicare, the federal program that provides medical coverage for the elderly and disabled, generally reimburses for physician-administered drugs, including biological products, on the basis of the product's average sales price, although the principal vaccines that are reimbursed under Part B, Influenza, Pneumococcal and Hepatitis B, are reimbursed based on average wholesale price. Outpatient drugs and other vaccines may be reimbursed under Medicare Part D, which is administered through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. The health care reform legislation enacted in 2010, known as the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, contains a number of cost-containment measures. For example, the legislation imposes an annual fee on prescription drug manufacturers, including biologics manufacturers, which will be allocated based on market share in the aggregate for certain government programs. In addition, the legislation establishes a program to phase out the coverage gap under Medicare Part D through a combination of manufacturer discounts and federal subsidies, increases the amount of Medicaid

rebates, extends Medicaid rebates to utilization by Medicaid managed care organizations, extends the scope of entities eligible for discounts under the 340B program and creates an Independent Payment Advisory Board to recommend changes in Medicare payment rates. Various states have also adopted further mechanisms that seek to control drug prices, including by disfavoring higher priced products and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place and exerts additional downward pressure on the prices of pharmaceutical products.

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

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

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

Regulations Regarding Government Contracting

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

Vaccine Injury Compensation Program

Because the cost of vaccine related litigation had reduced significantly the number of manufacturers willing to sell childhood vaccines, the U.S. Congress enacted the National Childhood Vaccine Injury Act, or Vaccine Injury Act, in 1986. The Vaccine Injury Compensation Program established under the Vaccine Injury Act is a no-fault compensation program funded by an excise tax on each dose of a covered vaccine and is designed to streamline the process of seeking compensation for those injured by childhood vaccines. The Vaccine Injury Act requires all individuals injured by certain vaccines to go through the compensation program, as administered by the U.S. Court of Federal Claims, before pursuing other remedies, and determines the circumstances under which a manufacturer of a covered vaccine may be found liable in a civil action. Nevertheless, the Vaccine Injury Act may not reduce or limit our liability arising out of product liability claims. In February 2011, the U.S. Supreme Court ruled that the compensation system implemented under Vaccine Injury Act pre-empts ordinary injury claims made against vaccine manufacturers.

Hazardous Materials and Select Agents

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

The Public Health Security and Bioterrorism Preparedness and Response Act and the Agricultural Protection Act require us to register with the CDC and APHIS 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 stringent safeguards and security measures for these select agents and toxins, including controlled access inspections and the screening of entities and personnel, and establishes a comprehensive national database of registered entities.

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

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

Other Regulations

In the United States and elsewhere, the research, manufacturing, distribution, sale and promotion of drug and biological products are subject to regulation by various federal, state and local authorities. In the United States, in addition to the FDA, such authorities include the Centers for Medicare and Medicaid Services; other divisions of HHS, such as the Office of Inspector General; the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice; and state and local governments. For example, sales, marketing, and scientific and educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act and the False Claims Act, with the privacy provisions of the Health Insurance Portability and Accountability Act of 1996 and the Health Information Technology for Economic and Clinical Health Act, and with similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992.

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

Personnel

As of December 31, 2011, we had 811 employees, including 253 employees engaged in product development, 353 employees engaged in manufacturing, 9 employees engaged in sales and marketing and 196 employees engaged in general and administrative activities. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees are represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

Available Information

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

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

ITEM 1A. RISK FACTORS

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

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

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales to the U.S. government, of BioThrax, our FDA-approved anthrax vaccine and only marketed product. We are currently party to a contract with the Centers for Disease Control and Prevention, or CDC, a U.S. federal agency under the U.S. Department of Health and Human Services, or HHS, to supply doses of BioThrax for placement into the Strategic National Stockpile, or SNS. If the SNS priorities change, our revenues could be substantially reduced.

Our contract with the CDC is for the supply of 44.75 million doses of BioThrax for placement into the SNS over a five-year period. The procurement of doses of BioThrax by the CDC is subject to availability of funding. Our existing and prior contracts with HHS and the DoD do not necessarily increase the likelihood that funding for the

procurement of doses will be available. If funding to procure doses of BioThrax is not available, our business, financial condition and operating results could be materially harmed. The success of our business and our operating results for the foreseeable future are substantially dependent on the terms of our BioThrax sales to the U.S. government, including price per dose, the number of doses and the timing of deliveries.

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

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

- § the commitment of 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;
- § the possibility that we may be ineligible to respond to a request for proposal issued by the government;
- § the submission by third parties of protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- § if our competitors protest or challenge contract awards made to us pursuant to competitive bidding, the potential that we may incur expenses or delays, and that any such protest or challenge would result in the resubmission of bids based on modified specifications, or in termination, reduction or modification of the awarded contract.

The U.S. government may choose not to award us future contracts for the development and supply of anthrax vaccines and other biodefense product candidates that we are developing, and may instead award such contracts to our competitors. 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. Additionally, if we are unable to consistently win new contract awards over an extended period, or if we fail to anticipate all of the costs and resources that will be required to secure and, if applicable, perform such contract awards, our growth strategy and our business, financial condition and operating results could be materially and adversely affected.

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

Our principal customer for BioThrax is the U.S. government. We anticipate that the U.S. government will also be the principal customer for any other biodefense products that we successfully develop. Over its lifetime, a U.S. government program may be implemented through the award of many different individual contracts and subcontracts. The funding for government programs is subject to Congressional appropriations, often made on a fiscal year basis, even for programs designed to continue for several years. These appropriations can be subject to political considerations and stringent budgetary constraints. For example, sales of BioThrax supplied under our multi-year procurement contracts with HHS were, and any sales of BioThrax under our new contract with the CDC will be, subject to available funding, mostly from annual appropriations. Additionally, our government-funded development contracts typically give the U.S. government the right, exercisable in its sole discretion, to extend these contracts for successive option periods following a base period of performance. The value of the services to be performed during these option periods may constitute the majority of the total value of the underlying contract. For example, the development contract we were awarded in September 2010 for development of PreviThrax consists of a two-year base period of performance valued at approximately $51 million, three successive one-year option periods valued at approximately $126 million and funding for optional non-clinical studies valued at approximately $9 million. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the U.S. government otherwise declines to exercise its options under our contracts with it, our business, revenues and operating results may suffer.

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

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

- procurement integrity;
- export control;
- government security;
- 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 costs. Failure to comply with these regulations and requirements could lead to suspension or debarment, from government contracting or subcontracting for a period of time. The termination of a government contract or relationship as a result of our failure to satisfy any of these obligations would have a negative impact on our operations and harm our reputation and ability to procure other government contracts in the future.

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

Our prior contracts for the supply of BioThrax with HHS and the DoD, as well as our current contract for the procurement of 44.75 million doses of BioThrax from the CDC, are fixed price contracts. We expect that our future contracts with the U.S. government for BioThrax, as well as contracts for biodefense product candidates that we successfully develop, also may be fixed price contracts. Under a fixed price contract, we are required to deliver our products at a fixed price regardless of the actual costs we incur and to absorb any costs in excess of the fixed price. Estimating costs that are related to performance in accordance with contract specifications is difficult, particularly where the period of performance is over several years. Our failure to anticipate technical problems, estimate costs accurately or control costs during performance of a fixed price contract could reduce the profitability of a fixed price contract or cause a loss, which could in turn harm our operating results.

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

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

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including by imposing equitable price adjustments;
- cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- decline to exercise an option to renew a contract;
- exercise an option to purchase only the minimum amount, if any, specified in a contract;
- decline to exercise an option to purchase the maximum amount, if any, specified in a contract;
- claim rights to products, including intellectual property, developed under the contract;

- take actions that result in a longer development timeline than expected;
- direct the course of a development program in a manner not chosen by the government contractor;
- suspend or debar the contractor from doing business with the government or a specific government agency;
- pursue criminal or civil remedies under the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

Generally, government contracts, including our CDC contract for BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the U.S. government's convenience. Under general principles of government contracting law, if the U.S. government terminates a contract for convenience, the other party to that contract may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the U.S. government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. One or more of our government contracts could be terminated under these circumstances. Some U.S. government contracts grant the U.S. 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 U.S. government.

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

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

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

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

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

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

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

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

- the Federal Acquisition Regulations, and agency-specific regulations supplemental to the Federal Acquisition Regulations, which comprehensively regulate the procurement, formation, administration and performance of government contracts;

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

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

Risks Related to Our Financial Position and Need for Additional Financing

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

Although we have been profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. For example, we incurred a net loss in the first quarter of 2011. Our profitability is substantially dependent on BioThrax product sales. BioThrax product sales have fluctuated significantly in recent quarters, and we expect that they will continue to fluctuate significantly from quarter to quarter based on several factors, including the timing of our fulfillment of orders from the U.S. government. Additionally, our profitability may be adversely affected as we progress through various stages of ongoing or planned clinical trials for our product candidates. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

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

As of December 31, 2011, we had $59.5 million principal amount of debt outstanding. We may seek to raise substantial external debt financing to provide additional financial flexibility. The assumption of debt could have significant adverse consequences, including:

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

We may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. In addition, a failure to comply with the covenants under our existing debt instruments could result in an event of default under those instruments. In the event of an acceleration of amounts due under our debt instruments as a result of an event of default, we may not have sufficient funds or may be unable to arrange for

additional financing to repay our indebtedness or to make any accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness. In addition, the covenants under our existing debt instruments and the pledge of our existing assets as collateral limit our ability to obtain additional debt financing.

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

We expect our development expenses to increase in connection with our ongoing activities, particularly as we conduct additional and later stage clinical trials for our product candidates. We also expect our commercialization expenses to increase in the future as we seek to broaden the market for BioThrax and if we receive marketing approval for additional products. We also may undertake additional facility projects in the future. In the event that our ability to sell BioThrax to the U.S. government is interrupted for an extended period of time, we will utilize our cash balances to help fund our ongoing operations.

As of December 31, 2011, we had $220.1 million of cash, cash equivalents, investments and accounts recievable. Our future capital requirements will depend on many factors, including:

- the level and timing of BioThrax product sales and cost of product sales;
- our ability to obtain funding from government entities and non-government and philanthropic organizations for our development programs;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to Building 55, our large-scale manufacturing facility in Lansing, Michigan, the build out of our facility in Baltimore, Maryland, and any other new facilities;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, other product candidates that we may pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the market acceptance and sales growth of any of our products or product candidates upon regulatory approval;
- the extent to which our growth generates increased administrative costs;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- the extent to which we acquire or invest in companies, businesses, products or technologies; and
- the effect of competing technological and market developments.

We may require additional sources of funds for future acquisitions that we may make or, depending on the size of the obligation, to meet balloon payments upon maturity of our current borrowings. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Current economic conditions may make it difficult to obtain financing on attractive terms or at all. Lenders may be able to impose covenants on us that could be difficult to satisfy, which could put us at increased risk of defaulting on debt. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

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

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

Risks Related to Manufacturing and Manufacturing Facilities

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

We continually evaluate alternatives for the manufacture of BioThrax and our various product candidates. We may seek to acquire one or more additional facilities or sign agreements with contract manufacturing organizations. We have constructed Building 55, a large-scale manufacturing facility on our Lansing, Michigan campus for which we received an award from BARDA in July 2010 for scale-up, qualification and validation to manufacture BioThrax. Additionally, in 2009, we acquired a facility in Baltimore, Maryland which we expect to utilize for certain product development or manufacturing projects.

Constructing, preparing and maintaining a facility for manufacturing purposes is a significant project. For example, the process for qualifying and validating Building 55 for FDA approval of the large-scale manufacture of BioThrax has been costly and time consuming, may result in unanticipated delays and may cost more than expected due to a number of factors, including regulatory requirements. The costs and time required to comply with cGMP regulations or similar regulatory requirements for sales of our products outside the U.S. may be significant. We may also need to hire and train significant numbers of employees to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. If our qualification, validation and licensure activities are delayed, we may limit our opportunities for growth and may be in breach of obligations included in our government funded development contracts. Costs associated with constructing, qualifying, validating and licensing manufacturing facilities could require us to raise additional funds from external sources, and we may not be able to do so on favorable terms or at all.

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

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

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

event of a problem with this strain, if we have not developed alternatives, we would not be able to provide the FDA with required potency testing data and not be able to release product.

Additionally, potency testing of each lot of BioThrax is performed against a qualified reference lot that we maintain. We continually monitor the status of our reference lot and periodically produce and qualify a new reference lot to replace the existing reference lot. For example, we prepared and qualified a new reference lot during the second quarter of 2011 to replace our prior, qualified reference lot. If we are not able to satisfy the FDA's requirements for release of BioThrax, our ability to sell BioThrax would be impaired until such time as we become able to meet such requirements, which would significantly impact our revenues, require us to utilize our cash balances to help fund our ongoing operations and otherwise harm our business.

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

Disruption at, damage to or destruction of our facilities could impede our ability to manufacture BioThrax, develop our product candidates, or perform our contractual obligations, any of which would harm our business, financial condition and operating results.

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

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

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

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

The factors listed above including, but not limited to, equipment malfunctions or failures, technology malfunctions, cyber attacks, protests and natural disasters could also cause disruption of, damage to or destruction of our other locations, including our research and product development facilities and our additional manufacturing facility currently under development in Baltimore, Maryland. Any such disruption, damage, or destruction could result in losses and delays, including delay in performance of our contractual obligations or delay in our clinical trials, any of

which could be costly to us and otherwise harm our business.

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

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

If we are unable to obtain supplies for our manufacture of BioThrax or our product candidates in sufficient quantities and at an acceptable cost, our ability to manufacture BioThrax or to develop and commercialize our product candidates could be impaired, which could harm our revenues, lead to a termination of one or more of our contracts, lead to delays in clinical trials or otherwise harm our business.

