UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2010

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 ☒

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

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

Indicate by check mark 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 ☐ 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 ☒ 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 ☒

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2010 was approximately $274 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 March 4, 2011, the registrant had 35,127,954 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2011 annual meeting of stockholders scheduled to be held on May19, 2011, 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, 2010, 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 2011 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™, *spi*-VEC™, MVAtor™, SMIP™, SCORPION™, TRU-ADhanCe™ and Typhella™ are 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, 2010
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K and the documents incorporated by reference herein contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risks and uncertainties. All statements, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," "would" and similar 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 for sales of 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 new contracts or modifications to existing contracts with the U.S. government;
- our plans to pursue label expansions and improvements for BioThrax;
- our ability to perform under our development contract with the U.S. government for our product candidate PreviThrax™ (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 preclinical studies and clinical trials of our product candidates and post-approval clinical utility of our products;
- our ongoing and planned development programs, preclinical studies and clinical trials;
- our ability to identify and acquire or in-license products and product candidates that satisfy our selection criteria;
- our ability to successfully integrate and develop the products or product candidates, programs, operations and personnel of any entities or businesses that we acquire, including those of Trubion Pharmaceuticals, Inc., which we acquired in October 2010;
- the potential benefits of our existing collaborations and our ability to selectively enter into additional collaborative arrangements;
- 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, 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 antibody 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.

Our BioDefense Division is directed to government-sponsored development and procurement of countermeasures against potential agents of bioterror or biowarfare and targets the infectious disease anthrax. Our programs in this division include a strong 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, marketing and sales 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, including B-cell malignancies chronic lymphocytic leukemia, or CLL, and non-Hodgkin's lymphoma, or NHL; autoimmune and inflammatory disorders, or AIID, including rheumatoid arthritis, or RA, and systemic lupus erythematosus, or SLE; and other infectious diseases such as tuberculosis, influenza and typhoid. 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 primarily through reinvestment of internally generated cash flows, which are a result of product sales of BioThrax, primarily to the U.S. government. Our product development efforts are also largely supported by financing from external sources, which both offsets our development costs and creates a dynamic of shared interest with our funding sources. In our BioDefense Division, our anthrax programs 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, our oncology programs are supported in part through funding from a third-party collaborator and our most advanced AIID product candidate is supported entirely through funding from another third-party collaborator.

We have derived substantially all of our product revenues from sales of BioThrax to the U.S. government, specifically and most notably the U.S. Department of Health and Human Services, or HHS, as well as the U.S. Department of Defense, or DoD. 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 $251.4 million in 2010, $217.2 million in 2009 and $169.1 million in 2008. 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 label expansions and improvements for BioThrax.

Contracts and grants revenues reflect development funds paid to us through funding arrangements with governmental and non-governmental agencies and philanthropic organizations. Revenues from contracts and grants were $34.8 million in 2010, $17.6 million in 2009 and $9.4 million in 2008. 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. In addition, we expect to advance development of certain of our product candidates through payments made to us by third-party collaborators resulting from achievement of success-based milestones in the development of our autoimmunity and oncology investigational product candidates.

We were incorporated as BioPort Corporation under the laws of Michigan in May 1998. In December 2003, we began a corporate reorganization in which we formed a new corporate parent, Emergent BioSolutions Inc., a Delaware corporation. In June 2004, we completed the corporate reorganization whereby Emergent BioSolutions Inc. 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 subsidiary entities, each primarily consisting of an operational component of the corporation, including, among others, manufacturing in Baltimore, Maryland and product development in Gaithersburg, Maryland, the United Kingdom and Germany. Most recently, we acquired a research and product development subsidiary in Seattle, Washington, as a result of our acquisition of Trubion Pharmaceuticals, Inc., or Trubion, in October 2010, which we subsequently converted to Emergent Product Development Seattle LLC.

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 immunoglobulins, 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.

Immunoglobulins

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 termed passive 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 are administered either intravenously or by intramuscular injection to patients. Similar to an immune globulin, use of a mAb is a form of passive immunization.

Antibody-like proteins. Antibody-like protein molecules target cell-surface antigens on B cells. When a therapeutic targeted to a particular cell surface antigen binds to that antigen, it can elicit particular biological effects that can include particular forms of cell killing or cell death or other effects. B cells 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 disease 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 therapeutic product candidates targeted to oncology and AIID are designed to counteract these conditions by selecting, targeting and binding to these B cells, which are then removed by the immune system by cell killing or cell death.

Platform Technologies

SMIP™ (mono-specific protein therapeutic). Our Small Modular ImmunoPharmaceutical, or SMIP, therapeutics are mono-specific, single-chain antibody-like proteins that recognize and attach to cell-surface antigens on B cells; our current SMIP –based 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, and the hinge domain can be varied to tune the strength of the response, which the binding domain recognizes and attaches to the specific antigen target. Using proprietary technology, we custom assemble SMIPs 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 characteristics that differ. 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. In addition, the structural format of SMIP proteins permits a range of distances between the binding domains to be engineered. We believe that these size and structural qualities could result in safer and more effective therapeutics for particular disease indications.

SCORPION™ (multi-specific protein therapeutic). Like SMIPs, SCORPION therapeutics are single-chain proteins that we custom assemble, and consist of an effector domain, a hinge domain and a binding domain. However, SCORPION therapeutics are different from SMIPs in that they have a second binding domain, which enables them to 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 broad 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 diseases in oncology and AIID. 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 approaches to ADCC enhancement that impose product development challenges, TRU-ADhanCe is a simple proprietary manufacturing methodology that is designed to achieve a desired change in glycosylation structures, 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 the amino acid sequence of a product and no change to a 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, including a broadly cross-protective influenza vaccine candidate.

Products

Our biodefense segment targets the infectious disease anthrax. Our biosciences segment focuses on vaccines and antibody therapies for use against infectious diseases and protein therapies to treat AIID and cancer.

The following table summarizes key information about BioThrax and our clinical and preclinical 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
Anthrax	BioThrax	Only FDA-approved vaccine for pre-exposure prevention of anthrax disease	Marketed
	NuThrax*	Pre-exposure prophylactic vaccine	Phase I
	PreviThrax*	Pre/post-exposure prophylactic vaccine	Phase II
	Anthrivig*	Human immunoglobulin therapeutic	Phase I/ II
	Thravixa*	Fully human monoclonal antibody therapeutic	Phase I
	Double-mutant rPA vaccine*	Pre/post-exposure prophylactic vaccine	Preclinical
Tuberculosis	MVA-85A	Prophylactic recombinant TB vaccine	Phase II
Typhoid	Typhella	Prophylactic vaccine	Phase II
Influenza	Multivalent, cross-protective pandemic influenza vaccine	Prophylactic vaccine	Preclinical
	Pandemic H5 influenza MAb	Monoclonal antibody therapeutic	Preclinical
Rheumatoid Arthritis	SBI-087	Humanized anti-CD20 SMIP therapeutic	Phase II
Systemic lupus erythematosus	SBI-087	Humanized anti-CD20 SMIP therapeutic	Phase I
Chronic lymphocytic leukemia	TRU-016	Humanized anti-CD37 SMIP therapeutic	Phase I/ II
Non-Hodgkin's lymphoma	TRU-016	Humanized anti-CD37 SMIP therapeutic	Phase I

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

We are evaluating for future development other preclinical product candidates and programs that we acquired in connection with our acquisition of Trubion in October 2010—specifically, Draco, X1 and X2 programs targeted for solid organ transplant, RA and inflammatory bowel disease.

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. A failure of one or more of our clinical trials can occur at any stage of testing.

The results of a clinical trial are statistically significant if they are unlikely to have occurred by chance. We have 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. 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 are neither required nor sufficient to enable a product candidate to proceed to Phase II or later stages of clinical development. Phase I clinical trials are required to establish the safety of a product candidate, not its immunogenicity, before Phase II clinical trials may begin.

For therapeutic products, the primary endpoint is frequently response in Phase I and Phase II clinical trials. For autoimmune diseases, response based on composite scores has typically been acceptable for Phase III clinical trials and regulatory approval. For oncology, response may be acceptable for accelerated approval in areas of unmet medical need. In general, however, response rates are useful for Phase I and Phase II trials but, for Phase III trials, applicable regulations usually require a significant impact on progression free survival or overall survival.

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 20%.

Gastrointestinal anthrax is also a rare form of anthrax. Gastrointestinal anthrax is generally acquired through the consumption of meat and other food products contaminated with anthrax spores.

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 hours of the onset of advanced respiratory complications. The fatality rate for inhalational anthrax is estimated to be between 45% and 90%, depending on whether aggressive, early treatment is provided.

Market opportunity and current treatments. To date, the principal customer for anthrax medical countermeasures has been the U.S. government, specifically HHS and the 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 development and procurement funding for academic institutions and biotechnology companies conducting biodefense research or developing vaccines and immunotherapies directed at potential agents of bioterror or biowarfare.

The Project BioShield Act of 2004 authorizes expedited procurement of countermeasures for chemical, biological, radiological and nuclear attacks for the Strategic National Stockpile, or SNS. Project BioShield provided appropriations of $5.6 billion to be expended over ten years into a special reserve fund. BARDA is the agency responsible for awarding procurement contracts for biomedical countermeasures and providing development funding for advanced research and development in the biodefense arena, supplements the funding available under Project BioShield for chemical, biological, radiological and nuclear countermeasures, and provides funding for infectious disease pandemics. Funding for BARDA is provided by annual appropriations by Congress. Congress also appropriates annual funding for the CDC for the procurement of medical assets and countermeasures for the SNS and for NIAID to conduct biodefense research. This appropriation funding supplements amounts available under Project BioShield.

The DoD, 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 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 application, or IND, with informed consent of the patient as a post-exposure prophylaxis 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.

Although BioThrax is not currently approved by the FDA for post-exposure prophylaxis, we are pursuing a label expansion for this indication. We are also developing Anthrivig, an anthrax immune globulin therapeutic product candidate, and Thravixa, an anthrax monoclonal antibody therapeutic product candidate, both of which are designed for treatment of symptomatic patients. Several other companies also are developing post-exposure anthrax therapeutic products. We intend to progress the development of and pursue development and procurement contracts for both Anthrivig and Thravixa. We believe that anthrax therapeutics would be eligible to be procured by HHS under Project BioShield for inclusion in the SNS prior to receiving marketing approval, provided that the specific product candidate is deemed to be licensable.