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

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

We currently rely, or plan to rely, on third parties to manufacture some or all of our vaccine and therapeutic product candidates that we require for preclinical and clinical development. For example, we currently depend on contract manufacturers for certain biopharmaceutical development and manufacturing services for product candidates we acquired from Trubion. Any significant delay in obtaining adequate supplies of our product candidates could adversely affect our ability to develop or commercialize these product candidates. For example, in 2008, the initial manufacturer of Thravixa informed us it was discontinuing contract manufacturing operations and we were forced to secure alternative manufacturing resources to continue development of this product candidate.

We also expect that we will rely on third parties for some or all of the manufacturing services necessary to produce commercial supplies of product candidates that we successfully develop. The manufacture and delivery of sufficient quantities of pharmaceutical products is a time-consuming and complex process. If our contract manufacturers are unable to scale-up production to generate enough materials for commercial launch, if manufacturing is of insufficient quality or not compliant with applicable rules and regulations, or if the costs of manufacturing are prohibitively high, the success of those products may be jeopardized. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our ability to develop product candidates and commercialize any products that receive regulatory approval on a timely and competitive basis.

Reliance on contract manufacturers, other vendors and collaborators limits our control regarding many aspects of the manufacturing and delivery process and therefore exposes us to a variety of significant risks, including:

§ limitations on our ability to schedule production with contract suppliers when needed to supply clinical trials;

- reliance on contract suppliers for legal and regulatory compliance and quality assurance;
- potential rejection by a contract supplier of a purchase order;
- contract supplier's insistence on exclusivity, minimum or maximum levels of supply and related restrictions on our ability to increase or decrease supply, including provisions whereby we pay a penalty if we fail to order a minimum amount;
- breach of agreements by contract suppliers; and
- termination, price increases, or non-renewal of agreements by contract suppliers, based on other business priorities, at times that are costly or inconvenient for us.

We operate under short-term supply agreements with a number of third party manufacturers that are not obligated to accept any purchase orders we may submit. Third party manufacturers may also be unable or unwilling to accommodate our production scheduling requests, or may insist on exclusivity or minimum or maximum levels of supply, or may raise prices or decline to renew contracts. If any third party terminates or declines to renew its agreement with us, or otherwise fails to fulfill our purchase orders on terms acceptable to us, we would need to rely on alternative sources or develop our own manufacturing capabilities to satisfy our requirements.

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

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

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

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

If we or third parties are unable to manufacture our product candidates in compliance with regulatory requirements, in sufficient quantities, at an acceptable cost and according to applicable timelines, our clinical trials could be delayed, production costs could be significantly increased and the development prospects and commercial viability of our product candidates could be harmed.

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

Our research and development and manufacturing processes may involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and produce waste products. Accordingly, we, the third parties that conduct clinical trials on our behalf and the third parties that manufacture our product candidates are subject to federal, state, local and foreign laws and regulations governing the use, manufacture, distribution, storage, handling, disposal and recordkeeping with respect to these materials. The Public Health Security and Bioterrorism Preparedness and Response Act and the Agricultural Protection Act require us to register with the CDC and the Animal and Plant Health Inspection Service, 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 stringent safeguards and security measures for these select agents and toxins, including controlled access and the screening of entities and personnel and establishes a comprehensive national database of registered entities.

We are also subject to a variety of environmental laws in Michigan, including those regarding underground storage tanks. One such tank on our Lansing, Michigan campus has leaked in the past. The State of Michigan removed the tank, continues to monitor the situation and has agreed to indemnify us for any resulting liabilities. In the event that the State of Michigan does not indemnify us, or if our insurance does not cover the exposure of any remediation that may be necessary, we may be required to spend significant amounts on remediation efforts. In addition to complying with environmental and occupational health and safety laws, we must comply with special regulations relating to biosafety administered by the CDC, HHS, U.S. Department of Agricture and the DoD.

We also are subject to export control regulations governing the export of BioThrax and technology and materials used to develop and manufacture BioThrax and our product candidates. These laws and regulations may limit the countries in which we may conduct development and manufacturing activities.

If we fail to comply with environmental, occupational health and safety, biosafety and export control laws, we could be held liable for fines, penalties and damages that may result from such non-compliance, and any such liability could exceed our assets and resources. In addition, we could be required to cease immediately all use of a select agent or toxin, and we could be prohibited from exporting our products, technology and materials or we could be suspended from the right to do business with the U.S. government. In addition, we cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of hazardous materials. In the event of injury or a future contamination event, we could be held liable for resulting damages, and any such liability could significantly impact our financial position.

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

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

These policies are subject to deductibles, exclusions and coverage limitations. We may be unable to maintain existing insurance or obtain new coverage or increase limits in the future on reasonable terms or at all. Circumstances may arise where we face liabilities that are not covered by our insurance policies, or where our coverage is not adequate,

which may expose us to significant liabilities and significantly and adversely affect our business or financial position.

Risks Related to Product Development

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

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

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

If we are prevented from developing and commercializing a product candidate in an economically acceptable manner, that product program may be adversely affected and the commercial success of the product candidate may be harmed.

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

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

We expect to rely on FDA regulations known as the "animal rule" to obtain approval for certain of our product candidates. The animal rule permits, in certain limited circumstances, the use of animal efficacy studies together with human clinical safety and immunogenicity trials to support an application for marketing approval. These regulations are relatively new, and we have limited experience in the application of these rules to the product candidates that we are developing. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our vaccine and therapeutic product candidates in humans. If we are not successful in completing the

development and commercialization of our vaccine and therapeutic product candidates, or if we are significantly delayed in doing so, our business will be materially harmed.

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

- regulators or institutional review boards may not authorize us, or our collaborators, to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;
- regulators may determine that service providers we use in the conduct of a clinical trial are precluded from providing such services;
- we or our collaborative partners may experience delay in beginning the clinical trial;
- we may experience competition in recruiting clinical investigators;
- the cost of our clinical trials could escalate and become cost prohibitive;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- regulatory requirements, policy and guidelines could change;
- we may experience limitations in our ability to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials;
- we or our collaborators may fail to adequately manage the increasing number, size and complexity of our clinical trials;
- any or all of our collaborators, the FDA and foreign regulatory agencies may interpret data differently;
- third parties conducting and overseeing the operations of our clinical trials may fail to perform their contractual or regulatory obligations in a timely fashion;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials or may experience delays in patient enrollment and variability in the number and types of patients available for clinical trials; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

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

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

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

§ not be able to obtain marketing approval.

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

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

If our drug discovery and development programs do not progress as anticipated, our revenue and stock price could be negatively impacted.

We estimate the timing of a variety of preclinical, clinical, regulatory and other milestones for planning purposes, including when a drug candidate is expected to enter clinical trials, when a clinical trial will be completed, when and if additional clinical trials will commence, or when an application for regulatory approval will be filed. We base our estimates on facts that are currently known to us and on a variety of assumptions that may prove not to be correct for a variety of reasons, many of which are beyond our control. For example, delays in the development of drugs by us or our collaborators may be caused by many factors, including regulatory or patent issues, negative or inconclusive interim or final results of on going clinical trials, scheduling conflicts with participating clinics and the rate of patient enrollment in clinical trials and the development priorities of our collaborators. In addition, in preparing these estimates we rely on the timeliness and accuracy of information and estimates reported or provided to us by our collaborators concerning the timing, progress and results of clinical trials or other development activities they conduct under our collaborations with them. If we or our collaborators do not achieve milestones when anticipated, we may not achieve our planned revenue or we may be forced to record an impairment charge to our intangible assets and our stock price could decline. In addition, any delays in obtaining approvals to market and sell drugs may result in the loss of competitive advantages in being on the market sooner than, or in advance of, competing products, which may reduce the value of these products and the potential revenue we receive from the eventual sale of these products, either directly or under agreements with our partners.

Our product development efforts could also result in large and immediate write-offs, significant milestone payment obligations, incurrence of debt and contingent liabilities or amortization of expense related to intangible assets, any of which could negatively impact our financial results. Additionally, if we were unable to develop any of our product candidates into viable commercial products, we will be reliant solely on sales of our currently approved product BioThrax for our revenues, thus limiting our growth opportunities and diversification.

Risks Related to Commercialization

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

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

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

U.S. government has represented a small portion of our revenue. If we fail to significantly increase our sales of BioThrax to these customers, our business and opportunities for growth could be materially harmed.

Government regulations may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, many foreign governments require licensure of BioThrax in their jurisdictions before they will consider procuring doses. Additionally, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of BioThrax and related technology, the U.S. government may decide, particularly in the current environment of elevated concerns about global terrorism, to increase the scope of export prohibitions. These prohibitions could limit our sales of BioThrax to foreign governments and other foreign customers. In addition, U.S. government demand for an anthrax vaccine may limit supplies of BioThrax available for sale to non-U.S. government customers. For example, our efforts to develop domestic commercial and international sales may be impeded by the DoD's right under the Defense Production Act to require us to deliver more doses than we currently anticipate. Furthermore, the DoD's sale of BioThrax to foreign governments under the Foreign Military Sales program has had and may continue to have an adverse effect on our ability to sell BioThrax internationally.

Our ability to meet any future potential increased demand for sales of BioThrax to customers other than the U.S. government also depends on our available production capacity. We use substantially all of our current production capacity at our FDA-approved manufacturing facility in Lansing, Michigan to manufacture BioThrax for current sales to U.S. government customers. Although, we have constructed Building 55, a large-scale manufacturing facility at our Lansing campus that is available for large-scale production of BioThrax, use of Building 55 for large-scale production remains subject to final qualification and validation activities.

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

We must comply with numerous laws and regulations relating to international business operations. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

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

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

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

growth potential and increase our development costs.

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

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

Any products that we bring to the market may not gain or maintain market acceptance by potential government customers, physicians, patients, healthcare payors and others in the medical community.

In particular, our biodefense product and product candidates are subject to the product criteria that may be specified by potential U.S. government customers. The product specifications in any government procurement request may prohibit or preclude us from participating in the government program if our products or product candidates do not satisfy the stated criteria.

The U.S. government could conduct clinical trials involving BioThrax in populations or in a manner that may attract negative public attention or otherwise have a detrimental effect on market acceptance of BioThrax.

The use of vaccines carries a risk of adverse health effects. The adverse reactions that have been associated with the administration of BioThrax include local reactions, such as redness, swelling, injection site cellulitus and temporary 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, including diabetes, heart attacks, autoimmune disorders, including Guillain-Barre syndrome, lupus, multiple sclerosis, lymphoma and death. None of these events have been causally linked to the administration of BioThrax. The report of any adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event.

The commercial success of many of our product candidates, including our oncology and autoimmune therapeutic product candidates, will depend upon, among other things, their acceptance by physicians, patients, third-party payors and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments.

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

§ our ability to provide acceptable evidence of safety and efficacy;
§ the prevalence and severity of any side effects;
§ availability, relative cost and relative efficacy of alternative and competing treatments;
§ the ability to offer our product candidates for sale at competitive prices;
§ the relative convenience and ease of administration;
§ the willingness of the target patient population to try new products and of physicians to prescribe these products;
§ the strength of marketing and distribution support;

§ publicity concerning our products or competing products and treatments; and
§ the sufficiency of coverage or reimbursement by third parties.

If our products and product candidates do not become widely accepted by potential government customers, physicians, patients, third-party payors and other members of the medical community, our business, financial condition and operating results could be materially and adversely affected.

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

Products developed to treat diseases caused by or to combat the threat of bioterrorism are subject to changing political and social environments. The political and social responses to bioterrorism may vary over time. We do not believe that the recent changes in the leadership of prominent terrorist networks are likely to reduce the risk of bioterrorism, but they could result in a public perception that risk is reduced. Political or social pressures or changes in the perception of the risk that military personnel or civilians could be exposed to biological agents as weapons of bioterrorism may delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, which would harm our business.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Furthermore, lawsuits brought against us by third parties or activists, even if not successful, require us to spend time and money defending the related litigation. The need to address political and social issues may divert our management's time and attention from other business concerns. For example, between 2001 and 2006, members of the military and various activist groups who oppose mandatory inoculation with BioThrax petitioned the FDA and the federal courts to revoke the license for BioThrax and to terminate the DoD program for the mandatory administration of BioThrax to military personnel. Although the DoD has prevailed in those challenges to date, the actions of these groups have created negative publicity about BioThrax. Additional lawsuits, publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of, and thereby limit the demand for, BioThrax and our biodefense product candidates. In such event, our ability to market and sell such products may be hindered and the commercial success of BioThrax and other products we develop will be harmed, thereby reducing our revenues.

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

To achieve commercial success for any approved product, we must either develop our own sales and marketing capabilities, enter into collaborations with third parties able to perform these services or outsource these functions to third parties. We currently market and sell BioThrax through a small, targeted sales and marketing group. We plan to continue to do so and expect that we will use a similar approach for sales to the U.S. government of any other biodefense product candidates that we successfully develop. This small sales group would not be capable of supporting sales efforts for our biosciences product candidates. If we do not enter into collaborative agreements with respect to our Biosciences product candidates with third parties with appropriate commercialization capabilities, we may need to further expand our sales, marketing and distribution infrastructure to effectively commercialize these product candidates.

Our efforts to develop our sales, marketing and distribution infrastructure are subject to the following risks.

§ potential difficulties in recruiting, training and retaining adequate numbers of effective sales and marketing personnel;
§ the potential that the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities could be delayed, resulting in us incurring related expenses too early relative to the product launch and causing personnel retention issues;

- our limited experience in the commercialization of pharmaceutical products other than BioThrax;
- difficulties in establishing an effective distribution network, including entering into marketing and distribution agreements with third parties on acceptable terms;
- the inability of sales personnel to obtain access to or persuade adequate numbers of potential government customers to purchase our products and physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and maintaining a sales and marketing organization.

If we are not successful in our efforts to expand our sales and marketing capability, our ability to market and sell BioThrax and any other product candidates that we successfully develop will be impaired, which could negatively impact our business, financial condition and operating results.

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

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid technological advances. We may face future competition with respect to BioThrax, our current product candidates and any products we may seek to develop or commercialize in the future from pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include biodefense companies, academic institutions, government agencies and other public and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than any products that we may develop or market. Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours. They may also devote greater resources to market or sell their products, adapt more quickly to new technologies and scientific advances, initiate or withstand substantial price competition more successfully than we can, more effectively negotiate third-party licensing and collaborative arrangements and take advantage of acquisition or other opportunities more readily than we can. Any therapeutic product candidate that we successfully develop and commercialize is likely to compete with currently marketed products and with other product candidates currently in development for the same indications. In many cases, the currently marketed products have well-known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. In particular, any new product candidate that competes with a generic market-leading product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome severe price competition and be commercially successful.

Although BioThrax is the only anthrax vaccine approved by the FDA for the prevention of anthrax infection, the U.S. government is funding the development of new products that could compete with BioThrax and could eventually procure those new products in addition to, or instead of, BioThrax, potentially reducing our BioThrax revenues. For example, HHS has awarded a development and SNS procurement contract to a competitor for an anthrax immune globulin therapeutic and is assisting this company in its production efforts by providing it with BioThrax doses that we delivered for placement into the SNS so that the competitor can immunize donors and obtain plasma for the competitor's product candidate. HHS has awarded another development and SNS procurement contract to another competitor for an anthrax monoclonal antibody as a post-exposure therapeutic for anthrax infection.

We believe that our most significant competitors in the area of biodefense and commercial vaccines are a number of pharmaceutical companies that have vaccine programs, including Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Pfizer and Novartis, as well as smaller more focused companies engaged in vaccine development, such as Human Genome Sciences, Soligenix, Dynport Vaccine Company, Elusys, Bavarian Nordic and PharmAthene. With respect to our tuberculosis vaccine product candidate specifically, the Aeras Global Tuberculosis Vaccine Foundation is developing or supporting the development of five tuberculosis vaccine product candidates in addition to ours, any of

which could present competitive risks.

With respect to protein therapeutics developed to target AIID and oncology indications, our competitors include Amgen, Pfizer, Takeda, Centocor Ortho Biotech, Merck, Mitsubishi Tanabe, Abbott, Eisai, Celgene, Bristol-Myers Squibb, UCB, Otsuka, Roche, Chugai, Genentech, Biogen Idec, Spectrum Pharmaceuticals, Inc., Bayer Schering AG, GSK, Genzyme, Cephalon Oncology, Genmab, Allos Therapeutics, AstraZeneca, Boehringer Ingleheim and ImmunoGen, Inc.

Numerous companies have products or product candidates in development that would compete with the protein therapeutic product candidates we are developing. If approved for the treatment of rheumatoid arthritis, or RA, we anticipate that some of our commercial product candidates would compete with other marketed protein therapeutics for the treatment of RA, including: Enbrel ® (Amgen, Pfizer and Takeda), Remicade ® (Centocor Ortho Biotech, Merck and Mitsubishi Tanabe), Humira ® (Abbott and Eisai), Orencia ® (BMS), Cimzia ® (UCB and Otsuka), Simponi ® (JNJ and Merck), Actemra ® (Roche and Chugai) and Rituxan ® (Genentech, Roche and Biogen Idec). If approved for the treatment of systemic lupus erythematosus, or SLE, our product candidates will compete with Benlysta ® (Human Genome Sciences and GSK) and other B-cell depleting therapies, including CD20-directed therapeutics.

If approved for the treatment of chronic lymphocytic leukemia, or CLL, or NHL, or other B-cell malignancies, we anticipate that our product candidates would compete with other B-cell depleting therapies and related therapeutics. Non-CD37-directed therapeutics marketed for the treatment of NHL or CLL, or both, include Rituxan ® (Genentech), Zevalin ® (Spectrum Pharmaceuticals, Inc. and Bayer Schering AG), Bexxar ® (GlaxoSmithKline), Campath ® (Genzyme and Bayer Schering AG), Treanda ® (Cephalon Oncology) and Arzerra ® (GlaxoSmithKline and Genmab). In addition, Boehringer Ingelheim and ImmunoGen, Inc. are both developing antibody therapies directed to CD37.

If approved for the treatment of cutaneous CTCL and PTCL or other T-cell lymphomas, we anticipate that our product candidates would compete with other T-cell therapies and related therapeutics. Therapeutics marketed for the treatment of CTCL or PTCL include Ontak and Targretin (Eisai), Istodax ® (Celgene), Zolinza ® (Merck), Folotyn ® (Allos Therapeutics) and Campath® (Bayer Schering AG). In addition, GlaxoSmithKline, Roche, Bristol-Myers Squibb, AstrZeneca and Spectrum Pharmaceuticals are developing therapies directed to CTCL or PTCL.

If we are not able to compete effectively against our current and future competitors, our business may not grow or it may decline, and our financial condition and operating results may suffer.

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

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

The PREP Act which was signed into law in December 2005, creates immunity for manufacturers of biodefense countermeasures when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is meant to provide immunity from all claims under state or federal law for loss arising out of the administration or use of a covered countermeasure. In October 2008, the Secretary of HHS issued a PREP Act declaration identifying BioThrax and Anthrivig as covered countermeasures. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct. Upon a declaration by the Secretary of HHS, a compensation fund is created to provide “timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure.” The “covered injuries” to

which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer only after they have exhausted their remedies under the compensation program. Therefore, a willful misconduct action could be brought against us if any individuals exhaust their remedies under the compensation program and thereby expose us to liability.

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

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

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

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

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

We currently have product liability insurance for coverage up to a $30 million annual aggregate limit with a deductible of $75,000 per claim up to $375,000 in aggregate. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Product liability insurance may be difficult and expensive to obtain. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. For example, from 2002 through February 2006, we were unable to obtain product liability insurance for sales of BioThrax on commercially reasonable terms. We do not believe that the amount of insurance we have been able to obtain for BioThrax is sufficient to manage the risk associated with the potential large scale deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on statutory protections in addition to insurance to help mitigate our liability exposure for BioThrax.

A successful product liability claim or series of claims brought against us could cause our stock price to fall and could decrease our financial resources and materially and adversely affect our business.

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

Our revenues and profits from any products that we successfully develop, other than with respect to sales of our biodefense products under government contracts, will depend heavily upon the availability of adequate reimbursement

for the use of such products from governmental and other third party payors, both in the U.S. and in other markets. Reimbursement by a third party payor may depend upon a number of factors, including the third party payor's determination that use of a product is:

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

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

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

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

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

Our future revenues and profitability will be adversely affected if third party payors do not sufficiently cover and reimburse the cost of future drug products we may market. If these entities do not provide coverage and reimbursement for our products, or if they provide an insufficient level of coverage and reimbursement, our products may be too costly for use, and physicians may not prescribe them or may prescribe them less frequently. In this manner, levels of reimbursement for drug products by government authorities, private health insurers and other organizations, such as Health Maintenance Organizations, may have a material adverse effect on our business, financial condition, cash flows and results of operations.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably and increase competition.

In both the U.S. and in foreign jurisdictions, legislative and regulatory actions may reduce the revenues that we derive from our future products. In particular, in March 2010, Congress enacted sweeping legislation to reform the U.S. health care system. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, contains a number of cost-containment measures that could

adversely affect our operating results and our overall financial condition. For example, the legislation imposes an annual fee on branded prescription drug manufacturers, including biologics manufacturers, which will be allocated based on market share in the aggregate for certain government programs. In addition, the legislation creates a licensure pathway for biological products shown to be biosimilar to previously licensed biological reference products and will permit litigation of patent infringement cases between patent owners and biosimilar manufacturers prior to biosimilar market entry. The legislation also establishes a program to phase out the coverage gap under Medicare Part D by 2020 through a combination of manufacturer discounts and federal subsidies, increases the minimum Medicaid drug rebates for pharmaceutical companies and creates an Independent Payment Advisory Board to recommend changes in Medicare payment rates.

We expect the reforms imposed by the new law to have a significant impact on our business and the entire life sciences industry. Until many of the provisions are implemented, however, the full impact of the legislation cannot be known. Our results of operations could be adversely affected by current and potential future healthcare reforms.

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

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

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

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

Proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could force us to lower the prices at which we sell any approved products and impair our ability to derive revenue from these products.

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

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

Our success depends on our continued ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel. We consider Fuad El-Hibri, chairman of our Board of Directors and our chief executive officer, and Daniel J. Abdun-Nabi, a member of our Board of Directors and our president and chief operating officer, to be key to our BioThrax operations and our efforts to develop and commercialize our product candidates. We expect that Mr. Abdun-Nabi will succeed Mr. El-Hibri as our chief executive officer on April 1, 2012. Mr. El-Hibri will continue to serve as executive chairman of the Board of Directors. Both of these key employees are at will employees and can terminate their employment at any time. We do not maintain "key person" insurance on any of our employees.

In addition, our growth will require us to retain and hire a significant number of qualified technical and commercial and management personnel, including scientific, clinical development, manufacturing and process development, regulatory, marketing and sales executives and field sales personnel, as well as administrative personnel. Our ability to achieve our business strategies, including advancing drug candidates through later stage development or commercialization, depends on our ability to hire and retain high caliber scientists and other qualified personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow.

Risks Related to Our Acquisition Strategy

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

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

- use of cash resources;
- higher than anticipated acquisition costs and expenses;
- potentially dilutive issuances of equity securities;
- the incurrence of debt and contingent liabilities, impairment losses or restructuring charges; and
- amortization expenses related to intangible assets.

We also may face significant challenges in effectively integrating entities and businesses that we acquire, and we may not realize the benefits anticipated from such acquisitions or realize them in the predicted timeframe. Achieving the anticipated benefits of any acquired entities or businesses will depend in part upon whether we can integrate them in an efficient and effective manner. Operational risks that could harm our existing operations or prevent realization of anticipated benefits from these transactions include:

- challenges associated with managing an increasingly diversified business;
- prioritization of product portfolios and related changes in resources available to each product portfolio;
- disruption of our pre-acquisition business;
- greater administrative burdens and operating costs;
- difficulty and expense in assimilating and integrating the operations, products, technology, information systems, culture or personnel of the acquired entities or businesses;
- potential loss of key collaborators;
- difficulty in entering markets in which we have limited or no direct experience;
- diversion of management's time and attention from other business concerns;
- difficulty in implementing uniform standards, controls, procedures and policies;

- the assumption of known and unknown liabilities of the acquired entities or businesses;
- increased exposure to uncertainties inherent in developing and commercializing new products;
- impairment of acquired intangible assets as a result of technological advances or worse-than-expected clinical results or performance of the acquired company or the partnered assets;
- challenges and costs associated with reductions in work force; and
- potential loss of key personnel.

If we are unable to integrate acquired entities and businesses successfully, our ability to develop new products and continue to expand our product pipeline may be limited and we may experience material adverse consequences to our business, financial condition or results of operations.

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

Since our inception we have pursued a strategy of growing our business through licensing and acquisition. We commenced operations in September 1998 through an acquisition of rights to BioThrax, vaccine manufacturing facilities at a multi-building campus on approximately 12.5 acres in Lansing, Michigan and vaccine development and production know-how, all from the Michigan Biologic Products Institute. We acquired vaccine and therapeutic product candidates through our acquisition of Microscience Limited in 2005, our acquisition of substantially all of the assets of ViVacs GmbH in 2006, our acquisition of Trubion in October 2010 and our acquisition of certain assets of Vaxgen, Inc. in 2008, Avanir Pharmaceuticals, Inc. in 2008 and TenX BioPharma, Inc. in May 2011. We have been unsuccessful in our efforts to develop and commercialize many of the product candidate acquired through these acquisitions.

In the future, we may be unable to license or acquire suitable products or product candidates from third parties for a number of reasons. A number of more established companies are also pursuing strategies to license or acquire products in the vaccine and therapeutic field and these established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, we expect competition for acquisition candidates in the vaccine and therapeutic field to increase, which may result in fewer suitable acquisition opportunities for us, as well as higher acquisition prices. Other factors that may prevent us from licensing or otherwise acquiring suitable products and product candidates include the following:

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

Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote resources to potential acquisitions that are never completed. If we are unable to successfully obtain rights to suitable products and product candidates and manage the risks and costs of pursuing an acquisition strategy, our business, financial condition and prospects for growth could suffer.

We may fail to manage our growth and increased breadth of our activities effectively.

We have expanded the scope of our business in recent years. We have acquired several drug candidates and have been advancing pre-clinical and multiple clinical stage product candidates. We plan to continue adding products and product candidates through internal development, in-licensing and acquisition over the next several years and to continue developing our existing product candidates that demonstrate the requisite efficacy and safety to advance into and through clinical trials. To manage the existing and planned future growth and the increasing breadth and complexity of our activities, we have grown our employee base substantially and will need to continue building our organization and making additional investments in personnel, infrastructure, information management systems and

resources. Our ability to develop and advance the commercialization of our products and product candidates, achieve our research and development objectives, add and integrate new products, and satisfy our commitments under our collaboration and acquisition agreements depends on our ability to respond effectively to these demands and expand our internal organization and infrastructure to accommodate our growth and additional anticipated growth. If we are unable to manage and advance these activities effectively, our ability to operate our business successfully and maximize the value of our product or our product candidates could suffer, which could materially and adversely affect our business, financial condition and prospects for future growth.

Risks Related to Regulatory Approvals

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

Our product candidates and the activities associated with their development and commercialization, including testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us and our collaborators from commercializing the product candidate. We have limited experience in preparing, filing and prosecuting the applications necessary to gain regulatory approvals and expect to rely on third party contract research organizations and consultants to assist us in this process.