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 post-exposure prophylaxis. Following the October 2001 anthrax letter attacks, however, the CDC provided BioThrax under an Investigational New Drug, or IND, protocol for administration as a post-exposure prophylaxis 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 diseases, Guillain-Barre syndrome, lupus, multiple sclerosis, lymphoma and death, have not been causally linked to the administration of BioThrax. In June 2009, we received approval from the FDA of our supplemental biologics license application, or BLA, 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.

BioThrax Related Programs

Reduced dosing schedule. 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, will confer an adequate immune response. In November 2010, the FDA sent us a complete response letter to our BLA efficacy supplement stating that it could not be approved because protection had not been demonstrated for the time after the last vaccination until the three-year booster vaccination. We expect to meet with the FDA in early 2011 to discuss the CDC trial findings and their applicability to our BLA supplement, and to establish a near-term plan for a reduced dosing schedule for BioThrax.

The CDC trial assessed 1,563 healthy civilian men and women between the ages of 18 and 61, randomized to one of six groups: Group A (original vaccination schedule of 0, 2, 4 weeks, and 6, 12, 18 months with annual boosters out to 42 months), Group B (same schedule as Group A, but all vaccinations given by intramuscular route), Group C (same as Group B, but with 2-week dose dropped), Group D (same as Group B, but with 2-week and 12- and 30-month doses dropped), Group E (same as Group B, but with 2-week and 12-, 19- and 30-month doses dropped), and the control group that received saline placebo. 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 the test arm with a modified vaccination schedule (Group C, D, or E) to the original approved schedule (Group A). 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 (i.e. Group A/Group C, D, or E) and less than 0.1 for differences in proportions of subjects achieving 4-fold increase in antibody titer (i.e. Group A – Group C, D, or E).

In this trial, the immunogenicity for Group C, Group D, and Group E were all non-inferior to Group A 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.

Expanded label indication to include post-exposure prophylaxis. We plan to seek approval of BioThrax as a post-exposure prophylaxis 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 a post-exposure prophylaxis against anthrax disease. In October 2007, we completed a human clinical trial of BioThrax for post-exposure 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 post-exposure prophylaxis 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 the antibiotic compared to rabbits treated with the antibiotic 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 post-exposure prophylaxis indication 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 post-exposure prophylaxis indication (for the prevention of disease caused by residual *B. anthracis* spores in exposed individuals who have received a full course of antibiotics) using appropriately designed GUP studies. In December 2010, we entered into an extension of our contract with BARDA to update and submit a new technical proposal to achieve post-exposure prophylaxis licensure. We submitted this proposal to BARDA in January 2011 and anticipate receiving a response from BARDA in early 2011. We submitted in February 2011 a proposed plan to the FDA for licensure of BioThrax for a post-exposure prophylaxis indication and are awaiting the FDA's response to the proposal. We believe that the data from our non-clinical efficacy studies such as our GUP studies and proof-of-concept post-exposure prophylaxis studies, together with pivotal data with respect to human immunogenicity and noninterference of the vaccine with antimicrobials, will be sufficient to support the filing with the FDA of a BLA supplement for marketing approval of BioThrax for the post-exposure indication.

NuThrax™ (Anthrax Vaccine Adsorbed with 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 a reduced number of doses to produce a protective immune response, or elicit an enhanced immune response. We obtained additional U.S. government funding through a NIAID award in September 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 and a clinical study 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 is being conducted in multiple sites within the United States and involves 105 healthy volunteers. Preliminary data from this study is expected to be available in the third quarter of 2011.

We previously collaborated with Coley Pharmaceuticals, the owner of CPG 7909 before its sale to Pfizer, to conduct 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 the Phase I clinical trial of BioThrax combined with CPG 7909 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 approximately 21 days earlier. This result was statistically significant, with a *p* value of less than 0.001. In this trial, there was a slightly higher frequency of moderate injection site reactions and systemic adverse events in the volunteers who received the product candidate as compared to volunteers who received BioThrax alone or 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.

Additional Anthrax Product Candidates

- *PreviThrax™ (Recombinant Protective Antigen Anthrax Vaccine, Purified).* We are developing a recombinant form of the protective antigen protein as an anthrax vaccine, based on original development work at USAMRIID. 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 the subject of two research and development grants from NIAID totaling approximately $100 million. It has also been evaluated in one Phase II clinical trial, but this trial did not achieve statistically significant results due to product stability issues. We believe these stability issues have since been resolved and 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 Immunoglobulin).* 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 plan to rely on the FDA's animal rule to support approval of Anthrivig, and to continue conducting non-clinical efficacy studies. In November 2010, BARDA requested that we submit a full proposal for late-stage development of Anthrivig, including all development activities through licensure. We submitted our proposal in January 2011 and expect to receive a response from BARDA in the second half of 2011. We are developing Anthrivig using plasma produced by healthy donors who have been immunized with BioThrax.

We have fractionated, purified and filled our AIG at the FDA-approved facilities of a third-party contract manufacturer, and have manufactured three full-scale lots under current Good Manufacturing Practice, or cGMP, conditions using the manufacturer's validated and approved process. In March 2009, we commenced a Phase I/II dose-escalation clinical trial to evaluate the safety and pharmacokinetics of Anthrivig in 145 healthy human volunteers. We completed dosing in July 2010 and completed subject follow-up in September 2010. We expect to generate a final study report for this trial during the second quarter of 2011. 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.

- *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 under our contract with NIAID to support efficacy testing in non-clinical studies, the establishment of a 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. The FDA granted our development program Fast Track Designation in October 2010, and Orphan Drug Designation in November 2010.

- *Double-mutant rPA vaccine.* We are developing an anthrax vaccine product candidate based on a double-mutant form of rPA, or dmPA, combined with CpG 7909 and Alhydrogel, an aluminum hydroxide adjuvant. In September 2009, we received an award from NIAID under the American Recovery and Reinvestment Act that included funding for development of a dry powder formulation and for the manufacture of bulk drug substance and final drug product in a current cGMP environment. We are currently evaluating our required 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 old. Between 1.7 million and 2 million people die annually worldwide with more than 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 Datamonitor, as of 2007, the commerical value of the global tuberculosis market was approximately $300 million with a cost adjusted growth rate of 2.2% for 2004 through 2007.

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. According to the WHO, each year up to an estimated 510,000 new MDR-TB cases occur, and an estimated 150,000 deaths are recorded worldwide as a result of MDR-TB infections. XDR-TB is caused by bacteria resistant to all of the most effective drugs, 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. 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 uses the attenuated, or weakened, MVA virus, as a vaccine platform 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 vector, or carrier, for our TB vaccine product candidate is MVA. MVA is an attenuated strain of vaccinia virus, the small pox vaccine, which does not replicate in mammalian cells. Another strain of MVA has been administered to more than 120,000 individuals as part of the smallpox eradication program and was found to be safe and well tolerated, despite the deliberate vaccination of high risk groups.

Our tuberculosis vaccine, designated as MVA85A, is a strain of MVA into which the Antigen 85A gene has been cloned. MVA85A has been designed to increase the immune response to Antigen 85A and thus increase vaccine protective efficacy in individuals previously vaccinated with BCG. The clinical development of MVA85A is aimed towards the production of an effective TB vaccine for infants, adolescents, and HIV-infected adults to augment the immunity induced by a previous BCG vaccination. We have licensed the commercial rights to our tuberculosis vaccine from the Oxford-Emergent Tuberculosis Consortium, or OETC.

To date, a total of thirteen Phase I and three Phase II clinical trials of MVA85A have been completed or are ongoing in the United Kingdom, South Africa, Senegal and the Gambia. A total of 158 healthy adults, 12 adolescents, 24 children and 251 infants have been immunized in the completed trials and 96 adults (including subjects with TB and/or HIV) have been immunized in the ongoing studies. All trials evaluated 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 were that the MVA85A vaccine was well tolerated, with no significant safety concerns, and previous vaccination with BCG did not affect the safety profile. Additionally, MVA85A was 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. Designed as a double-blind, randomized placebo-controlled evaluation of MVA85A/AERAS-485 for safety, immunogenicity and prevention of TB in BCG-vaccinated, HIV-negative infants, this trial is expected to include 2,784 infants. The trial is being conducted at a single site in South Africa and infants participating in this trial will be followed both for the development of tuberculosis and for adverse events. As of February 2011, over 2,000 subjects have been immunized and we currently expect this trial to conclude in 2012.

We expect to commence a Phase IIb trial in HIV infected adults in the first half of 2011. This trial is designed as a double-blind, randomized placebo controlled evaluation of MVA85A/Aeras-485 in 1,400 HIV positive adults with no evidence of active TB disease for prevention of TB disease. The trial will be conducted in Senegal and South Africa and participants will be followed for the development of tuberculosis and for immunogenicity and safety.

Typhoid

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

Prevalence, market opportunity and current treatment. Typhoid fever continues to be a public health problem in many developing countries with an estimated 22 million cases occurring per year worldwide, resulting in approximately 200,000 deaths annually. Increasing multi-drug resistance of the typhoid bacterium reduces effective treatment options, increases treatment costs and results in higher rates of serious complications and deaths. According to the CDC, approximately 400 cases of typhoid are reported annually in the United States, of which approximately 70% are contracted abroad. The CDC recommends that all persons from the United States traveling to developing countries consider receiving a typhoid vaccination, with travelers to Asia, Africa and Latin America deemed to be especially at risk. According to the U.S. Office of Travel and Tourism, over 30 million people travel annually to typhoid endemic areas. This travelers market represents our primary target market. Potential additional markets include U.S. military personnel deployed in regions where typhoid is endemic, as well as children and adults living in these areas.

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

Typhella. We are developing Typhella, a live attenuated typhoid vaccine, which contains deletions in two genes of the *Salmonella Typhi* bacterium designed to attenuate virulence and limit replication in the host. We have designed Typhella to be administered in a single drinkable dose prior to travel to countries where typhoid is endemic. We are currently evaluating manufacturing alternatives in countries in which we believe manufacturing costs will be feasible because we do not currently have manufacturing resources, either internally or through a contract manufacturer, to produce Typhella at competitively viable costs. If we are not able to engage a contract manufacturer on acceptable terms, we may seek to outlicense this product candidate and the associated *spi*-VEC platform technology for development by a third party, or otherwise discontinue our clinical development of this product candidate.

We have completed the following clinical trials of Typhella in the United States and Europe:

- An open-label, non-placebo controlled, pilot study conducted in the United Kingdom in nine healthy adult volunteers. The purpose of this study was to evaluate the safety and immunogenicity of our vaccine product candidate. In this study, Typhella was immunogenic, eliciting both cell mediated and humoral immune responses, and well tolerated.
- A double-blind, placebo controlled, single dose escalating Phase I clinical trial conducted in the United States in 60 healthy adult volunteers. The purpose of this trial was to evaluate the safety, tolerability and immunogenicity of three dose levels of our vaccine product candidate. In this trial, Typhella was immunogenic and well tolerated at all dose levels.
- An open-label, non-placebo controlled, single dose Phase I clinical trial conducted in the United States in 32 healthy adult volunteers. The purpose of this trial was to evaluate the safety and immunogenicity of two different presentations of Typhella, one using bottled water and another using tap water for reconstitution before administration. We vaccinated 16 subjects with each presentation. Because the two presentations were similarly immunogenic and both were well tolerated by trial participants, we selected the tap water presentation for further development based on its relative convenience.
- A single-blind, placebo controlled Phase I clinical trial of Typhella in Vietnam in 27 healthy adult volunteers using the dose and regimen established in our Phase I clinical trials in the United States. The Wellcome Trust provided funding for the Phase I trial in Vietnam. The purpose of the trial was to evaluate the safety and immunogenicity of Typhella when administered as a single oral dose in adults living in an endemic area. The primary immunogenicity endpoint for this trial was the proportion of trial participants with an immune response to *Salmonella typhi* following administration of a single oral dose of Typhella. Based on initial data from this trial, Typhella met the criterion for immunogenicity, with approximately 68% of subjects who received the vaccine product candidate mounting a humoral antibody response. Typhella was well tolerated by trial participants, with no serious adverse events reported.

- § A single-blind randomized, placebo controlled, Phase II clinical trial of Typhella in Vietnam in 151 healthy children between the ages of 5 and 14 years. A total of 101 children received Typhella and 50 children received placebo. This was our first trial involving a pediatric population. We conducted this trial in collaboration with the Wellcome Trust, Oxford University and the Hospital for Tropical Diseases, Ho Chi Minh City, Vietnam. The Wellcome Trust provided funding for this trial. The purpose of this trial was to evaluate the safety and immunogenicity of Typhella in children in an endemic area. The immunogenicity parameter for this trial was the percentage of trial participants with an immune response to *Salmonella Typhi* following administration of a single oral dose of Typhella. In this trial, 93% of the children receiving a vaccine dose developed an immune response as measured by increases in serum *Salmonella Typhi* LPS-specific IgG antibody levels, 94% of the children receiving a vaccine dose developed an immune response as measured by increase in serum *Salmonella Typhi* LPS-specific IgA antibody levels, and 97% of the children receiving a vaccine dose developed an immune response, which was statistically significantly greater than the percentage of children receiving placebo who developed an immune response. Typhella was well tolerated by trial participants, with no serious adverse events reported.
- § A randomized, double blind, placebo controlled, single dose, dose escalating Phase II clinical trial conducted in the United States in 187 healthy adult volunteers. The purpose of this trial was to determine the immunogenicity, safety and tolerability of the vaccine product candidate manufactured at a new facility at dose levels across the range of the proposed manufacturing potency specification. The primary immunogenicity endpoint for this trial was the proportion of trial participants with an immune response to *Salmonella Typhi* following administration of a single oral dose of Typhella. In this trial, the vaccine was immunogenic and well tolerated across the range of doses tested.

In these six clinical trials, Typhella demonstrated immunogenicity response levels following a single drinkable dose similar to those seen with multiple doses of the currently approved oral vaccine. As a result of these trials, we were able to establish the safety and immunogenicity of a single dose regimen at an appropriate dose level in populations in both endemic and non-endemic areas.

Influenza

Disease overview. Influenza, or the flu, is a highly contagious respiratory illness caused by influenza viruses. While there are only two types of influenza viruses that cause significant illness in humans, types A and B, these flu viruses can easily mutate to give rise to new subtypes, such as H1N1, H3N2 or H5N1. These new subtypes are often sufficiently different from previous strains so that prior immunity from vaccination or natural illness provides little to no protection against infection. Once infected, illness can range from a mild, upper-respiratory infection to an acute, life-threatening illness. Influenza is often characterized by a sudden onset of high fever, cough (usually dry), headache, muscle and joint pain, severe malaise, sore throat and runny nose. Influenza viruses are transmitted from person to person primarily through contact with infected airborne droplets generated by coughing and sneezing. The time from infection to illness can be as short as two days. The infectious period for influenza is defined as one day before fever begins until 24 hours after the fever ends.

Prevalence, market opportunity and current treatment. Influenza tends to spread rapidly in seasonal epidemics that occur yearly during autumn and winter in temperate regions. Illness resulting in hospitalization or death occurs mainly among high-risk groups, including the very young, elderly or chronically ill. According to the WHO, these annual epidemics result in approximately three to five million cases of severe illness and 250,000 to 500,000 deaths worldwide. According to the CDC, in the United States on an annual basis, influenza affects on average 5% to 20% of the population, more than 200,000 people are hospitalized from flu-related complications and approximately 30,000 to 35,000 people die from flu or flu-related causes.

The WHO recommends vaccination as the most effective way to prevent the disease or severe outcomes from the illness. Safe and effective vaccines have been available and used for more than 60 years. Among healthy adults, an influenza vaccine can prevent 70% to 90% of influenza-specific illness during seasons where there has been little change in the virus. Among the elderly, the vaccine reduces severe illnesses and complications by up to 60% and deaths by up to 80%. Most healthy symptomatic people recover within a week without requiring medical attention. In some cases, an antiviral drug may be prescribed.

According to a 2009 Datamonitor report, the current commercial value of the seasonal flu market, based on the 2008-2009 flu season, is estimated to be approximately $2.8 billion across the seven major markets, with growth of 12.6% since 2005-2006. This is the result of expanded recommendations in the United States regarding vaccination of infants and an increasing disease awareness resulting from recent pandemic flu threats. Improved vaccines for the elderly, and faster and more flexible manufacturing technologies are key unmet needs.

Manufacturing overview. Current flu vaccine manufacturing typically requires growing the influenza virus in fertilized chicken eggs. This can be a lengthy and time-consuming process and depends on the availability of a suitable supply of eggs. Most flu vaccines, both seasonal and pandemic, are currently produced using egg-based manufacturing processes. Influenza viruses can also be grown using more modern cell culture technologies, in which the influenza virus is allowed to infect and grow in mammalian cells that were propagated to high levels using bioreactors and sterile media. This manufacturing method is a simpler and more predictable process than traditional egg-based manufacturing processes, but has not yet been implemented domestically on a commercial scale.

Influenza Vaccine. 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. This broad spectrum pandemic flu vaccine product candidate is expected to be based on multiple antigens held by our partner and to be delivered as a single vaccine using our MVAtor platform technology. We expect to design this product candidate to overcome the limitations of current seasonal influenza vaccines, which are highly strain specific and need to be manufactured every year to match the current circulating strains. Our approach relies on using our live, attenuated MVA vector as a vaccine delivery system. We believe that presentation of influenza antigens using this delivery vector could induce broad immune responses sufficient to provide protection against multiple influenza viruses and over multiple seasons. Unlike traditional influenza vaccines that predominately target the variable hemagglutinin, or HA, and neuraminidase, or NA, antigens present on the surface of the virus, we are evaluating both the HA antigen as well as internal, conserved antigens that do not change from year to year. In addition, MVA has the potential for cell-based, rather than egg-based manufacture, and we are developing this capability as part of this program. To date, we have generated initially promising preclinical data with these antigens and are in the process of conducting additional preclinical studies to optimize our MVA-based product candidates for potential future clinical development.

Influenza Therapeutic. Our Singaporean joint venture is also planning to develop monoclonal antibodies for the treatment of pandemic H5 influenza using our partner's monoclonal antibody technology. We anticipate that this therapeutic product candidate will offer broad protection against most circulating H5 influenza strains and will limit the ability of the influenza virus to mutate and escape therapy.

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 Datamonitor, by 2019 RA is estimated to affect approximately 5.2 million people in the United States, Japan and the five major European markets and will grow to reach in excess of $13 billion. Datamonitor also estimates that sales in the combined seven major RA markets grew by 15% from 2008 through 2009, reaching $8.2 billion in 2009. 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. It is estimated that 20% of the RA patient population takes a combination of therapies that include 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 our next generation, humanized, CD20-directed product candidate for the treatment of RA, SLE and other autoimmune and inflammatory diseases. Preclinical trials conducted by Pfizer 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 more profound and sustained in SBI-087-treated groups compared with rituximab. Pfizer, in collaboration with us, 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 by the end of 2011. The second is a Phase I trial of SBI-087 for RA in Japan. These trials are necessary to assess the pharmacokinetic and pharmacodynamic attributes of SBI-087 in the Japanese population in preparation to seek potential regulatory approval 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. We believe that B cell depletion therapy is a promising approach toward a targeted therapy in SLE.

Prevalence, market opportunity and current treatment. According to Datamonitor, drug sales for the treatment of SLE totaled approximately $1.1 billion in 2008 across the seven major markets. Based on reports from Datamonitor, we expect significant market growth during the forecast period, driven by novel targeted therapies, with high uptake expected for moderate and severe patients. Datamonitor projects that, by 2019, novel therapies will add $2.9 billion into the U.S. and five major European markets alone. No new pharmaceutical or biologic treatments have been approved for SLE in over 40 years. 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. No protein therapeutic has been approved specifically for treatment of SLE. 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. Pfizer, in collaboration with us, is conducting a Phase I clinical trial of SBI-087 in SLE in which patient dosing has commenced and recruitment is ongoing. This 30 patient trial is an ascending dose pharmacokinetics and pharmacodynamics trial evaluating intravenous and subcutaneous dosing of SBI-087.