Securing FDA approval requires the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to establish the product candidate's safety and efficacy. Our future products may not be effective, may be only moderately effective or may prove to have significant side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

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

We intend to use the animal rule in pursuit of FDA approval of Anthrivig, PreviThrax, Thravixa, NuThrax and BioThrax as a PEP. We cannot guarantee that the FDA will permit us to proceed with licensure of any of our BioThrax related programs or our other product candidates under the animal rule. Even if we are able to proceed pursuant to the animal rule, the FDA may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products.

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

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

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

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

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

The FDA conducted six routine, biannual inspections of our Lansing facilities with the most recent occuring in August 2011. Following each of these inspections, the FDA issued inspectional observations on Form FDA 483, some of which were significant. We responded to the FDA regarding the inspectional observations relating to each inspection and, where necessary, implemented corrective action. All observations from inspections prior to 2011 have been successfully closed out. We are in the process of implementing corrective action where necessary in response to the FDA observations during the August 2011 inspection and we anticipate that all observations from the 2011 inspection will also be successfully closed out. If in connection with any future inspection the FDA finds that we are not in substantial compliance with cGMP requirements, or if the FDA is not satisfied with the corrective actions we take in connection with any such inspection, the FDA may undertake enforcement action against us.

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

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

If we experience any of these post-approval events, our business, financial condition and operating results could be materially and adversely affected.

If our competitors are able to obtain orphan drug exclusivity for any products that are competitive with our products or if we fail to maintain orphan drug status for our product candidates, we may be precluded from selling or obtaining approval of our competing products by the applicable regulatory authorities for a significant period of time.

If one of our competitors obtains orphan drug exclusivity for an indication for a product that competes with one of the indications for one of our product candidates before we obtain orphan drug designation, and if the competitor's product is the same drug as ours, the FDA would be prohibited from approving our product candidate for the same orphan indication unless we demonstrate that our product is clinically superior or the FDA determines that the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the drug.

We have obtained orphan drug status from the FDA for Anthrivig, Thravixa, TRU-016 (CLL indication), and zanolimumab (CTCL indication), and in the European Union for Anthrivig, Thravixa and our tuberculosis vaccine product candidate. None of our other products or product candidates have been designated as an orphan drug and there is no guarantee that the FDA will grant such designation in the future. Even if we obtain orphan drug exclusivity for one or more indications for one of our product candidates, we may not be able to maintain it. For example, if a competitive product that is the same drug or biologic as our product is shown to be clinically superior to our product, any orphan drug exclusivity we may have obtained will not block the approval of that competitive product.

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

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

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

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

The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval, or may include different or additional risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in another jurisdiction, including approval by the FDA. For example, a provision of the European Pharmacopoeia may prevent use of our preferred cell line for the manufacture of our TB vaccine product candidate in the European Union unless such provision can be interpreted in a manner consistent with our product candidate's manufacturing process, despite the fact that the FDA had provided differing recent guidance. We are continuing to work to clarify the provision but we cannot be certain that our efforts will be successful, which could preclude our ability to commercialize this product candidate in the European

Union. We and our collaborators may not be able to obtain regulatory approvals to commercialize our products in any market. The failure to obtain regulatory approval in foreign jurisdictions could materially harm our business.

Risks Related to Our Dependence on Third Parties

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

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

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

Any collaboration that we enter into may not be successful. For example, in June 2010 Pfizer decided to discontinue development of TRU-015, a SMIP directed to CD20, based on preliminary results from a Phase II study. Even though these results were consistent with previous studies and similar to results obtained with respect to other B-cell-depleting therapies, they did not meet the internally predefined endpoint of the study. In addition, in December 2011, Abbott decided to terminate its collaboration with us for the development and commercialization of TRU-016 as a result of Abbott's portfolio prioritization process. Additionally, the success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. It is likely that our collaborators will have significant discretion in determining the efforts and resources that they will apply to these collaborations.

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

- § we may not be able to control the amount and timing of resources that our collaborators devote to the development or commercialization of product candidates;
- § our collaborators may delay clinical trials, design clinical trials in a manner with which we do not agree, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new version of a product candidate for clinical testing;
- § our collaboration agreements are likely to be for fixed terms and may be subject to termination by our collaborators;
- § our collaborators may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not do so, our ability to maintain and defend our intellectual property rights may be compromised by our collaborators' acts or omissions;
- § our collaborators may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;
- § our collaborators may decide not to pursue further development and commercialization of products and product candidates resulting from the collaboration, or may elect to discontinue research and development programs, which could delay development and increase the cost of developing our product candidates;
- § our collaborators may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;

- § we may experience difficulties in the day-to-day activities required by collaboration including close and frequent communications between several different teams, technology transfer and a collaborative sharing of responsibilities;
- § disputes may arise between us and our collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- § our collaborators may experience financial difficulties;
- § business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations; and
- § our collaborators could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

Any of these potential outcomes could harm our business reputation and adversely affect us financially including by resulting in lower than expected revenues or increased development costs, delaying development, leading to a loss of market opportunities or impairing the value of the related product candidate.

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

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

Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. We may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult. If we must replace any contract research organization, our trials may have to be suspended until we find another contract research organization that offers comparable services. The time that it takes us to find alternative organizations may cause delay in the commercialization of our product candidates or may cause us to incur significant expenses to replicate data that may be lost. Although we do not believe that the contract research organizations on which we rely offer services that are not available elsewhere, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost. Any delay in or inability to complete our clinical trials could significantly compromise our ability to secure regulatory approval of the relevant product candidate and preclude our ability to commercialize the product, thereby limiting our ability to generate revenue from the sales of product candidates, which may result in a decrease in our stock price. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates.

In addition, in certain cases, we encourage government entities and non-government organizations to conduct studies of, and pursue other development efforts for, our product candidates. For example, we expect to rely on data from clinical trials conducted by third parties seeking marketing approval for certain of our product candidates, including our BLA supplement for a label expansion of BioThrax for a regimen of fewer doses, which is based on the results of

a clinical trial conducted by the CDC. These government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. In addition, government entities depend on annual Congressional appropriations to fund these development efforts.

We face potential liability related to the privacy of health information we obtain from research institutions.

Most health care providers, including research institutions from which we or our collaborators obtain patient information, are subject to privacy regulations promulgated under the Health Insurance Portability and Accountability Act, or HIPAA. Our clinical research efforts are not directly regulated by HIPAA. However, conduct by a person that may not be prosecuted directly under HIPAA's criminal provisions could potentially be prosecuted under aiding and abetting or conspiracy laws. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we receive individually identifiable health information from a health care provider or research institution that has not satisfied HIPAA's disclosure standards. In addition, international data protection laws including the European Union Data Protection Directive and member state implementing legislation may apply to some or all of the clinical data obtained outside of the U.S. Furthermore, certain privacy laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our use and dissemination of individuals' health information.

Moreover, patients about whom we or our collaborators obtain information, as well as the providers who share this information with us, may have contractual rights that limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Risks Related to Our Intellectual Property

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

Our success, particularly with respect to the Biosciences portion of our business, will depend in large part on our ability to obtain and maintain protection in the U.S. and other countries for the intellectual property covering or incorporated into our technology, products and product candidates, including those which are the subject of collaborations. Obtaining and maintaining this protection is very costly. The patentability of technology in the field of vaccine and therapeutic development and other pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions.

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

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, we know that other entities have filed patent applications in various jurisdictions that relate to several areas in which we are developing products. Some of these patent applications have already resulted in patents and some are still pending. If use of technology incorporated into or used to produce our

product candidates is challenged, or if our processes or product candidates conflict with patent rights of others, third parties could bring legal actions against us in Europe, the U.S. and elsewhere claiming damages and seeking to enjoin manufacturing and marketing of the affected products. Further, patents generally expire, regardless of their date of issue, 20 years from the earliest claimed non-provisional filing date. As a result, the time required to obtain regulatory approval for a product candidate may consume part or all of the patent term. We are not able to accurately predict the remaining length of the applicable patent term following regulatory approval of any of our product candidates.

Should third parties file patent applications or obtain patents claiming technology also claimed by us in pending applications, we may be required to participate in deviation proceedings in the U.S. Patent and Trademark Office to determine inventorship, which could result in substantial costs to us and an adverse decision as to the inventorship, and therefore ownership, of our inventions. An unfavorable outcome in a deviation proceeding could require us to cease using the technology or to license rights from prevailing third parties. We cannot assure you that any prevailing party would offer us a license or that we could acquire any license made available to us on commercially acceptable terms.

The cost of litigation to uphold the validity of patents to prevent infringement or to otherwise protect our proprietary rights could be substantial. Some of our competitors may be better able to sustain the costs of complex patent litigation because they may have substantially greater resources. Intellectual property lawsuits are expensive and unpredictable and would consume time and other resources, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also a risk that, even if the validity of a patent were upheld, a court would refuse to stop the other party from using the invention(s), including on the grounds that its activities do not infringe the patent. If any of these events were to occur, our business, financial condition and operating results could be materially and adversely affected.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not do so, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties. For example, we license an oligonucleotide adjuvant, CPG 7909, for use in NuThrax from Pfizer. One of the licensed U.S. patents has been revoked by the U.S. Patent and Trademark Office, as a result of a patent interference between Pfizer and a third party.

We also will rely on current and future trademarks to establish and maintain recognized brands. If we fail to acquire and protect such trademarks, our ability to market and sell our products, and therefore our business, financial condition and operating results, could be materially and adversely affected.

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

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

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

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

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

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

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

If we infringe or are alleged to infringe intellectual property rights of third parties, we may be limited in our ability to commercialize our products.

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

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

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology and pharmaceutical industries. For example, modified vaccinia Ankara, or MVA,-based vaccines have been the subject of significant intellectual property litigation. Specifically, Bavarian Nordic sued Acambis for patent infringement and other claims arising out of Acambis' importation of an MVA-based smallpox vaccine for biodefense use by the U.S. government. Bavarian Nordic claimed that its patents broadly covered the manufacture of

MVA-based biological products and that Bavarian Nordic had rights in the biological materials used by Acambis. That litigation was terminated in July 2007 by a settlement and consent order. Bavarian Nordic subsequently sued Oxford BioMedica PLC, Oxford BioMedica Ltd. and Biomedica Inc., collectively Oxford BioMedica, alleging that Oxford BioMedica has infringed certain Bavarian Nordic U.S. patents by making, using and importing and inducing others to use Oxford BioMedica's experimental drug TroVax®, which is an MVA-based therapeutic cancer vaccine. The lawsuit was settled in January 2010 by agreement between the parties. We are also involved in several patent oppositions filed in the European Patent Office against certain of Bavarian Nordic's patents covering certain aspects of MVA technology. In each of the opposition proceedings, the subject patents have also been opposed by one or more additional parties, including Sanofi Pasteur, Transgene, Baxter, Virbac and Innogenetics. These oppositions have resulted in the European Patent Office narrowing the claims in each of the contested Bavarian Nordic patents, and each is now subject to appeal proceedings before the Technical Board of Appeal of the European Patent Office.

The strain of MVA that we use in our platform technology is a distinct lineage from the strains used by Acambis and Oxford BioMedica; however, we cannot be certain that we will not become the target of an infringement action. We also cannot be certain that the oppositions pending in the European Patent Office will be resolved in our favor. If we are sued for infringement, we could incur expensive legal costs, development delays or other costs and delays that could harm our business.

Risks Related to Information Technology

Disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to interruption, invasion, computer viruses, destruction, malicious intrusion and additional related disruptions which may result in the impairment of production and key business processes.

In addition, our systems are potentially vulnerable to data security breaches—whether by employees or others—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal or sensitive information of our employees, the U.S. government, and others.

Such disruptions and breaches of security could have a material and adverse effect on our business, prospects, operating results, and financial condition.

Risks Related to Our Common Stock

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

Mr. El-Hibri has the ability to control the election of the members of our Board of Directors through his ownership interests in our significant stockholders. As of February 29, 2012, Mr. El-Hibri was the beneficial owner of approximately 28% of our outstanding common stock. Because Mr. El-Hibri has significant influence over the election of the members of our board, and because of his substantial control of our capital stock, Mr. El-Hibri will likely have the ability to delay or prevent a change of control of us that may be favored by other directors or stockholders and otherwise exercise substantial control over all corporate actions requiring board or stockholder approval, including any amendment of our certificate of incorporation or by-laws. The control by Mr. El-Hibri may prevent other stockholders from influencing significant corporate decisions and may result in conflicts of interest that

could cause our stock price to decline.

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

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

These provisions include:

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

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

In addition, Section 203 of the General Corporation Law of Delaware prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns or within the last three years has owned 15% or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us.

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

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

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

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

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through February 29, 2012, our common stock has traded as high as $27.00 per share and as low as $4.40 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of our product candidates or those of our competitors and success in our research and development programs;
- decisions and procurement policies by the U.S. government affecting BioThrax and our biodefense product candidates;
- regulatory developments in the U.S. and foreign countries;
- public concern as to the safety of drugs developed by us or others;
- announcements of issuances of common stock or acquisitions by us;
- the announcement and timing of new product introductions by us or others;
- termination or delay of development program(s) by our collaborative partners, or delay in achievement of collaboration milestones;
- announcements of technological innovations or new therapeutic products or methods by us or others;
- acts or omissions of our licensees, collaborators and suppliers;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions or other external factors, such as disaster or crisis; and
- the other factors described in this "Risk Factors" section.

In the past, securities class action litigation often has been instituted following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in potential liabilities, substantial costs and the diversion of management's attention and resources, regardless of whether we win or lose.