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. NHL includes a diverse group of lymphocytic malignancies, approximately 85% of which are B cell malignancies. CLL is a type of cancer affecting B cells in the blood and bone marrow.

Prevalence, market opportunity and current treatment. According to a 2010 Decision Resources report, CLL is estimated to afflict approximately 80,000 people in the United States. Approximately 12,000 to 15,000 new cases of CLL are diagnosed each year in the United States according to Datamonitor and the American Cancer Society. About 66,000 people in the United States were expected to be newly diagnosed with NHL in 2010 according to the American Cancer Society. Total reported worldwide sales of Rituxan®, one of the most commonly used biologics in the treatment of NHL and CLL, surpassed $3.5 billion for NHL and $1 billion for CLL in 2009.

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. Biologic therapies for NHL include antibodies such as Rituxan®/Mabthera, Bexxar®, Zevalin® and Arzerra®. These therapies all target CD20 on B cells. 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. Two chemotherapeutic agents, fludarabine and cyclophosphamide, in combination with Rituxan®, is currently the most effective combination for the treatment of CLL.

TRU-016 for treatment of B cell Malignancies. Our TRU-016 program, a collaboration with Abbott Laboratories, or Abbott, is focused on the development of a novel therapy for B cell malignancies such as CLL and NHL. Specifically, this therapeutic is directed at the CD37 antigen on the surface of B cells of 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. In addition, CD37 is known to be over expressed in patients with CLL. 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, against primary B-CLL cells, demonstrated significant in vivo therapeutic efficacy, and induced potent apoptosis, or direct programmed cell death, in primary CLL cells. In addition, combination therapy with a CD37-directed SMIP product candidate and CD20-directed therapy with Rituxan® has shown greater preclinical efficacy than either therapy alone.

A TRU-016 Phase I clinical trial for patients with CLL is currently underway with approximately 92 patients enrolled as of February 2011. 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 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. In addition, we have amended our study protocol to include treatment of patients with NHL and patient dosing has commenced and recruitment is ongoing.

In December 2010, we announced positive data following preliminary analyses from our Phase I trial of TRU-016 in patients with relapsed and refractory CLL. Evidence of TRU-016 biological activity 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 has not been reached as of February 2011.

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 standalone bendamustine treatment in a total of 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 criteria. Secondary endpoints include complete and partial response rates as defined by 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.

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 large-scale 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 is based on a technical proposal provided to BARDA that projects an annual large-scale manufacturing capacity of 26 million doses in Building 55 and provides funding for activities related to process validation, assay validation, fill/finish and, if required, non-clinical and clinical studies as well as regulatory activities in support of the submission to the FDA of a supplemental BLA for BioThrax at the expanded scale.

In November 2009, we paid approximately $8.2 million to purchase 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 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 a stored supply 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 other 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 to support some of our product candidates.

Hollister-Stier Laboratories LLC, or Hollister-Stier, performs contract filling for BioThrax at its FDA-approved facility located in Spokane, Washington. Hollister-Stier has agreed to meet all of our firm purchase orders for contract filling of BioThrax based on a good faith annual estimate that we provide prior to each calendar year 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 commencing 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. We have also entered into an agreement for contract filling operations with JHP Pharmaceuticals, LLC, which must now be qualified and licensed by the FDA to fill BioThrax at its facilities.

Talecris Biotherapeutics, Inc. has agreed to perform plasma fractionation and purification and contract filling of Anthrivig at its FDA-approved facilities located in Melville, New York and Clayton, North Carolina. Subject to limited exceptions, we have agreed to obtain all manufacturing requirements for Anthrivig exclusively from Talecris. While our agreement with Talecris remains in effect, Talecris has agreed not to market, sell or acquire any competing product that contains anthrax immune globulin as an active ingredient. We have agreed to pay Talecris mid-single digit royalties on net sales on a country-by-country basis for commercial product manufactured by Talecris. Our contract with Talecris expires December 31, 2014, and we have the option to extend the term for an additional five-year period upon notice to Talecris at least 12 months prior to the expiration of the initial term. Our contract with Talecris initially provided for the commencement of commercial manufacturing activities as of January 1, 2010, after which we would have been obligated to purchase a significant amount of source plasma per year for a five-year term. Because Anthrivig is not currently ready for commercial-scale manufacturing, we recently agreed to extend commencement of the commercial term to July 31, 2011 and are in negotiations with Talecris for a longer-term resolution regarding commercial production. In the event that we are not able to negotiate a satisfactory resolution, we may be required to explore other options for our anthrax immune globulin program. 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 used a contract manufacturer for the supply of Typhella for the Phase I and Phase II trials in Vietnam, the United Kingdom and the United States. We have also entered into an agreement with a new contract manufacturer for Thravixa.

We also expect that we will rely on third parties for a portion of the manufacturing process for commercial supplies of other product candidates that we successfully develop, including fermentation for some of our vaccine product candidates and contract fill and finish operations. The manufacture of biologic products and the scale-up process necessary to manufacture quantities of product sufficient for commercial launch are complex. If we are unable to secure relationships with third party contract manufacturers that can provide sufficient supplies for the commercial launch of our product candidates on commercially attractive terms, our ability to capture market share may be adversely affected.

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 will be interest in these products to protect emergency responders such as police, fire and emergency medical personnel, and other personnel whose occupation may cause them to be at a high risk of exposure to biothreats.

We have established a 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 or co-commercialization rights. For example, our collaborations with each of Abbott and Pfizer provide for certain commitments by us and our respective collaborator with respect to the resources required for commercialization of the relevant products. 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 leading pharmaceutical and biotechnology companies, especially in situations in which the collaborator has particular expertise or resources for the commercialization of our products or product candidates or 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, academic institutions, government agencies and private and public research institutions. Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Novartis and Wyeth (now Pfizer) generated over 90% of the total worldwide vaccine revenues in 2007. The concentration of the industry reflects a number of factors, including:

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

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

Many of our competitors, including those named above, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring products, product candidates and technologies complementary to, or necessary for, our programs. Smaller or more narrowly focused companies, including Aeras, Crucell (recently acquired by Johnson & Johnson), Cangene, Human Genome Sciences, Soligenix, Dynport Vaccine Company LLC, Elusys, Bavarian Nordic, Panacea and PharmAthene, 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, we may not be able to compete effectively if our products and product candidates do not satisfy government procurement requirements, particularly requirements of the U.S. government with respect to biodefense products. Our opportunities to succeed in this industry could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient or are less expensive than any products that we may develop.

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

- *BioThrax.* Although BioThrax is the only product approved by the FDA for human use for the prevention of anthrax infection, we face potential 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 an anthrax vaccine based on recombinant protective antigen. 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*. PharmAthene is currently developing a rPA based anthrax vaccine and has submitted a response to a Broad Agency Announcement, or BAA, for rPA vaccine development. BARDA cancelled its Request for Proposal, or RFP, for the procurement of rPA vaccines in favor of this BAA. BARDA has awarded a modification to an existing development contract to PharmAthene to fund the development of their rPA vaccine. Vaxin and Panacea are also developing rPA vaccines.
- *BioThrax related programs and double-mutant rPA vaccine*. PharmAthene is currently developing a rPA based anthrax vaccine as well as a third-generation anthrax vaccine.
- *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; Human Genome Sciences is developing a monoclonal antibody to *Bacillus anthracis*, referred to as ABthrax™, as a post-exposure therapeutic for anthrax infection; Elusys Therapeutics is developing a monoclonal antibody to *Bacillus anthracis*, known as Anthim™, as a pre-exposure and post-exposure prophylaxis against anthrax infection, as well as an active treatment of disease; and PharmAthene and Medarex are collaborating to develop a human antibody to *Bacillus anthracis*, known as Valortim™, to protect human cells from damage by anthrax toxins. The FDA has granted Fast Track designation and orphan drug status for ABthrax and Valortim. HHS awarded development and procurement contracts to Human Genome Sciences and Cangene to supply their anthrax therapeutics for evaluation of efficacy as a post-exposure therapeutic for anthrax infection.

Biosciences

Vaccine product candidates in our BioSciences Division will face significant competition from companies that are developing competitive products that employ alternative technologies, as well as from companies that have already commercialized products for the same targeted markets or that treat the same indications. These companies may succeed in developing competitive products or obtaining regulatory approvals earlier than us, or develop products that are safer and more effective, or more cost effective, than those we develop. Specifically, the competition for our commercial vaccine product candidates includes the following:

- *Tuberculosis vaccine.* The Aeras Global Tuberculosis Vaccine Foundation is developing or supporting the development of five tuberculosis vaccine product candidates, one of which is 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.
- *Influenza vaccine*. Seasonal and pandemic influenza vaccines produced using conventional egg-based manufacturing methodologies have been licensed and are being sold in both the United States and internationally by GlaxoSmith Kline, Novartis, MedImmune and others. Several flu vaccine manufacturers are transitioning the production of their seasonal and pandemic vaccines from egg-based processes to cell culture in an effort to increase supply of these products. These cell culture-based products are in various stages of advanced development. New influenza vaccines containing HA, antigens and/or other flu antigens produced using recombinant DNA technology and/or incorporate adjuvants are also under development. Some of these second generation flu vaccine candidates are in clinical development.
- *Typhella.* One oral typhoid vaccine and one type of injectable typhoid vaccine are currently approved and administered in the United States and Europe for the prevention of typhoid. In addition, combination vaccines are available for the prevention of hepatitis A and typhoid infections. Antibiotics typically are used to treat typhoid after infection. Vi-conjugable injectable vaccines are also in development.

AIID and Oncology Therapeutics

We believe our AIID and oncology therapeutic product development programs will be also 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 highly competitive. Pharmaceutical companies, biotechnology companies, and academic and research institutions may succeed in developing products based upon the principles underlying our proprietary technologies earlier than us, obtaining approvals for such products from the FDA more rapidly than us or developing products that are safer, more effective, and/or more cost effective than those under development or proposed to be developed by us.