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

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

A significant portion of our shares may be sold into the market at any time. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 8.8 million shares of our common stock outstanding as of February 29, 2011 have the right to require us to register these shares of common stock under specified circumstances.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

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

Location	Use	Segment	Approximate square feet	Owned/leased
Lansing, Michigan	Manufacturing operations facilities, office space and laboratory space	Biodefense	214,000	Owned
Baltimore, Maryland	Future manufacturing facilities and office and laboratory space	Biosciences	56,000	Owned
Gaithersburg, Maryland	Office and laboratory space	Biodefense	48,000	Owned
Seattle, Washington	Office and laboratory space	Biosciences	51,000	Lease expires 2013
Rockville, Maryland	Office space	Biodefense/Biosciences	41,000	Lease expires 2016
Munich, Germany	Office and laboratory space	Biosciences	16,000	Lease expires 2015
Wokingham, England	Office and laboratory space	Biosciences	8,000	Lease expires 2016
Frederick, Maryland	Held for sale	Biosciences	290,000	Owned

Lansing, Michigan. We own a multi-building campus on approximately 12.5 acres in Lansing, Michigan that includes facilities for bulk manufacturing of BioThrax, including fermentation, filtration and formulation, as well as for raw material storage and in-process and final product warehousing. It also includes Building 55, our 50,000 square foot large scale manufacturing facility. The campus is secured through perimeter fencing, limited and controlled ingress and egress and 24-hour on-site security personnel. We acquired these facilities in 1998 from the Michigan Biologic Products Institute. In December 2001, the FDA approved a supplement to our manufacturing facility license for the manufacture of BioThrax at the renovated facilities.

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

Other. We own or lease four separate product development facilities. Our facility in Gaithersburg, Maryland is approximately 48,000 square feet and contains a combination of laboratory and office space. Our facility in Seattle, Washington is approximately 51,000 square feet and contains a combination of laboratory and office space. Our facility in Munich, Germany is approximately 16,000 square feet and contains a combination of laboratory and office space. Our facility in Wokingham, England consists of approximately 8,000 square feet and contains primarily office space. Our facility in Rockville, Maryland contains approximately 41,000 square feet of office space, including our executive offices.

We own two buildings of approximately 145,000 square feet each on a 15-acre site in Frederick, Maryland. We are actively seeking to sell these facilities. Accordingly, we have classified these buildings as held for sale in our balance sheet, and have recorded impairment charges of approximately $1.0 million, $1.2 million and $7.3 million in 2011, 2010 and 2009, respectively, related to costs previously capitalized based on the difference between the carrying value of the assets and their estimated fair value less costs to sell.

ITEM 3. LEGAL PROCEEDINGS

Patent Oppositions. Our live attenuated modified vaccinia Ankara virus, or MVA, platform technology, which has the potential to be used as a viral vector for delivery of certain vaccine antigens for different disease-causing organisms, is based in part on rights to certain MVA-related materials and technology that we acquired from the Bavarian State Ministry of the Environment and Public Health. From 2006 to 2008, we filed patent oppositions in the European Patent Office against four of Bavarian Nordic's patents covering certain aspects of MVA technology. In each of the four pending opposition proceedings, the subject patents have also been opposed by one or more additional parties, including Sanofi Pasteur, Transgene, Baxter, Virbac and Innogenetics. We and the other opponents have alleged that the opposed patents should be revoked for failure to fulfill one or more of the patentability requirements of the European Patent Convention, such as the requirements for novelty and inventive step.

In each opposition, a single hearing was held before the Opposition Division of the European Patent Office, in which each opponent presented oral argument and Bavarian Nordic presented rebuttal arguments. The first of these hearings, which occurred in June 2010, resulted in the Bavarian Nordic patent under consideration being maintained but narrowed in scope. Hearings in two of the other pending oppositions occurred in October 2010. Bavarian Nordic introduced amended patent claims into the record, which claims were upheld strictly and expressly conditioned on such claims being interpreted within a narrowly-defined scope. The Opposition Division held its hearing for the fourth pending opposition in January 2011. As for the previous oppositions, Bavarian Nordic introduced amended patent claims into the record, and the Opposition Division upheld the amended claims, which are narrower in scope than the originally granted claims. We timely filed our appeal briefs for each of the foregoing oppositions and each remains pending on appeal. We routinely monitor the grant of further Bavarian Nordic European patents to determine whether any additional oppositions should be filed.

Other. From time to time, we are involved in product liability claims and other litigation considered normal in the nature of our business. We do not believe that any such proceedings would have a material adverse effect on the results of our operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information and Holders

Our common stock trades on the New York Stock Exchange under the symbol "EBS". The following table sets forth the high and low sales prices per share of our common stock during each quarter of the years ended December 31, 2011 and 2010:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year Ended December 31, 2011				
High	$25.07	$26.41	$22.84	$19.77
Low	$18.32	$20.44	$14.90	$15.14
Year Ended December 31, 2010				
High	$17.24	$17.30	$19.98	$23.93
Low	$13.22	$14.11	$14.86	$17.10

As of February 29, 2012, the closing price per share of our common stock on the New York Stock Exchange was $15.27 and we had 33 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend Policy

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Not applicable.

Purchases of Equity Securities

Not applicable.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

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

We have derived the consolidated statement of operations data for the years ended December 31, 2011, 2010 and 2009 and the consolidated balance sheet data as of December 31, 2011 and 2010 from our audited consolidated financial statements, which are included in this annual report on Form 10-K. We have derived the consolidated statements of operations data for the years ended December 31, 2008 and 2007 and the consolidated balance sheet data as of December 31, 2009, 2008 and 2007 from our audited consolidated financial statements, which are not included in this annual report on Form 10-K. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,				
(in thousands, except share and per share data)	2011	2010	2009	2008	2007
Statements of operations data:					
Revenues:					
Product sales	$202,409	$251,381	$217,172	$169,124	$169,799
Contracts and grants	70,975	34,790	17,614	9,430	13,116
Total revenues	273,384	286,171	234,786	178,554	182,915
Operating expenses:					
Cost of product sales	42,171	47,114	46,262	34,081	40,309
Research and development	124,832	89,295	74,588	59,470	53,958
Selling, general & administrative	74,282	76,205	73,786	55,076	55,555
Total operating expenses	241,285	212,614	194,636	148,627	149,822
Income from operations	32,099	73,557	40,150	29,927	33,093

Other income (expense):					
Interest income	105	832	1,418	1,999	2,809
Interest expense	-	-	(7)	(47)	(71)
Other income (expense), net	(261)	(1,023)	(50)	134	156
Total other income (expense)	(156)	(191)	1,361	2,086	2,894
Income before provision for income taxes	31,943	73,366	41,511	32,013	35,987
Provision for income taxes	15,830	26,182	14,966	12,055	13,051
Net income	$16,113	$47,184	$26,545	$19,958	$22,936
Net loss attributable to noncontrolling interest	6,906	4,514	4,599	724	-
Net income attributable to Emergent BioSolutions Inc.	$23,019	$51,698	$31,144	$20,682	$22,936
Earnings per share — basic	$0.65	$1.63	$1.02	$0.69	$0.79
Earnings per share — diluted	$0.64	$1.59	$0.99	$0.68	$0.77
Weighted average number of shares — basic	35,658,907	31,782,286	30,444,485	29,835,134	28,995,667
Weighted average number of shares — diluted	36,206,052	32,539,500	31,375,305	30,458,098	29,663,127

	As of December 31,				
(in thousands)	2011	2010	2009	2008	2007
Balance Sheet Data:					
Cash and cash equivalents	$143,901	$169,019	$102,924	$91,473	$105,730
Working capital	190,285	167,774	139,113	98,866	88,649
Total assets	546,864	500,319	344,689	290,788	273,508
Total long-term liabilities	59,083	51,039	46,173	37,418	46,688
Total stockholders' equity	416,727	373,561	243,815	199,349	171,159

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

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

Overview

Product Portfolio

We are a biopharmaceutical company focused on protecting and enhancing life by developing and manufacturing vaccines and therapeutics that are supplied to healthcare providers and purchasers for use in preventing and treating disease. For financial reporting purposes, we operate in two business segments, Biodefense and Biosciences.

Our Biodefense segment is directed to government-sponsored development and supply of countermeasures against potential agents of bioterror or biowarfare and targets the infectious disease anthrax. Our programs in this division include a pipeline of investigational product candidates and one marketed product, BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine approved by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax disease. Operations in this segment include biologics manufacturing, regulatory and quality affairs in support of BioThrax and a product development infrastructure in support of our investigational product candidates.

Our Biosciences segment is directed to commercial opportunities and targets oncology, including the B-cell malignancies chronic lymphocytic leukemia, or CLL, and non-Hodgkin's lymphoma, or NHL; the T-cell malignancies cutaneous T-cell lymphoma, or CTCL, and peripheral T-cell lymphoma, or PTCL; autoimmune and inflammatory disorders, or AIID, including rheumatoid arthritis, or RA, and systemic lupus erythematosus, or SLE; and infectious diseases such as tuberculosis and influenza. Our programs in this segment include clinical and preclinical stage investigational product candidates and development programs for our platform technologies. Operations in this segment include product development in support of our investigational product candidates, and manufacturing and related infrastructure initiatives in support of our technology platforms.

Our Biodefense segment has generated net income for each of the last five fiscal years. Over this timeframe, our Biosciences segment has generated revenue through development contracts and collaborative funding, but none of our Biosciences product candidates have received marketing approval and, therefore, our Biosciences segment has not generated any product sales revenues. As a result, our Biosciences segment has incurred a net loss for each of the last five fiscal years.

Product Sales

We have derived substantially all of our product sales revenues from BioThrax sales to the U.S. government. We are currently a party to a contract with the Centers for Disease Control and Prevention, or CDC, an operating division of the U.S. Department of Health and Human Services, or HHS, to supply 44.75 million doses of BioThrax for placement into the Strategic National Stockpile, or SNS, over a five year period. We expect for the foreseeable future to continue to derive substantially all of our product sales revenues from our sales of BioThrax to the U.S. government. Our total revenues from BioThrax sales were $202.4 million, $251.4 million and $217.2 million for the years ended December 31, 2011, 2010 and 2009, respectively. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers domestically and internationally and pursuing label expansions and improvements for BioThrax.

Contracts and Grants

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

§ BioThrax as a post-exposure prophylaxis, or PEP;
§ NuThrax;
§ Large-scale manufacturing for BioThrax;
§ PreviThrax;
§ Anthrivig;
§ Thravixa;
§ Double mutant recombinant protective antigen anthrax vaccine; and
§ Recombinant botulinum vaccine.

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

Developing Countries Clinical Trial Partnerships. Our SBI-087 product candidate is substantially funded by Pfizer Inc., or Pfizer, which is developing and commercializing SBI-087. Our TRU-016 product candidate has been funded via our collaboration with Abbott Laboratories, or Abbott, in which we and Abbott shared all funding responsibilities equally. In December 2011, Abbott notified us that they are terminating the collaboration agreement effective March 20, 2012.

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

Manufacturing Infrastructure

We conduct our primary vaccine manufacturing operations at a multi-building campus on approximately 12.5 acres in Lansing, Michigan. To augment our existing manufacturing capabilities, we have constructed Building 55, a 50,000 square foot large-scale manufacturing facility on our Lansing campus. In July 2010, we entered into an agreement with the Biomedical Advanced Research and Development Authority, or BARDA, to finalize development of and obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55. This agreement provides for funding from BARDA of up to approximately $107 million over a five-year contract term, including a two-year base period of performance valued at approximately $55 million.

In November 2009, we purchased a building in Baltimore, Maryland for product development and manufacturing purposes, and are in the process of completing renovation, improvement and equipment acquisitions at this facility. We have entered into two loan agreements with PNC Bank totaling up to $42.0 million to fund these renovations, improvements and equipment acquisitions. Our specific plans for this facility will be contingent on the progress of our existing development programs and the outcome of our efforts to acquire new product candidates.

Critical Accounting Policies and Estimates

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

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

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

Revenue Recognition

We recognize revenues from product sales if four basic criteria have been met:

- there is persuasive evidence of an arrangement;
- delivery has occurred or title has passed to our customer based on contract terms;
- the fee is fixed or determinable; and
- collectibility is reasonably assured.

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

From time to time, we are awarded reimbursement contracts for services and development grant contracts with government entities and philanthropic organizations. Under these contracts, we typically are reimbursed for our costs as we perform specific development activities, and we may also be entitled to additional fees. Revenue on our reimbursable contracts is recognized as costs are incurred, generally based on the allowable costs incurred during the period, plus any recognizable earned fee. The amounts that we receive under these contracts vary greatly from quarter to quarter, depending on the scope and nature of the work performed. We record the reimbursement of our costs and any associated fees as contracts and grants revenue and the associated costs as research and development expense.

We also generate revenues from our collaborations in which certain internal and external research and development costs and patent costs are reimbursed in connection with our collaboration agreements. Reimbursed costs under our agreement with Pfizer are recognized as revenue in the period in which the costs are incurred. Under the collaboration agreement with Abbott, which Abbott terminated effective March 20, 2012, Abbott shares development and clinical costs with us equally. Each quarter the parties are required to report the total costs incurred for development. The total spending by each party is then compared to the spending by the other party. In the event that our spending for a given quarter exceeds the spending of Abbott, we record a net receivable in our financial statements for the difference between our spending and 50% of the total spending for the period, and recognize revenue equal to this amount. If Abbott's spending for the quarterly period exceeds our spending, we record a net payable in our financial statements equal to the difference between our spending and 50% of the total spending, and record additional research and development expenses in this amount. As a result, our revenues and research and development expenses for periods that end prior to or include the termination date of the collaboration agreement may fluctuate depending on which party in the collaboration incurred the majority of the development costs in any particular quarterly period.