Product Candidates for Autoimmune and Inflammatory Diseases. If approved for the treatment of RA, we anticipate that our product candidates would compete with other marketed protein therapeutics for the treatment of RA in this $10 billion market 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).

If approved for the treatment of SLE, we anticipate that our product candidates would compete with Benlysta (Human Genome Sciences and GlaxoSmithKline) and other B cell depleting therapies, including CD20-directed therapeutics.

Product Candidates for B cell Malignancies. If approved for the treatment of CLL, NHL, or other B cell malignancies, we anticipate that our product candidates would compete with other B cell depleting therapies in these billion dollar markets. 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 recently announced its development of a monoclonal antibody directed to CD37.

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, for instance, our partnered product candidates, TRU-016 and SBI-087, SCORPION therapeutic product candidates and TRU-ADhanCe technology. 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 collaboration arrangements with them.

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.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, our competitors may independently develop similar technologies or duplicate any technology developed by us, and the rights granted under any issued patents may not provide us with any meaningful competitive advantages against these competitors. We may become subject to patent interference proceedings or claims that our products infringe or violate the intellectual property rights of third parties. Moreover, we may not be able to obtain patent term extensions for the patents that claim its marketed products, or the patent term extensions that it obtains may not be sufficiently broad enough to preclude competitors from commercializing or making similar competing products. Also, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. Furthermore, although we may seek patent term extension or a supplementary protection certificate for a given patent with respect to an approved product, it is possible that it will not be awarded or that it will be awarded for a period of time that does not significantly extend the patent life.

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, Abbott and Pfizer, 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 U.S. patent application that will expire in 2026, as well as eight foreign patents and 20 foreign patent applications, which, if issued as patents, would expire in 2025.

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 also reimbursed patent costs of approximately $120,000 incurred by the University of Oxford and Isis Innovation Limited prior to entering into the license agreement and 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 if regulatory approval is not obtained to commence the planned Phase IIb clinical trial of the licensed product in infants by December 1, 2009 or if no subjects in such trial have been dosed by May 31, 2010; 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 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 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. We and OETC each have the right to terminate the license agreement following the occurrence of a material uncured breach by the other party.

Abbott collaboration. We are a party to a collaboration agreement with Abbott for the joint development and commercialization of TRU-016 and other protein therapeutics that bind to the CD37 antigen. Under the collaboration agreement, Abbott holds 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. We may utilize this license, and Abbott's patents and know-how relating to collaboration products, to the degree necessary to enable us to perform our obligations and exercise our rights under the collaboration agreement. Certain events provide Abbott and us with the right to opt-out of further development and commercialization of a collaboration product. If Abbott opts out of the further development or commercialization of a collaboration product, such as TRU-016, or if we opt-out of the further development and commercialization of a collaboration product, and Abbott does not choose to continue the development and commercialization of that product, the exclusive license to Abbott will terminate with respect to the product in question.

Pfizer License. We are a party to an exclusive out-licensing agreement with Pfizer that grants Pfizer an exclusive license to develop and commercialize TRU-015 and SBI-087, SMIPs that bind to CD20. In the license, we have reserved the right to develop SMIPs specific for targets other than those selected by Pfizer as well as a right to perform pre-clinical research using SMIPs specific for the licensed targets. The license contains a non-compete clause which precludes both parties from developing human therapeutics against any CD20 until there has been a first commercial sale of a licensed product. Certain events provide Pfizer with the right to terminate the license. If Pfizer terminates the license without cause, its exclusive license terminates, and provisions exist whereby we would re-acquire the licensed programs from Pfizer on commercially reasonable terms. If Pfizer terminates the license as a result of our material breach of the license, its licenses terminate, and we have a 1 year option to license back any intellectual property, know-how, regulatory filings and the like that Pfizer created while developing the licensed programs on commercially reasonable terms.

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 a clinical trial at any time on various ground, 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 the next year. 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 effectiveness in humans, these studies add complexity and uncertainty to the testing and approval process. In addition, products approved under the animal rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

Marketing Approval

In the United States, if a product is regulated as a drug, an NDA must be submitted and approved before commercial marketing may begin. If the product is regulated as a biologic, a BLA must be submitted and approved before commercial marketing may begin. The NDA or BLA must include a substantial amount of data and other information concerning the safety and effectiveness and, in the case of a 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 process for the drug or biological product and determines that the facility is 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 is 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 a post-exposure prophylaxis against anthrax infection. Additionally, in October 2010, the FDA granted Fast Track designation for Thravixa for the treatment of inhalation anthrax. 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.

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 which an application may be reviewed within six months after a complete NDA or BLA is accepted for filing or sponsors may rely on a surrogate endpoint for approval, respectively. 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:

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

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 is sufficient and satisfactory clinical results or research data, including data, if available, from preclinical and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years. Project BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA. To exercise this authority, the Secretary of HHS must conclude that:

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

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

Safety Act

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

Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act, or PREP Act, enacted by Congress in 2005 provides immunity 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 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, last year, Congress enacted comprehensive health reform legislation that, among other things, creates a licensure pathway for biological products shown to be biosimilar to previously licensed biosimilar products and permits litigation of patient infringement cases between patent owners and biosimilar manufacturers prior to market entry. This legislation, known as the Biologics Price Competition and Innovation Act of 2009, or BPCIA, gives broad rulemaking discretion to the FDA for purposes of enacting the BPCIA. Until the FDA develops recommendations for the application review process, which the FDA must present to Congress by January 15, 2012, and until the BPCIA is implemented, it is not possible to predict the impact of the BPCIA 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 usually 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 has for many years been subject to the granting of marketing authorizations by regulatory agencies. European Union member states require both regulatory clearance and a favorable ethics committee opinion prior to the commencement of a clinical trial, whatever its phase. Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized/mutual recognition procedure.

The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is currently mandatory for products developed by means of a biotechnological process, including recombinant DNA technology, the controlled expression of genes coding for biologically active proteins and monoclonal antibody methods, and new chemical entities for the treatment of acquired immune deficiency syndrome, cancer, neurodegenerative disorder, diabetes, auto-immune diseases 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 clinically superior or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug or biologic to meet the public’s need. The FDA also may approve another application for the same drug or biologic that has orphan exclusivity but for a different use, in which case the competing drug or biologic could be prescribed by physicians outside its FDA approval for the orphan use notwithstanding the existence of orphan exclusivity. A grant of an orphan designation is not a guarantee that a product will be approved.

The European Union operates 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 has 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, Thravixa has 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. 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. Part D is administered through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. The health care reform legislation enacted last year, 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, 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, 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 the USDA our possession, use or transfer of select biological agents or toxins that could pose a threat to public health and safety, to animal or plant health or to animal or plant products. This legislation requires increased safeguards and security measures for these select agents and toxins, including controlled access 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, 2010, we had 767 employees, including 229 employees engaged in product development, 338 employees engaged in manufacturing, 13 employees engaged in sales and marketing and 187 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 HHS or the DoD. If HHS or DoD 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 U.S. Department of Health and Human Services, or HHS, to supply doses of BioThrax for placement into the Strategic National Stockpile, or SNS. We are not currently party to a procurement contract with the U.S. Department of Defense, or DoD, which currently procures doses of BioThrax directly from the SNS. If the SNS priorities change, or if the DoD dose requirements from the SNS are reduced, our revenues could be substantially reduced.

Our existing and prior contracts with HHS and the DoD do not necessarily increase the likelihood that we will secure future comparable contracts with the U.S. government. The success of our business and our operating results for the foreseeable future are substantially dependent on the 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, 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 that 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 or could suffer 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 adversely affected.

Our U.S. government contracts require ongoing funding decisions by the 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 of some government programs is subject to Congressional appropriations, generally made on a fiscal year basis even though a program may continue for several years. Our government customers are subject to political considerations and stringent budgetary constraints. For example, the sale of most of the doses of BioThrax supplied under our most recent procurement contract with HHS was subject to the annual appropriations process. Additionally, our government-funded development contracts typically consist of a base period of performance followed by successive option periods for performance of certain future activities. The value of these optional services, which options are exercisable in the sole discretion of the government, may constitute the majority of the total value of the underlying contract. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, our business, revenues and operating results may suffer.

The success of our business with the U.S. government depends on our compliance with 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 performance and compliance costs. Failure to comply with these regulations and requirements could lead to suspension or debarment, for cause, from government contracting or subcontracting for a period of time. The termination of a government contract or relationship as a result of our failure to satisfy any of these obligations would have a negative impact on our operations and harm our reputation and ability to procure other government contracts in the future.

The pricing under our fixed price government contracts is based on estimates of the time, resources and expenses required to 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 existing and prior contracts for the supply of BioThrax with HHS and the DoD have been 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 government substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the government to:

- § terminate existing contracts, in whole or in part, for any reason or no reason;
- § unilaterally reduce or modify contracts or subcontracts, including 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 HHS contracts for BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the government's convenience. Under general principles of government contracting law, if the government terminates a contract for convenience, the 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 government terminates a contract for default, the defaulting company is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source.

One or more of our government contracts could be terminated under these circumstances. Some government contracts grant the government the right to use, for or on behalf of the U.S. government, any technologies developed by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the government.

Legal proceedings challenging the U.S. government's use of BioThrax may be costly to defend and could limit future purchases of BioThrax by the U.S. government.

Legal proceedings could be costly to defend, and the results could reduce demand for BioThrax by the U.S. government. For example, a group of unnamed military personnel filed a lawsuit in 2003 seeking to enjoin the DoD from administering BioThrax on a mandatory basis without informed consent of the recipient or a Presidential waiver, and a federal court issued the requested injunction in 2004. In 2005, the FDA issued an order affirming the BioThrax license and, as a result, an appellate court ruled in February 2006 that the injunction was dissolved.

In October 2006, the DoD announced that it was resuming a mandatory vaccination program for BioThrax for designated personnel and contractors. In December 2006, the same counsel who brought the prior lawsuit filed a new lawsuit contending that the FDA's 2005 Final Order should be set aside and that BioThrax is not properly approved for use in the DoD's vaccination program. In February 2008, the federal district court in which that case was pending dismissed the action, concluding that the FDA did not make a clear error of judgment in reaffirming the safety and efficacy of BioThrax. On September 29, 2009, the United States Court of Appeals for the District of Columbia Circuit issued its opinion in *Rempfer v. Torti*, affirming the February 29, 2008 finding of the District Court that the FDA did not violate the Administrative Procedure Act in connection with its December 19, 2005 Final Order classifying BioThrax as safe and effective. The plaintiffs' petition for writ of certiorari in the United States Supreme Court was denied on March 1, 2010.

Although we are not a party to any lawsuits challenging the DoD's mandatory use of BioThrax, if a court were to again enjoin the DoD's use of BioThrax on a mandatory basis, the amount of future purchases of BioThrax by the U.S. government could be affected. Furthermore, contractual indemnification provisions and statutory liability protections may not fully protect us from all related liabilities, and statutory liability protections could be revoked or amended to reduce the scope of liability protection. For example, we have invoiced the DoD for reimbursement of our costs incurred with respect to the lawsuits filed against us by current and former members of the U.S. military claiming damages as the result of personal injuries allegedly suffered from vaccination with BioThrax, and we are continuing our efforts to negotiate with the DoD for a satisfactory resolution of that claim. In addition, lawsuits brought directly against us by third parties, even if not successful, would require us to spend time and money defending the related litigation that may not be reimbursed by insurance carriers or covered by indemnification under existing contracts.

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. Our profitability is substantially dependent on revenues from BioThrax product sales. Revenues from BioThrax product sales have fluctuated significantly in recent quarters, and we expect that they will continue to fluctuate significantly from quarter to quarter based on several factors, including the timing of our fulfilling 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, 2010, we had $47.4 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;
- § 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 expect to require additional funding and may be unable to raise capital when needed, which would harm our business, financial condition and operating results.

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

As of December 31, 2010, we had $171.0 million of cash, cash equivalents and investments. 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 level of participation of collaborative partners in our development programs, including those recently acquired in our acquisition of Trubion Pharmaceuticals, Inc., or Trubion;
- 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 new 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 extent to which we lend money to, and are able to obtain repayment from, third parties;
- 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;
- the effect of competing technological and market developments; and
- the extent to which we become obligated to make cash payments in connection with our acquisition of Trubion related to the contingent value rights we issued to former holders of Trubion common stock that are not offset by corresponding cash inflows from our collaborative partners.

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

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

Risks Related to Manufacturing and Manufacturing Facilities

We are in the process of expanding our manufacturing facilities and entering into arrangements with contract manufacturing organizations. 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 the Biomedical Advanced Research and Development Authority, or BARDA, in July 2010 for scale-up, qualification and validation to manufacture BioThrax.

Additionally, in 2009, we acquired a facility in Baltimore, Maryland that we expect to utilize for certain product development or manufacturing projects. In order to do so, we anticipate that we will be required to make certain capital expenditures to upgrade and maintain this facility.

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 licensure will be 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 current good manufacturing practices, or 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 and validation activities are delayed, we may not be able to meet our obligations to our customers, which may limit our opportunities for growth. Costs associated with constructing, qualifying and validating 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.

We also 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 our products could be adversely affected and also 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.

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.

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 are currently in the process of preparing and qualifying a new reference lot to replace our existing, qualified reference lot, which we expect to complete later this year. 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 we were able to meet such requirements, which would be costly to us 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 manufacturing facilities could impede our ability to manufacture BioThrax, which would harm our business, financial condition and operating results.

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

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

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

We have outsourced the operation for filling BioThrax into vials to a single company. We have not established internal redundancy for our filling functions; however, we have identified and contracted with an additional provider that we believe can handle our filling needs. Before this additional provider can perform filling services for us, it must be qualified and licensed by the FDA. Such qualification and licensure may require use of a significant number of doses of BioThrax for consistency lots and stability testing that we may not be able to sell in the future once testing is complete. If our existing BioThrax filler were unable to perform filling services for us, we would need to obtain FDA approval of our potential substitute filler, engage, qualify and license an alternative filling company or develop our own filling capabilities. Any new contract filling company or filling capabilities that we acquire or develop will need to be approved by the FDA. Identifying and engaging a new contract filling company or developing our own filling capabilities and obtaining FDA approval could involve significant time and cost. As a result, we might not be able to deliver BioThrax orders on a timely basis and our revenues could decrease.

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

The timing and amount of customer demand is difficult to predict. We may not be able to scale-up our production quickly enough to fill any new customer orders on a timely basis. This could cause us to lose new business and possibly existing business. For example, we, 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 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 the supplies of some or all of our vaccine and therapeutic product candidates that we require for preclinical and clinical development, including the product candidates from our recently-completed acquisition of Trubion. For example, we currently depend on contract manufacturers for certain biopharmaceutical development and manufacturing services for TRU-016, our clinical candidate that we are developing in collaboration with Abbott Laboratories, or Abbott, and plan to have Abbott perform certain TRU-016 manufacturing services in 2011. We also rely on third-party manufacturers for filling and finishing services for our product candidates. 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.

In addition, we expect that we will rely on third parties for a portion of the manufacturing process for commercial supplies of product candidates that we successfully develop and we will rely on those manufacturers to comply with a wide variety of rules and regulations. 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;
- § lack of obligation by a contract supplier to accept 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 will rely for these purposes on any third party that we use for production of commercial supplies of product candidates that we successfully develop. Manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP regulations and other governmental regulations and corresponding foreign standards.

We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the 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;
- § 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 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 of these materials. 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 Centers for Disease Control and Prevention, or CDC, HHS and the DoD.

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

We also are subject to export control regulations governing the export of BioThrax and technology and materials used to develop and manufacture BioThrax and our product candidates. 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 result, and any such liability could exceed our assets and resources. In addition, we could be required to cease immediately all use of a select agent or toxin, and we could be prohibited from exporting our products, technology and materials 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 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, exposing 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, obtain new coverage or increase limits in the future, and may be unable to do so on reasonable terms. 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 therapeutic 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 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, as a result of the foregoing factors or otherwise, 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. For example, we recently agreed with one of our contract manufacturers to extend the commencement date of the commercial term for manufacture of Anthrivig. We are currently in negotiations with that contract manufacturer for a longer-term resolution regarding commercial production; however, in the event that we are not able to negotiate a satisfactory resolution we may be required to explore other options for our anthrax immune globulin program that could result in less favorable commercial success for this product candidate, or no commercial success at all.

We depend on our collaborative relationships with Pfizer and Abbott to develop, manufacture, and commercialize certain of our recently acquired product candidates.

We are party to collaboration agreements with each of Pfizer Inc., or Pfizer, and Abbott Laboratories, or Abbott. Under the terms of the Pfizer collaboration, Pfizer is responsible for regulatory approval of and any subsequent commercialization of SBI-087. Under the Abbott collaboration for the development and commercialization of TRU-016, we and Abbott must jointly agree to all development and commercialization plans and timelines for TRU-016. If either of our collaborative partners opts-out of or terminates its agreement with us or fails to fulfill its obligations, we would need to obtain the capital necessary to fully fund the development and commercialization of the related product candidates or enter into alternative arrangements with a third party. We could also become involved in disputes with either of these collaborative partners, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration. If either Pfizer or Abbott terminates or breaches its agreement with us, or otherwise fails to complete its obligations in a timely manner, our collaboration product development programs would be substantially delayed and the chances of successfully developing or commercializing our collaboration product candidates would be materially and adversely affected.

In June 2010 Pfizer decided to discontinue development of TRU-015, an investigational drug in Phase II evaluation for the treatment of Rheumatoid Arthritis, or RA based on preliminary results from the study, which, although consistent with previous studies and similar to other B-cell-depleting therapies, did not meet the internally predefined primary endpoint of the Phase II study. We cannot predict how or whether Pfizer will proceed with the collaboration or the development of any of the remaining collaboration product candidates, including SBI-087 and other therapeutics directed to CD20, as well as certain other product candidates directed to targets other than CD20 that have been established pursuant to our collaboration agreement with Pfizer. Our ability to receive any significant revenue from our product candidates covered by the collaboration agreement depends on the efforts of Pfizer and on our ability to collaborate effectively. Any future payments, including royalties to us, will depend on the extent to which we and Pfizer advance product candidates through development and commercialization. Pfizer may terminate the collaboration relationship, in whole or in part, without cause, by giving 90 days' written notice to us. Pfizer also has the right to terminate the agreement, on a target-by-target basis, upon 60 days' written notice, if any safety or regulatory issue arises that would have a material adverse effect on Pfizer's ability to develop, manufacture, or commercialize one or more product candidates.

With respect to control over decisions and responsibilities, the collaboration agreement provides for a research committee and a CD20-directed therapy development committee consisting of representatives of Pfizer and us. Ultimate decision-making authority as to most matters within the collaboration, including development plans and timelines, however, is vested in Pfizer.

In August 2009, Trubion entered into a collaboration agreement with Facet Biotech, or Facet, for the joint worldwide development and commercialization of TRU-016, a product candidate in Phase I clinical development for chronic lymphocytic leukemia, or CLL, and other CD37-directed protein therapeutics. Facet became a wholly-owned subsidiary of Abbott in April 2010. Under the terms of the collaboration agreement, neither we nor Abbott have the right to develop or commercialize protein therapeutics directed to CD37 outside of the collaboration, and development and commercialization expenses incurred by both companies in the development and commercialization of TRU-016 are shared equally. Our ability to receive funding for TRU-016 under the collaboration depends on our ability to collaborate effectively with Abbott. Any future payments, including milestones payable to us, will depend on the extent to which we and Abbott advance TRU-016 through development and commercialization. Abbott may terminate the collaboration agreement without cause, and would not be obligated to pay us a termination fee. Abbott also has the right upon 90 days' written notice to terminate the agreement for any uncured material breach by us, and has the right to opt out of the collaboration during the six-month period following a change in control of Trubion, which includes the right to opt out of the collaboration as a result of our acquisition of Trubion until April 28, 2011. With respect to control over decisions and responsibilities, the collaboration agreement provides for a joint steering committee that must make decisions by consensus. Failure to reach consensus on material aspects of the development or commercialization of TRU-016 would lead to dispute resolution by our respective designated officers, and potentially arbitration, any of which could delay the development of TRU-016, which may harm our business.