Contracts and grants revenues are subject to the estimation processes to the extent that the reimbursable costs underlying these revenues are incurred but not billed and agreed to on a timely basis, and are subject to change in future periods when actual costs are known. To date we have not made material adjustments to these estimates.

We recognize revenues from the achievement of research and development milestones, if deemed substantive, when the milestones are achieved. If not deemed substantive, we recognize revenue on a straight line basis over the remaining expected term of continued involvement in the research and development process.

Inventories

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

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

Income Taxes

Under the asset and liability method of income tax accounting, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax basis of assets and liabilities and are measured using the

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

We have historically incurred net operating losses for income tax purposes in some states, primarily Maryland, and in some foreign jurisdictions, primarily the United Kingdom. In connection with our October 2010 acquisition of Trubion Pharmaceuticals, Inc., or Trubion, we acquired significant federal net operating losses and research and development tax credits along with other tax attributes. The amount of the deferred tax assets on our balance sheet reflects our expectations regarding our ability to use our net operating losses and research and development tax credit carryforwards, including those acquired in our acquisition of Trubion, to offset future taxable income. The applicable tax rules in particular jurisdictions limit our ability to use net operating losses and research and development tax credit carryforwards as a result of ownership changes. In particular, we believe that these rules will significantly limit our ability to use net operating losses generated by Microscience Limited, or Microscience, and Antex Biologics, Inc., or Antex, prior to our acquisition of Microscience in June 2005 and our acquisition of substantially all of the assets of Antex in May 2003. We do not expect that these limitation rules will significantly limit the net operating losses and research and development tax credit carryforwards acquired in the Trubion acquisition.

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

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

Contingent Value Rights

In accordance with the terms of our acquisition of Trubion in October 2010, we have committed to make potential future contingent value right, or CVR, payments to former shareholders and stock option holders of Trubion. The obligation to make CVR payments expires on October 28, 2013. CVR payments generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. The obligation for these contingencies has been recorded in our financial statements at fair value. The fair value model used for the CVR obligations is based on a discounted cash flow model that has been risk adjusted based on the probability of achievement of the milestones. We re-evaluate the fair value of the CVR obligations on a quarterly basis. Any future increase in the fair value of the CVR obligations, based on an increased likelihood that the underlying milestones will be achieved and the associated payment or payments will therefore become due and payable, will result in a charge to research and development expense in the period in which the increase is determined. Similarly, any future decrease in the fair value of the CVR obligation will result in a reduction in research and development expense.

Acquired In-process Research and Development

Acquired in-process research and development, or IPR&D, represents the fair value assigned to research and development assets that we acquire that have not been completed at the date of acquisition. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flows to present value. The revenue and costs projections used to value acquired IPR&D were, as applicable, reduced based on the probability of developing a new product. Additionally, the projections considered the relevant market sizes and growth factors, expected trends in technology, and the nature and expected timing of new product introductions by us and our competitors. The resulting net cash flows from such projects are based on management's estimates of cost of sales, operating expenses, and income taxes from such projects. The rates utilized to discount the net cash flows to their present value were commensurate with the stage of development of the projects and uncertainties in the economic estimates used in the projections described above. We determine the fair values of these assets as of the acquisition date using discounted cash flow models. These models require the use of significant estimates and assumptions, including but not limited to:

- estimating the timing of and expected costs to complete the in-process projects;
- projecting regulatory approvals;
- estimating future cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates and probability rates by project.

We believe the fair values assigned to the IPR&D assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition date.

If these product candidates are not successfully developed, our sales and profitability will be adversely affected in future periods. Additionally, the value of the acquired IPR&D assets may become impaired. Our annual assessment includes a comparison of the fair value of IPR&D to our existing carrying value. We recognize an impairment when the carrying value is greater than the determined fair value. We believe that the assumptions used in valuing the IPR&D are reasonable and are based upon our best estimate of likely outcomes of our clinical development. The underlying assumptions and estimates used to value these IPR&D assets are subject to change in the future, and actual results may differ significantly from the assumptions and estimates. Our IPR&D assets are assessed on an annual basis for impairment or more frequently if indicators of impairment are present. We performed our annual assessment on October 1, 2011 and determined there was no impairment. On December 21, 2011, Abbott terminated our collaboration on TRU-016 effective March 20, 2012. In light of this termination, we performed an interim assessment and determined that there was no impairment of the TRU-016 IPR&D asset as of December 31, 2011.

Goodwill

We assess the carrying value of goodwill annually, or whenever events or changes in circumstances indicate the carrying value of goodwill may not be recoverable, to determine whether any impairment in this asset may exist and, if so, the extent of such impairment. The provisions of the relevant accounting guidance require that we perform a two-step impairment test. In the first step, we compare the fair value of our reporting unit to the carrying value of the reporting unit. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, then the second step of the impairment test is performed in order to determine the implied fair value of the reporting unit's goodwill. If the carrying value of the reporting unit's goodwill exceeds its implied fair value, an impairment loss equal to the difference is recorded and charged to general and administrative expense. We have determined that all of our goodwill is assigned to our Biosciences therapeutics reporting unit, which is a component of our Biosciences reporting segment.

We calculate the fair value of the reporting unit utilizing the income approach. The income approach utilizes a discounted cash flow model, using a discount rate based on our estimated weighted-average cost of capital. The results of the fair value calculations are then compared to our reporting unit's carrying value. We have selected October 1st as our annual impairment test date. We performed our annual assessment of goodwill at October 1, 2011 and determined

no impairment existed. On December 21, 2011 Abbott notified us that they were terminating our collaboration agreement effective March 20, 2012. In light of this termination, we performed an interim assessment and determined that there was no impairment of goodwill as of December 31, 2011.

The determination of the fair value of our reporting units is judgmental in nature and involves the use of significant estimates and assumptions. The estimates and assumptions used in calculating fair value include identifying future cash flows for ongoing development programming, which requires that we make a number of critical legal, economic, market and business assumptions that reflect our best estimates as of the testing date. Our assumptions and estimates may differ significantly from actual results, or circumstances could change that would cause us to conclude that an impairment exists or that we previously understated the extent of impairment review.

Stock-based Compensation

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

We determine the grant date fair value of restricted stock units using the closing market price of our common stock on the day prior to the date of grant. We utilize the Black-Scholes valuation model for estimating the grant date fair value of all stock options granted. We measure the amount of compensation cost based on the fair value of the underlying equity award on the date of grant. We recognize compensation cost over the period that an employee provides service in exchange for the award.

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

Financial Operations Overview

Revenues

On September 30, 2008, we entered into an agreement with HHS to supply up to 14.5 million doses of BioThrax for placement into the SNS. In April 2011, we entered into a modification to this contract to supply an additional 3.4 million doses at a value of up to $101 million. The term of the modified agreement was from September 30, 2008 through September 30, 2011. On September 28, 2011 we entered into a further modification of this contract that extended the period of performance of the contract at no additional cost, from September 30, 2011 to December 31, 2011. The total value of the modified contract for 17.9 million doses was approximately $500 million. As of December 31, 2011, we completed deliveries of doses under this agreement. We recognized revenue under the contract upon acceptance of each delivery of BioThrax doses to the SNS.

Effective September 30, 2011, we have a contract with the CDC to supply up to 44.75 million doses of BioThrax over a five-year period. The maximum amount that could be paid to us under the contract is up to $1.25 billion, subject to availability of funding. The period of performance under the award is from September 30, 2011 through September 29, 2016. We began delivery of doses under the contract in December 2011. Through December 31, 2011, we had delivered and, upon CDC acceptance, recognized revenue on approximately 750,000 doses under this contract.

We have received contract and grant funding from the National Institute of Allergy and Infectious Diseases, or NIAID, and BARDA for the following development programs:

Product Candidate/Manufacturing	Funding Source	Award Date	Performance Period

Anthrivig	NIAID	8/2006	8/2006 — 12/2011
Anthrivig	NIAID	9/2007	9/2007 — 12/2011
Recombinant botulinum vaccine	NIAID	6/2008	6/2008 — 5/2012
NuThrax	NIAID	7/2008	7/2008 — 6/2013
Thravixa	NIAID/BARDA	9/2008	9/2008 — 8/2012
NuThrax	NIAID/BARDA	9/2008	9/2008 — 7/2012
Double mutant recombinant protective antigen anthrax vaccine	NIAID	9/2009	9/2009 — 8/2012
Large-scale manufacturing for BioThrax	BARDA	7/2010	7/2010 — 7/2015
NuThrax	NIAID	7/2010	8/2010 — 8/2014
PreviThrax	BARDA	9/2010	9/2010 — 9/2015

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

Cost of Product Sales

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

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

Research and Development Expenses

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

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

We believe that significant investment in product development is a competitive necessity and plan to continue these investments in order to be in a position to realize the potential of our product candidates. We expect that spending for our product pipeline will increase as our product development activities continue based on ongoing advancement of our product candidates, and as we prepare for regulatory submissions and other regulatory activities. We expect that the magnitude of any increase in our research and development spending will be dependent upon such factors as the results from our ongoing preclinical studies and clinical trials, participation of third-party collaborators, number of product candidates under development, the size, structure and duration of any follow-on clinical programs that we

may initiate, costs associated with manufacturing our product candidates on a large-scale basis for later-stage clinical trials, and our ability to use or rely on data generated by government agencies, such as studies involving BioThrax conducted by the CDC.

Selling, General and Administrative Expenses

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

Total Other Income (Expense)

Total other income (expense) consists primarily of interest income and interest expense, and in 2010, a charge to reduce previously accrued interest income related to a settlement agreement with Protein Sciences Corporation, or PSC. We earn interest income on our cash, cash equivalents and in 2010, on a note receivable, and we incur interest expense on our indebtedness. We capitalize interest expense based on the cost of major ongoing projects which have not yet been placed in service, such as new manufacturing facilities. Some of our existing debt arrangements provide for increasing amortization of principal payments in future periods. See “Liquidity and Capital Resources — Debt Financing” for additional information.

Results of Operations

Year Ended December 31, 2011 Compared to Year Ended December 31, 2010

Revenues

Product sales revenues decreased by $49.0 million, or 19%, to $202.4 million for 2011 from $251.4 million for 2010. This decrease in product sales revenues was primarily due to a 21% decrease in the number of doses of BioThrax delivered. This decrease was due to the redeployment of our potency testing capacity from BioThrax release testing to qualification of replacement reference standards and other development testing during the first quarter of 2011, coupled with lower production yields in the period in which the doses were produced. Product sales revenues in 2011 consisted of BioThrax sales to HHS and the CDC of $200.9 million and aggregate international and other sales of $1.5 million. Product sales revenue in 2010 consisted of BioThrax sales to HHS of $248.5 million and aggregate international and other sales of $2.9 million.

Contracts and grants revenues increased by $36.2 million, or 104%, to $71.0 million in 2011 from $34.8 million in 2010. The increase in contracts and grants revenues was primarily due to revenues from our contract with BARDA for large-scale manufacturing for BioThrax and our collaborations with Abbott and Pfizer, along with increased activity and associated revenue from our development contracts with NIAID and BARDA for NuThrax and PreviThrax. Contracts and grants revenues in 2011 consisted of $48.6 million in development contract and grant revenue from NIAID and BARDA, $22.1 million from Abbott and Pfizer and $250,000 from the Wellcome Trust. Contracts and grants revenue for 2010 primarily consisted of $30.6 million from NIAID and BARDA, $2.2 million from Abbott and Pfizer, $1.2 million related to the U.S. government’s Therapeutic-Discovery Project Program and $750,000 from a milestone payment related to the 2008 sale of technology rights and related materials to our pertussis technology.

Cost of Product Sales

Cost of product sales decreased by $4.9 million, or 10%, to $42.2 million for 2011 from $47.1 million for 2010. This decrease was attributable to the 21% decrease in the number of BioThrax doses sold, partially offset by an increase in the cost per dose sold associated with decreased production yields in the period in which the doses were produced.

Research and Development Expenses

Research and development expenses increased by $35.5 million, or 40%, to $124.8 million for 2011 from $89.3 million for 2010. This increase primarily reflects higher contract service and personnel-related costs, and includes increased expenses of $30.0 million for product candidates and technology platform development activities that are categorized in the Biosciences segment, increased expenses of $4.0 million for product candidates that are categorized in the Biodefense segment, and increased expenses of $1.6 million in other research and development, which are in support of central research and development activities. During 2011 and 2010, we incurred research and development expenses net of development contract and grant reimbursements along with the net loss attributable to noncontrolling interests of $47.0 million and $50.0 million, respectively.

The increase in spending on Biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials. The increase in spending for NuThrax was due to manufacturing, process characterization, assay validation and the conduct of clinical trial activities. The increase in spending for our large-scale manufacturing for Biothrax program was primarily due to characterization assay development, validation activities and manufacturing that increased subsequent to the associated development contract award in July 2010. The spending for BioThrax related programs was related to clinical and non-clinical studies to support applications for marketing approval of these programs. The increase in spending for PreviThrax was primarily due to formulation development, stability studies and model optimization subsequent to the associated development contract awarded in September 2010. The decrease in spending for Anthrivig was primarily due to the timing of a clinical trial and animal model development. The decrease in spending for Thravixa was primarily due to the timing of process development, non-clinical studies and animal model development. The decrease in spending for our other biodefense activities was primarily due to decreased spending associated with our double mutant recombinant protective antigen anthrax vaccine in light of reduced funding by the U.S. government for this product candidate. As such, we expect that spending for our double mutant recombinant protective antigen anthrax vaccine will be minimal in the future.