Under certain circumstances, the parties have the right to opt-out of the collaboration or may be deemed to have opted-out of the collaboration. If Abbott opts-out of the collaboration with respect to a product, then we would become responsible for all development and commercialization costs for that product and be obligated to pay Abbott certain royalty payments upon the sale of that product. We are currently the lead manufacturing party for TRU-016 and if we opt-out of the collaboration, and are the lead TRU-016 manufacturing party at that time, we would be obligated to continue to supply TRU-016 to Abbott for up to 18 months.

While SBI-087 or TRU-016 may never be successfully developed or commercialized, if either Pfizer or Abbott were to fail to perform its obligations in a timely manner or were to terminate or opt out of its collaboration with us, the development and commercialization of the affected product would be substantially delayed and may be otherwise adversely affected, which could have a material adverse effect on our results of operations.

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. For example, in December 2008, we and Sanofi Pasteur determined that the joint efforts of our collaboration related to our meningitis B product development program had not identified a viable product candidate, which effectively ended most development activities under this collaboration. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials.

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 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 a collaborative partner 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 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 payments, 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 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 expect will be interested in BioThrax to protect emergency responders such as police, fire and emergency medical personnel, multinational companies, non-governmental organizations and hospitals.

The market for sales of BioThrax to customers other than the U.S. government is 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 several 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 jurisdiction 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 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. Additionally, we have constructed Building 55, a large-scale manufacturing facility at our Lansing campus that is available for large-scale production of BioThrax, subject to final qualification and validation activities. To prepare for the event that we obtain significant orders for BioThrax from customers other than the U.S. government that cannot be accommodated by our existing facilities, we may explore additional manufacturing alternatives that would enable us to increase our manufacturing capacity and, as a result, allow us to increase sales of BioThrax to customers other than the U.S. government. If we are successful in this effort, it could be several years until a facility is qualified and validated and able to produce saleable vaccine. If we are unsuccessful in this effort, our opportunities for growth could be limited.

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.

As we continue to expand our operations outside of the United States, 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.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of 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 in the United States 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. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice. The Securities and Exchange Commission, or SEC, is involved with enforcement of the books and records provisions of the FCPA.

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. China is an example of one jurisdiction in which we are contemplating future expansion where we will need to exercise caution to ensure our compliance with the FCPA.

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

In addition, notwithstanding favorable findings regarding the safety and efficacy of BioThrax by the FDA in its final ruling in December 2005, the Government Accountability Office reiterated concerns regarding BioThrax in Congressional testimony in May 2006 that it had previously identified beginning in 1999. These concerns include the then-licensed six-dose regimen and annual booster doses, questions about the long-term and short-term safety of the vaccine, including how safety is affected by gender differences, and uncertainty about the vaccine's efficacy against inhalational anthrax. Continued reiteration of these concerns could have a detrimental effect on the market's 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 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 diseases, 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 adversely affected.

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

Products developed to treat diseases caused by or to combat the threat of bioterrorism are subject to changing political and social environments. The political and social responses to bioterrorism have been highly charged and unpredictable. Political or social pressures or changes in the perception of the risk that military personnel or civilians could be exposed to biological agents as weapons of bioterrorism may delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, which would harm our business.

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Furthermore, lawsuits brought against us by third parties or activists, even if not successful, require us to spend time and money defending the related litigation. The need to address political and social issues may divert our management's time and attention from other business concerns. For example, between 2001 and 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.

In addition, we are a party to a collaboration agreement with Pfizer to develop and commercialize therapeutics directed to CD20 and other targets, and to a collaboration agreement with Abbott to develop and commercialize TRU-016.

To increase our sales of BioThrax to state and local governments and foreign governments and create an infrastructure for future sales of other biodefense products to these customers, we plan to expand our sales and marketing organization. In addition, if we do not enter into collaborative agreements with respect to product candidates not covered by the Pfizer or Abbott collaborations, or if any of our product candidates are the subject of collaborative agreements with third parties that are not able to commercialize such product candidates, 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 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 face 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 academic institutions, government agencies and other public and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. 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.

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

We believe that our most significant competitors in the area of vaccine and therapeutics 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 and therapeutic development, such as Aeras, Crucell, Cangene, Human Genome Sciences, Soligenix, Dynport Vaccine Company, Elusys, Bavarian Nordic and PharmAthene. With respect to oncology and autoimmune disease, our competitors include Amgen, Pfizer, Takeda, Centocor Ortho Biotech, Merck, Mitsubishi Tanabe, Abbott, Eisai, Bristol-Myers Squibb, UCB, Otsuka, Roche, Chugai, Genentech, Biogen Idec, Spectrum Pharmaceuticals, Inc., Bayer Schering AG, GSK, Genzyme, Cephalon Oncology and Genmab.

Any therapeutic product candidate that we successfully develop and commercialize is likely to compete with currently marketed products and with other product candidates that are in development for the same indications. In many cases, the currently marketed products have well-known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. In 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. We also face competition for our biodefense product candidates. 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 anthrax immune globulin therapeutic 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.

Numerous companies have products or product candidates in development that would compete with the commercial product candidates for which we are seeking to obtain marketing approval. If approved for the treatment of 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 ® (Centocor Ortho Biotech 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 other therapies. If approved for the treatment of CLL, non-Hodgkin's lymphoma, or NHL, or other B cell malignancies, we anticipate that our product candidates would compete with other B cell depleting therapies.

While we are not aware of any CD37- directed therapeutics in development or on the market, other biologic therapies are marketed for the treatment of NHL or CLL or both, such as Rituxan/Mabthera ® (Genentech, Roche and Biogen Idec), Zevalin ® (Spectrum Pharmaceuticals, Inc. and Bayer Schering AG), Bexxar ® (GlaxoSmithKline), Campath ® (Genzyme and Bayer Schering AG), Treanda ® (Cephalon Oncology) and Arzerra ® (GlaxoSmithKline and Genmab). With respect to our vaccine product candidates, one oral typhoid vaccine and one injectable typhoid vaccine are currently approved and administered in the U.S. and Europe. 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.

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

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

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

The Public Readiness and Emergency Preparedness Act, or PREP Act, which was signed into law in December 2005, creates 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. 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 exhausted their remedies under the compensation program and thereby expose us to liability. In October 2008, the Secretary of HHS issued a PREP Act declaration identifying BioThrax and Anthrivig as covered countermeasures. We do not know, however, whether the PREP Act will provide adequate protection or survive anticipated legal challenges to its validity.

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

In addition, although our prior contracts with the DoD and HHS provided that the U.S. government would indemnify us for any damages resulting from product liability claims, 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.

BioThrax is currently identified as a covered countermeasure under a PREP Act declaration issued in October 2008, which provides us with immunity with respect to the manufacture, administration or use of BioThrax. Under our prior BioThrax contracts with the DoD and HHS, the U.S. government agreed to indemnify us against claims by third parties for death, personal injury and other damages related to BioThrax, including reasonable litigation and settlement costs, to the extent that the claim or loss results from specified risks not covered by insurance or caused by our grossly negligent or criminal behavior. As required under our prior BioThrax contracts, we have notified the DoD of personal injury claims that have been filed against us as a result of the vaccination of U.S. military personnel with BioThrax and are seeking reimbursement from the DoD for uninsured costs incurred in defending these claims. The collection process can be lengthy and complicated, and there is no guarantee that we will be able to recover these amounts from the U.S. government.

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 will 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 $15 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 is difficult to obtain and increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. For example, from 2002 through February 2006, we were unable to obtain product liability insurance for sales of BioThrax on commercially reasonable terms. We do not believe that the amount of insurance we have been able to obtain for BioThrax is sufficient to manage the risk associated with the potential large scale deployment of BioThrax as a countermeasure to bioterrorism threats. We rely on 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 capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by health care providers. If third party payors do not provide adequate coverage or reimbursement for any products we may develop, it could have a negative effect on our revenues and results of operations.

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

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

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

Our success depends on our continued ability to attract, retain and motivate highly qualified managerial and key scientific personnel. We consider Fuad El-Hibri, 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. 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 personnel, including scientific, clinical development, manufacturing and process development, regulatory, marketing and sales executives and field sales personnel, as well as additional 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 acquisitions, including our acquisition of Trubion, our ability to develop our product candidates and expand our product candidate pipeline may be harmed.

As part of our business strategy, we intend to continue to seek to obtain marketed products and development stage product candidates through acquisitions and licensing arrangements with third parties. The failure to adequately address the financial, operational or legal risks of these transactions, including our acquisition of Trubion, 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 other intangible assets.

We also may face significant challenges in effectively integrating entities and businesses that we acquire, such as Trubion, and we may not realize the benefits anticipated from such acquisitions. Achieving the anticipated benefits of our acquisition of Trubion and any other 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;
- prioritizing product portfolios;
- 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;
- 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, including intellectual property claims;
- 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 successfully integrate acquired entities and businesses, including Trubion, 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 a portion of our pipeline of vaccine and therapeutic product candidates through our acquisition of Microscience Limited in a share exchange in 2005 and our acquisitions of substantially all of the assets, for cash, of Antex Biologics, Inc. in 2003 and of ViVacs GmbH in 2006. More recently, we acquired additional pipeline product candidates as a result of our acquisition of Trubion in October 2010.

In the future, we may be unable to license or acquire suitable products or product candidates from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical and biological products is a competitive area. A number of more established companies are also pursuing strategies to license or acquire products in the vaccine and therapeutic field. 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 also have grown our employee base substantially. 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 will need to continue building our organization and making significant 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 additional anticipated growth. If we are unable to effectively manage and advance these activities, our ability to maximize the value of one or more of our product candidates could suffer, which could materially and adversely affect our business.

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 adversely affect our revenues and results of operations.

We rely on property and equipment owned by the U.S. government in the manufacturing process for BioThrax.