The increase in spending on Biosciences product candidates, detailed in the table below, was primarily attributable to the timing of development efforts and the acquisition of certain Biosciences product candidates. The increase in spending for our tuberculosis vaccine product candidate is related to the costs incurred for the continued conduct of a Phase IIb clinical trial along with process development and manufacturing activities. The increase in spending for our TRU-016, ES-301 and X1 product candidates, is a result of our October 2010 acquisition of Trubion and its development programs for product candidates to treat certain autoimmune disorders and oncology, and is primarily related to clinical trials, process development and manufacturing costs. In December 2011, Abbott terminated our collaboration for the development and commercialization of TRU-016 effective March 20, 2012. As a result of this termination, Abbott will no longer share the cost of ongoing development, and as such we anticipate that our costs for this program will increase. The spending for our zanolimumab product candidate was primarily for upfront and milestone payments related to the May 2011 acquisition of certain assets of TenX BioPharma, Inc. The decrease in spending for our influenza vaccine product candidate is related to the timing of process and analytical development. The decrease in spending for Typhella was primarily due to the substantial completion of manufacturing and clinical studies. We have significantly reduced ongoing spending with regard to Typhella while we investigate options to sell or outlicense the related technology, and we expect that future spending will further be reduced. The increase in spending for our other Biosciences activities was primarily due to increased spending associated with development of platform technologies along with preclinical product candidates as a result of our acquisition of Trubion.

The spending for other research and development activities was primarily due to central research and development activities not attributable to product candidates.

Our principal research and development expenses for 2011 and 2010 are shown in the following table:

(in thousands)	Year ended December 31, 2011	2010
Biodefense:		
NuThrax	$11,632	$9,876
Large-scale manufacturing for BioThrax	13,138	9,099
BioThrax related programs	6,961	7,201
PreviThrax	14,404	3,767
Anthrivig	2,608	5,937
Thravixa	3,460	8,148
Other Biodefense	2,363	6,585
Total Biodefense	54,566	50,613
Biosciences:		
Tuberculosis vaccine	19,025	13,690
TRU-016	13,500	2,205
ES-301 (formerly DRACO)	7,172	693
X1	3,376	-
Zanolimumab	4,820	-
Influenza vaccine	2,520	4,088
Typhella	1,271	3,398
Other Biosciences	12,723	10,338
Total Biosciences	64,407	34,412
Other	5,859	4,270
Total	$124,832	$89,295

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $1.9 million, or 3%, to $74.3 million for 2011 from $76.2 million for 2010. This decrease is primarily due to reduced spending related to professional services partially offset by increased personnel costs. The majority of the expense is attributable to the Biodefense segment, in which selling, general and administrative expenses increased by $293,000, or 1%, to $52.4 million during 2011 from $52.1 million during 2010. Selling, general and administrative expenses related to our Biosciences segment decreased by $2.2 million, or 9%, to $21.9 million during 2011 from $24.1 million during 2010.

Total Other Income (Expense)

Total net other expense decreased by $35,000, or 18%, to $156,000 for 2011 from $191,000 for 2010. The net decrease was due primarily to a reduction in interest income recorded related to our note receivable from PSC offset by a 2010 charge to reduce previously accrued interest income related to the settlement with PSC in October 2010.

Income Taxes

Provision for income taxes decreased by $10.4 million, or 40%, to $15.8 million for 2011 from $26.2 million for 2010. The provision for income taxes for 2011 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of $38.9 million and an effective annual tax rate of approximately 41%. The provision for income taxes for 2010 resulted primarily from our income before provision for income taxes

and the loss attributable to noncontrolling interest of $77.9 million and an effective annual tax rate of approximately 34%. The increase in the effective annual tax rate is primarily related to the timing of deductions related to our large scale manufacturing facility and the utilization of state net operating losses. The provision for income taxes also reflects research and development tax credits of $1.4 million for 2011 and $1.8 million for 2010.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest increased by $2.4 million, or 53%, to $6.9 million for 2011 from $4.5 million for 2010. The increase resulted primarily from the timing of clinical and development activities and related expenses incurred by our joint ventures. These amounts represent the portion of the losses incurred by the joint ventures for the years ended December 31, 2011 and 2010, respectively, that is attributable to our joint venture partners.

Year Ended December 31, 2010 Compared to Year Ended December 31, 2009

Revenues

Product sales revenues increased by $34.2 million, or 16%, to $251.4 million for 2010 from $217.2 million for 2009. This increase in product sales revenues was primarily due to a 15% increase in the number of doses of BioThrax delivered. Product sales revenue in 2010 consisted of BioThrax sales to HHS of $248.5 million and aggregate international and other sales of $2.9 million. Product sales revenues in 2009 consisted of BioThrax sales to HHS of $216.4 million and aggregate international and other sales of $703,000.

Contracts and grant revenues increased by $17.2 million, or 98%, to $34.8 million in 2010 from $17.6 million in 2009. The increase in contracts and grants revenue was primarily due to revenues from our large-scale manufacturing for BioThrax contract and our collaborations with Abbott and Pfizer along with increased activity and associated revenue from our development contracts with NIAID and BARDA for NuThrax, PreviThrax, and our double mutant recombinant protective antigen anthrax vaccine. Contracts and grants revenue for 2010 primarily consisted of $30.6 million from NIAID and BARDA, $2.2 million from Abbott and Pfizer, $1.2 million related to the U.S. government's Therapeutic-Discovery Project Program and $750,000 from a milestone payment related to the 2008 sale of technology rights and related materials to our pertussis technology. Contracts and grants revenues for 2009 consisted of $17.4 million in development contract revenue from NIAID and BARDA and $211,000 from Sanofi Pasteur under a collaboration agreement that was terminated in December 2008.

Cost of Product Sales

Cost of product sales increased by $852,000, or 2%, to $47.1 million for 2010 from $46.3 million for 2009. This increase was primarily attributable to the 15% increase in the number of BioThrax doses sold, substantially offset by a decrease in cost per dose sold associated with increased production yield in the period during which the doses sold were produced.

Research and Development Expenses

Research and development expenses increased by $14.7 million, or 20%, to $89.3 million for 2010 from $74.6 million for 2009. This increase primarily reflects higher contract service and personnel-related costs, and includes increased expenses of $7.2 million for product candidates and technology platform development activities that are categorized in the Biosciences segment, increased expenses of $7.7 million for product candidates that are categorized in the Biodefense segment, and decreased expenses of $217,000 in other research and development, which are in support of central research and development activities. During 2010 and 2009, we incurred research and development expenses net of development contract and grant reimbursements along with the net loss attributable to noncontrolling interests of $50.0 million and $52.4 million, respectively.

The increase in spending on Biodefense product candidates, detailed in the table below, was primarily attributable to the timing of development efforts on various programs as we completed various studies and prepared for subsequent studies and trials. The increase in spending for our NuThrax program was due to the conduct of stability and clinical studies along with potency assay development. The increase in spending for our large-scale manufacturing for Biothrax program was primarily due to characterization assay and process development that increased subsequent to the associated development contract award in July 2010. The decrease in spending for BioThrax related programs was related to timing of clinical and non-clinical studies to support applications for marketing approval of these programs. The decrease in spending for our PreviThrax product candidate was primarily due to reduced spending while awaiting a development contract award from BARDA, which we received in September 2010. The spending for our Anthrivig product candidate was primarily for clinical studies, model development and regulatory activities. The spending for our Thravixa product candidate was primarily due to process and formulation development along with safety studies. The increase in spending for our double mutant recombinant protective antigen anthrax vaccine product candidate resulted from spending for process manufacturing and assay development. The 2009 spending for our botulinum vaccine product candidates resulted from conducting non-clinical studies.

The increase in spending on Biosciences product candidates, detailed in the table below, was primarily attributable to the timing of development efforts partially offset by the termination or scaling back of certain programs. The increase in spending for our tuberculosis vaccine product candidate is related to the costs incurred for the continued conduct of a Phase IIb clinical trial, which commenced in April 2009. The increase in spending for our TRU-016 and SBI-087 product candidates, primarily for clinical studies and manufacturing costs, is due to our October 2010 acquisition of Trubion and its development programs for product candidates to treat certain autoimmune disorders and cancer, including RA, SLE, CLL and NHL. The increase in spending for our influenza vaccine product candidate is related to process and analytical development. The decrease in spending for Typhella was primarily due to the timing of stability and clinical studies. The increase in spending for our other Biosciences activities was due to increased spending associated with development of platform technologies along with preclinical product candidates that we acquired in the acquisition of Trubion.

The spending for other research and development activities was primarily due to central research and development activities not attributable to product candidates.

Our principal research and development expenses for 2010 and 2009 are shown in the following table:

	Year ended December 31,	
(in thousands)	2010	2009
Biodefense:		
NuThrax	$9,876	$5,543
Large-scale manufacturing for BioThrax	9,099	1,881
BioThrax related programs	7,201	8,324
PreviThrax	3,767	8,450
Anthrivig	5,937	6,890
Thravixa	8,148	7,215
Double mutant recombinant protective antigen	5,938	560
Botulinum vaccines	647	4,027
Total Biodefense	50,613	42,890
Biosciences:		
Tuberculosis vaccine	13,690	11,710
TRU-016	2,205	-
ES-301 (formerly DRACO)	693	-
Influenza vaccine	4,088	3,653

Typhella	3,398	5,083
Other Biosciences	10,338	6,765
Total Biosciences	34,412	27,211
Other	4,270	4,487
Total	$89,295	$74,588

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $2.4 million, or 3%, to $76.2 million for 2010 from $73.8 million for 2009. This increase includes increased personnel and professional services to support the business, along with approximately $3.1 million in costs related to a restructuring of the Company's U.K. operations and approximately $2.8 million in transaction costs related to the acquisition of Trubion. These increases are partially offset by a $6.1 million decrease in impairment charges related to the Frederick buildings and lower legal service costs due primarily to the settlement of the PSC litigation. The majority of the expense is attributable to the Biodefense segment, in which selling, general and administrative expenses increased by $3.2 million, or 7%, to $52.1 million for 2010 from $48.9 million for 2009. Selling, general and administrative expenses related to our Biosciences segment decreased by $793,000, or 3%, to $24.1 million for 2010 from $24.9 million for 2009.

Total Other Income (Expense)

Total other income (expense) decreased by $1.6 million, or 114%, to an expense of $191,000 for 2010 from income of $1.4 million for 2009. The decrease was due primarily to reduced interest income and a charge of approximately $1.0 million to reduce previously accrued interest income related to the settlement with PSC.

Income Taxes

Provision for income taxes increased by $11.2 million, or 75%, to $26.2 million for 2010 from $15.0 million for 2009. The provision for income taxes for 2010 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of $77.9 million and an effective annual tax rate of approximately 34%. The provision for income taxes for 2009 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of $46.1 million and an effective annual tax rate of approximately 32%. The provision for income taxes also reflects research and development tax credits of $1.8 million for 2010 and $835,000 for 2009.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest decreased by $85,000, or 2%, to $4.5 million for 2010 from $4.6 million for 2009. The spending was primarily from clinical and development activities and related expenses incurred by our joint venture with the University of Oxford. These amounts represent the portion of the loss incurred by the joint venture for the years ended December 31, 2010 and 2009, respectively, that is attributable to the University of Oxford.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our cash requirements from inception through 2011 principally with a combination of revenues from BioThrax product sales, debt financings and facilities leases, development funding from government entities and non-government and philanthropic organizations and collaborative partners, the net proceeds from our initial public offering and from the sale of our common stock upon exercise of stock options. We have operated profitably for each of the five years ended December 31, 2011.

As of December 31, 2011, we had cash, cash equivalents and investments of $145.9 million. Additionally, at December 31, 2011, our accounts receivable balance was $74.2 million.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2011, 2010 and 2009.

	Year ended December 31,		
(in thousands)	2011	2010	2009
Net cash provided by (used in):			
Operating activities(1)	$14,594	$98,909	$29,894
Investing activities	(53,963)	(23,456)	(33,287)
Financing activities	14,251	(9,358)	14,844
Total net cash provided by (used in)	$(25,118)	$66,095	$11,451

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

Net cash provided by operating activities of $14.6 million in 2011 was principally due to our net income attributable to Emergent BioSolutions Inc. of $23.0 million, a net increase in income taxes of $21.6 million related to timing differences, non-cash charges of $10.7 million for stock-based compensation, $9.4 million for depreciation and amortization, and $5.3 million for development expenses primarily from our joint ventures partially offset by a decrease in accounts receivable of $34.8 million due to the timing of collection of amounts billed primarily to HHS and a decrease in deferred revenue of $10.9 million primarily from our Abbott collaboration.

Net cash provided by operating activities of $98.9 million in 2010 was due principally to net income attributable to Emergent BioSolutions Inc. of $51.7 million, a decrease in accounts receivable of $19.1 million due to the timing of collection of amounts billed primarily to HHS, a net increase in income taxes related to timing differences of $4.8 million, a $6.2 million increase in accrued compensation and non-cash charges of $7.1 million for stock-based compensation, $6.0 million for depreciation and amortization, and $6.0 million for development expenses from our joint ventures.

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

Net cash used in investing activities in 2011 was $54.0 million, primarily due to capital expenditures of $54.0 million related to the construction and related costs for our facility in Baltimore, Maryland, and infrastructure investments and other equipment, along with the purchase of U.S. Treasury securities of $4.2 million, partially offset by proceeds from the maturity of U.S. Treasury securities of $4.3 million.

Net cash used in investing activities of $23.5 million for the year ended December 31, 2010 was primarily due to capital expenditures of approximately $22.1 million for validation and qualification activities for Building 55 and build-out activities for our Baltimore, Maryland facility and infrastructure investments and other equipment along with net cash paid to acquire Trubion of $17.9 million, partially offset by the repayment of $10.0 million for the PSC note receivable and proceeds from the sale of investments of approximately $6.5 million.

Net cash used in investing activities of $33.3 million for the year ended December 31, 2009 was primarily due to the capital expenditures of $8.2 million for the purchase of our Baltimore facility, $6.4 million for the purchase of our Gaithersburg facility, $7.6 million in construction and related costs for our new manufacturing facility in Lansing, Michigan and approximately $11.1 million in infrastructure investments and other equipment.

Net cash provided by financing activities of $14.3 million in 2011 resulted primarily from $27.5 million in advances under our construction and equipment loans with PNC Bank related to the renovation, improvement and equipment purchase at our Baltimore facility, $10.0 million in proceeds from stock option exercises and $2.2 million related to excess tax benefits from the exercise of stock options, partially offset by $15.5 million in principal payments on indebtedness and a $10.0 million CVR payment to former Trubion stockholders and option holders.

Net cash used in financing activities of $9.4 million for 2010 resulted primarily from $33.3 million in principal payments on indebtedness, including $30.0 million in payments on our revolving line of credit with Fifth Third Bank, partially offset by $15.0 million in proceeds from borrowings under our revolving line of credit with Fifth Third Bank, $7.2 million in proceeds from stock option exercises and $1.7 million related to excess tax benefits from the exercise of stock options.

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

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2011:

		Payments due by period					
(in thousands)	Total	2012	2013	2014	2015	2016	After 2016
Contractual obligations:							
Long-term indebtedness including current portion	$59,454	$5,360	$7,518	$21,505	$1,072	$1,108	$22,891
Operating lease obligations	9,913	3,188	2,233	1,773	1,583	1,136	-
Total contractual obligations	$69,367	$8,548	$9,751	$23,278	$2,655	$2,244	$22,891

There are a number of uncertainties that we face in the development of new product candidates that prevent us from making a reasonable estimate of the cash obligations under our material license and collaboration agreements. Because of these uncertainties, the preceding table excludes contingent contractual payments that we may become obligated to make under such agreements. These agreements typically provide for the payment of milestone fees upon achievement of specified research, development and commercialization milestones, such as the commencement of clinical trials, the receipt of funding awards, the receipt of regulatory approvals, and the achievement of sales milestones. The amount of contingent contractual milestone payments that we may become obligated to make is variable based on the actual achievement and timing of the applicable milestones and the characteristics of any products or product candidates that are developed, including factors such as number of products or product candidates developed, type and number of components of each product or product candidate, ownership of

the various components and the specific markets affected, and the aggregate payments could be as much as approximately $179 million. The success of our efforts to commercialize our product candidates depends on many factors, including those set forth in "Risk Factors—Our business depends significantly on our success in completing development and commercialization of our product candidates at acceptable costs" and is highly uncertain. Even if these efforts are successful, the timing of success is highly unpredictable and variable. The same is true for any contingent contractual royalty payments that we may be obligated to make upon successful commercialization of these product candidates. We do not expect that any such payments would have an adverse effect on our financial position, operations and capital resources because, if payable, we expect that the benefits associated with the achievement of the relevant milestones or the achievement of revenue would offset the burden of making these payments. We are not obligated to pay any minimum royalties under our existing contracts.

Debt Financing

As of December 31, 2011, we had $59.5 million principal amount of debt outstanding, comprised primarily of the following:

- § $2.5 million outstanding under a loan from the Department of Business and Economic Development of the State of Maryland used to finance eligible costs incurred to purchase our first facility in Frederick, Maryland;
- § $5.3 million outstanding under a mortgage loan from PNC Bank used to finance the remaining portion of the purchase price for our first Frederick facility;
- § $19.7 million outstanding under a term loan from HSBC Realty Credit Corporation used to finance a portion of the costs of our facility expansion in Lansing, Michigan;
- § $4.5 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance a portion of the purchase price of our facility in Gaithersburg, Maryland;
- § $26.1 million outstanding under a construction loan from PNC Bank used to fund the ongoing renovation of our Baltimore, Maryland facility; and
- § $1.4 million outstanding under an equipment loan from PNC Bank used to fund equipment purchases at our Baltimore, Maryland facility.

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

- § Under our loan from the State of Maryland, we were not required to repay the principal amount of the loan if we maintained a specified number of employees at the Frederick site, if we invested at least $42.9 million in total funds toward financing the purchase of the buildings on the site and for related improvements and operation of the facility, and if we occupied the facility through 2012. Our plans for this facility have changed, and we currently plan to sell both Frederick buildings. As such we have not met the requirements for the loan to be forgivable. We have reached an agreement with the State of Maryland to repay the loan in full by March 31, 2012, with an earlier repayment due upon sale of the building.
- § Under our mortgage loan from PNC Bank for our Frederick facility, we are required to maintain at all times a minimum tangible net worth of not less than $5.0 million. In addition, we are required to maintain at all times a ratio of earnings before interest, taxes, depreciation and amortization to the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable within the following 12 months, of not less than 1.1 to 1.0.
- § Under our term loan with HSBC Realty Credit Corporation to finance a portion of the costs of our facility expansion in Lansing, Michigan, we are required to maintain on an annual basis a book leverage ratio of less than 1.00. In addition, we are required to maintain on a quarterly basis a debt coverage ratio of not less than 1.25 to 1.00.
- § Under our mortgage loan with HSBC Realty Credit Corporation for our Gaithersburg facility, we are required to maintain on an annual basis a book leverage ratio of less than 1.00. In addition, we are required to maintain on a quarterly basis a debt coverage ratio of not less than 1.25 to 1.00.
- § Under our mortgage loan with HSBC Realty Credit Corporation for our Baltimore facility, we are required to maintain on an annual basis a book leverage ratio of less than 1.00. In addition, we are required to maintain on a

quarterly basis a debt coverage ratio of not less than 1.25 to 1.00.

- § Under our construction and equipment loans with PNC Bank to finance a portion of the construction costs and equipment purchases of our facility expansion in Baltimore, Maryland, we are required to maintain on a rolling four-quarter basis a leverage ratio of less than 2.00 and a debt coverage ratio of not less than 1.25 to 1.00. In addition, we are required to maintain at all times a minimum cash balance of $50.0 million.

Our debt instruments also contain negative covenants restricting our activities. Our term loan with HSBC Realty Credit Corporation limits the ability of Emergent BioDefense Operations LLC to incur indebtedness and liens, sell assets, make loans, advances or guarantees, enter into mergers or similar transactions and enter into transactions with affiliates. Our construction and equipment loans from PNC Bank limits our ability to incur indebtedness, make loans and enter into mergers or similar transactions.

The facilities and other equipment that we purchased with the proceeds of our loans from PNC Bank, the State of Maryland and HSBC Realty Credit Corporation serve as collateral for these loans. Our term loan with HSBC Realty Credit Corporation is secured by substantially all of Emergent BioDefense Operations Lansing LLC assets, other than accounts receivable under our BioThrax supply contracts. Our construction loan with PNC Bank is secured by our Baltimore building along with Emergent BioDefense Operations Lansing LLC's accounts receivable under our BioThrax supply contracts. Our equipment loan with PNC Bank is secured by the equipment purchased for our Baltimore facility. The covenants under our existing debt instruments and the pledge of our existing assets as collateral limit our ability to obtain additional debt financing.

Under our mortgage loan from PNC Bank, which we modified in October 2011, the fixed annual interest rate is 3.48% and a monthly payment of $64,000. All unpaid principal and interest is due in full in October 2013. A residual principal payment of approximately $4.2 million is due upon maturity in October 2013.

Under our term loan with HSBC Realty Credit Corporation, which we refinanced in December 2009, we are required to make monthly principal payments of $126,000. A residual principal payment of approximately $15.3 million is due upon maturity in December 2014. Interest is payable monthly and accrues at an annual rate equal to the three month LIBOR plus 3.25%.

Under our mortgage loan from HSBC Realty Credit Corporation to purchase our Gaithersburg facility, we are required to make monthly principal payments of $28,000. A residual principal payment of approximately $3.5 million is due upon maturity in November 2014. Interest is payable monthly and accrues at an annual rate equal to the three month LIBOR plus 3.25%.

Under our construction loan from PNC Bank to finance a portion of the construction and renovation costs at our Baltimore, Maryland facility, we are required to make monthly interest only payments through July 2012. Beginning in July 2012, we will be required to make monthly payments of principal and interest based upon a 20-year amortization schedule with a balloon payment for the remaining unpaid principal and interest due in July 2017. Interest is payable monthly and accrues at an annual rate equal to the LIBOR plus 3.0%.

Under our equipment loan from PNC Bank to finance a portion of the equipment purchase for our Baltimore, Maryland facility, we are required to make monthly interest only payments through August 2012. Beginning is August 2012, we will be required to make monthly payments of principal and interest based on a 10-year amortization schedule with a balloon payment for the remaining principal and interest due in August 2017.

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures and debt service requirements from existing cash and cash equivalents, revenues from BioThrax product sales, collaboration funding, development contract and grant funding, and any lines of credit we may establish from time to time. There are numerous risks and

uncertainties associated with BioThrax product sales and with the development and commercialization of our product candidates. We may seek additional external financing to provide additional financial flexibility. Our future capital requirements will depend on many factors, including:

- the level and timing of BioThrax product sales and cost of product sales;
- our ability to obtain funding from government entities and non-government and philanthropic organizations for our development programs;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the timing of, and the costs involved in, completion of qualification and validation activities related to Building 55, our large-scale manufacturing facility in Lansing, Michigan, the build out of our facility in Baltimore, Maryland, and any other new facilities;
- the scope, progress, results and costs of our preclinical and clinical development activities;
- the costs, timing and outcome of regulatory review of our product candidates;
- the number of, and development requirements for, other product candidates that we may pursue;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the market acceptance and sales growth of any of our products and product candidates upon regulatory approval;
- the extent to which our growth generates increased administrative costs;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs, including litigation costs and the results of such litigation;
- the extent to which we acquire or invest in companies, businesses, products or technologies; and
- the effect of technological and market developments.

We may require additional sources of funds for future acquisitions that we may make or, depending on the size of the obligation, to meet balloon payments upon maturity of our current borrowings. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Current economic conditions may make it difficult to obtain financing on attractive terms or at all. Lenders may be able to impose covenants on us that could be difficult to satisfy, which could put us at increased risk of defaulting on debt. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

Our ability to borrow amounts under any line of credit we may establish will likely be subject to our satisfaction of specified conditions. Additional equity or debt financing, grants, or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that may not be favorable to us.

Recent Accounting Pronouncements

In December 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2011-12 which deferred certain amendments under ASU 2011-05 related to the presentation of reclassification updates. This amendment is effective for fiscal years, and interim periods within those years, after December 15, 2011. We do not anticipate this amendment will have a material impact on our financial statements.

In September 2011, the FASB issued ASU No. 2011-08, which amended ASC Topic 350 regarding testing goodwill for impairment. The amendments in ASU No. 2011-08 states an entity has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads to a determination that it is more likely than not

that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, an entity determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. These amendments are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. We do not anticipate this amendment will have a material impact on our financial statements.

In June 2011, the FASB issued ASU No. 2011-05, which amended ASC Topic 220 regarding presentation of comprehensive income. The amendments in ASU No. 2011-05 require that all nonowner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In the two-statement approach, the first statement should present total net income and its components followed consecutively by a second statement that should present total other comprehensive income, the components of other comprehensive income, and the total of comprehensive income. This amendment is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We do not anticipate this amendment will have a material impact on our financial statements.

In May 2011, the FASB issued ASU No. 2011-04 which amended ASC Topic 820 to achieve common fair value measurements and disclosure requirements in U.S. GAAP and International Financial Reporting Standards, or IFRS. The amendments in ASU No. 2011-05 result in common fair value measurement and disclosure requirements in U.S. GAAP and IFRSs. Consequently, the amendments change the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. This amendment is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We do not anticipate this amendment will have a material impact on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is currently confined to our cash and cash equivalents and restricted cash that have maturities of less than three months, our investments, and our long-term indebtedness. We currently do not hedge interest rate exposure or foreign currency exchange exposure, and the movement of foreign currency exchange rates could have an adverse or positive impact on our results of operations. We have not used derivative financial instruments for speculation or trading purposes. Because of the short-term maturities of our cash and cash equivalents and the small amount of our non-cash investments, which equaled $2.0 million at December 31, 2011, we believe that an increase in market rates would likely not have a significant impact on the realized value of our investments, but any increase in market rates would likely increase the interest expense associated with our debt.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm on the Consolidated Financial Statements

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

We have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. and Subsidiaries as of December 31, 2011 and 2010, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about

whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Emergent BioSolutions Inc. and Subsidiaries at December 31, 2011 and 2010, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2011, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Emergent BioSolutions Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 9, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia
March 9, 2012

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

	December 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$143,901	$169,019
Investments	1,966	2,029
Accounts receivable	74,153	39,326
Inventories	14,661	12,722
Deferred tax assets, net	1,735	2,638
Income tax receivable, net	9,506	8,728
Restricted cash	220	217
Prepaid expenses and other current assets	8,276	8,814
Total current assets	254,418	243,493
Property, plant and equipment, net	208,973	152,701
In-process research and development	51,400	51,400
Goodwill	5,502	5,029
Assets held for sale	11,765	12,741
Deferred tax assets, net	13,999	33,757
Other assets	807	1,198
Total assets	$546,864	$500,319
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$40,530	$25,409
Accrued expenses and other current liabilities	1,170	1,309
Accrued compensation	20,884	23,975
Contingent value rights, current portion	1,748	-
Long-term indebtedness, current portion	5,360	17,187
Deferred revenue, current portion	1,362	7,839
Total current liabilities	71,054	75,719
Contingent value rights, net of current portion	3,005	14,532
Long-term indebtedness, net of current portion	54,094	30,239
Deferred revenue, net of current portion	-	4,386
Other liabilities	1,984	1,882
Total liabilities	130,137	126,758
Commitments and contingencies		
Stockholders’ equity:		