We have the right to use certain property and equipment that is owned by the U.S. government, referred to as government furnished equipment, or GFE, at our Lansing, Michigan site in the manufacture of BioThrax. We have the option to purchase all or part of the existing GFE from the U.S. government on terms to be negotiated with the U.S. government. If the U.S. government modifies the terms under which we use the GFE in a manner that is unfavorable to us or we are unable to reach an agreement with the U.S. government concerning the terms of the purchase of that part of the GFE necessary for our business, our business could be harmed. If the U.S. government were to terminate or fail to extend all BioThrax supply contracts with us, we potentially could be required to rent or purchase that part of the GFE necessary for the continued production of BioThrax in our current manufacturing facility.

Risks Related to Regulatory Approvals

If we 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 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 must 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 for BioThrax as a post-exposure prophylaxis, Anthrivig, PreviThrax, Thravixa, and NuThrax. 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.

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

After approving the renovated Lansing facilities in December 2001, the FDA conducted routine, biannual inspections of the Lansing facilities in September 2002, May 2004, May 2006, March 2008 and December 2009. 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 each of those inspections were successfully closed out. In December 2005, the FDA stated in its final order on BioThrax that at that time we were in substantial compliance with all regulatory requirements related to the manufacture of BioThrax and that the FDA would continue to evaluate the production of BioThrax to assure compliance with federal standards and regulations. 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 adversely affected.

If our competitors are able to obtain orphan drug exclusivity for any products that are competitive with our products, 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 Thravixa, from the FDA and in the European Union for our Anthrivig and in the European Union for our tuberculosis vaccine product candidate; however, 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 post-exposure prophylaxis against anthrax infection, for Anthrivig and Thravixa. 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 will have responsibility to obtain regulatory approvals outside the United States, and we will depend on our collaborators to obtain these approvals. The approval procedure varies among countries and can involve additional testing 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, in 2010 the United Kingdom Medicines and Healthcare products Regulatory Authority, or MHRA, informed us that a provision of the European Pharmacopoeia may prevent licensure 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 recent guidance to the contrary. We are continuing to work with the MHRA and outside advisors 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 leading pharmaceutical or biotechnology companies or non-governmental organizations. We expect that we will selectively pursue collaboration arrangements in situations in which the collaborator has particular expertise or resources for the development or commercialization of our products and product candidates or for accessing particular markets.

If we are unable to reach agreements with suitable collaborators, we may fail to meet our business objectives for the affected product or program. We face, and will continue to face, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements, 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, based on preclinical studies performed under a license agreement that we entered into with Sanofi Pasteur, both parties determined that the joint efforts had not identified a promising meningitis B vaccine product candidate and we mutually terminated the collaboration. 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 subject to termination by our collaborators in the event of a material breach by us;
- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not do so, our ability to maintain and defend our intellectual property rights may be compromised by our collaborators' acts or omissions;
- our collaborators may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;
- 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, 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 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 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 our biosciences 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. 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 interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial costs to us and an adverse decision as to the priority of our inventions. An unfavorable outcome in an interference 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 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 licensed an oligonucleotide adjuvant, CpG 7909, for use in our double mutant rPA product candidate and NuThrax from Coley Pharmaceutical Group, Inc., or Coley. Coley, which was subsequently acquired by Pfizer is responsible for prosecuting, maintaining and defending these licensed patent rights. Coley notified us that a patent interference had been declared in the U.S. Patent and Trademark Office between our licensed patent and a third party patent application, which could result in revocation of the patent we have licensed. We may not know the outcome for a considerable period of time.

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 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 Oxford-Emergent Tuberculosis Consortium 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, with agreements with our employees, consultants and third parties.

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

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

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

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 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 among our significant stockholders. As of March 4, 2011, Mr. El-Hibri was the beneficial owner of approximately 32% 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 and those of our stockholders and may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares.

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 March 4, 2011 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 for our common stock may be influenced by many factors, including:

- § the success of competitive products or technologies;
- § results of clinical trials of our product candidates or those of our competitors 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 total outstanding shares may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. For example, we have filed a registration statement that would permit us to issue up to $100 million in common stock. Moreover, holders of an aggregate of approximately 10.0 million shares of our common stock outstanding as of March 4, 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
Wokingham, England	Office and laboratory space	Biosciences	29,000	Leases expire 2016
Seattle, Washington	Office and laboratory space	Biosciences	51,000	Leases expire 2013
Rockville, Maryland	Office space	Biodefense/Biosciences	33,000	Lease expires 2016
Munich, Germany	Office and laboratory space	Biosciences	16,000	Lease expires 2015
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 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, which we purchased in November 2009, is approximately 48,000 square feet and contains a combination of laboratory and office space. Our facility in Wokingham, England consists of approximately 29,000 square feet in two buildings, and contains a combination of laboratory and office space. In conjunction with the restructuring of our operations in England, we are currently in negotiations to terminate or modify the leases associated with this space. We expect to vacate all or a significant portion of this space in the first half of 2011. Our facility in Seattle, Washington is approximately 51,000 square feet and contains a combination of laboratory and office space. Our facility in Rockville, Maryland contains approximately 33,000 square feet of office space, including our executive offices. Our facility in Munich, Germany is approximately 16,000 square feet and contains a combination of laboratory and office space.

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 $1.2 million and $7.3 million in 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

Litigation Against Protein Sciences Corporation. Until reaching settlement with Protein Sciences Corporation, or PSC, on November 2, 2010, we had been pursuing several legal actions against PSC and its senior management arising out of a letter of intent, a loan and security agreement and related promissory note, and an asset purchase agreement between us and PSC that were entered into in 2008.

On June 8, 2009, we initiated legal proceedings in the Superior Court of the State of Connecticut, Judicial District of New Haven, to acquire possession of the physical assets by foreclosing on PSC's physical assets that secured the loan. On July 9, 2008, we initiated legal proceedings against PSC in the Supreme Court of the State of New York including, among other claims, claims for fraud, breach of contract, breach of the duty of good faith and fair dealing, unjust enrichment and unfair business practices. On October 3, 2008, we initiated legal proceedings in the United States District Court for the District of Connecticut against PSC's executive management team of Daniel D. Adams, PSC's Executive Chairman, and Manon M.J. Cox, PSC's President and Chief Executive Officer alleging, among other things, that these individuals engaged in fraudulent conduct in connection with their efforts to obtain $10 million in bridge financing from us. On July 19, 2010, the Company filed a motion for summary judgment in lieu of complaint in the Supreme Court of the State of New York seeking repayment of its loan and interest.

On November 2, 2010, we and PSC entered into a settlement and mutual release of claims with respect to the letter of intent, the loan and security agreement and related promissory note and forbearance agreement, the asset purchase agreement and all other claims related thereto. Under the terms of the settlement, PSC paid us $11.5 million, consisting of full repayment of the original $10 million principal plus $1.5 million in interest, and the parties filed stipulations with the relevant courts to dismiss all litigation with prejudice.

Class-action Litigation Related to Trubion Pharmaceuticals Acquisition. On August 17, 2010, two class action lawsuits were filed in the Superior Court of Washington, King County, or State Court, against Trubion Pharmaceuticals, Inc., or Trubion, its board of directors, and us, or collectively, the Defendants, alleging in summary that, in connection with the proposed merger of Trubion with a subsidiary of ours, or the Acquisition, the members of the Trubion board of directors breached their fiduciary duties by conducting an unfair sale process and agreeing to an unfair price. Both complaints also claim that Trubion and us aided and abetted the Trubion board of directors in its breach of fiduciary duties. On September 9, 2010, the actions were consolidated into a single action, or State Action. On October 1, 2010, the plaintiffs in the State Action served on the Defendants a consolidated amended class action complaint, or Amended Complaint. The Amended Complaint alleges, among other things and in addition to the matters alleged in the initial complaints, that the Defendants omitted material information from the Proxy Statement/Prospectus.

On October 4, 2010, a class action lawsuit was filed in the U.S. District Court for the Western District of Washington against the Defendants, or Federal Action and, collectively with the State Action, the Actions, which makes allegations related to the Acquisition that are substantially similar to those matters alleged in the Amended Complaint, includes additional allegations regarding purported violations of the federal securities laws and seeks substantially similar relief.

On October 8, 2010, the Defendants reached agreement in principle with the plaintiffs in the Actions regarding the settlement of the Actions. In connection with the settlement contemplated by that agreement in principle, the Actions will be stayed pending approval of the settlement of the State Action by the State Court. Thereafter, the State Action and all claims asserted therein will be dismissed with prejudice and counsel for the plaintiff in the Federal Action will take all necessary steps to dismiss the Federal Action and all claims asserted therein with prejudice. The terms of the settlement contemplated by that agreement in principle require that Trubion and we make certain additional disclosures related to the Acquisition, as set forth in our Current Report on Form 8-K filed on October 8, 2010. The parties also agreed that the plaintiffs in the Actions may seek attorneys' fees and costs in an aggregate amount up to $475,000, to be paid by Trubion if such fees and costs are approved by the State Court.

There will be no other payment by Trubion, any of the members of the Trubion board of directors or us to the plaintiffs or their respective counsels in connection with the settlement and dismissal of the Actions. The agreement in principle further contemplates that the parties will enter into a stipulation of settlement, which will be subject to customary conditions, including State Court approval following notice to Trubion's shareholders. In the event that the parties enter into a stipulation of settlement, a hearing will be scheduled at which the State Court will consider the fairness, reasonableness and adequacy of the settlement. There can be no assurance that the parties will ultimately enter into a stipulation of settlement, that the State Court will approve any proposed settlement, or that any eventual settlement will be under the same terms as those contemplated by the agreement in principle

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. The Opposition Division set a date of November 27, 2010 for all parties to file appeals, and we timely filed our appeal. 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 set due dates of January 29, 2011 and February 7, 2011 for Notices of Appeal to be filed for these oppositions, and we timely filed our Notices of Appeal. Our Appeal Briefs are due on March 29, 2011 and April 7, 2011. 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. A due date has not yet been set for the parties to file their appeals. We routinely monitor the grant of further Bavarian Nordic European patents to determine whether any additional oppositions should be filed.

Other. We are, and may in the future become, subject to other legal proceedings, claims and litigation arising in the ordinary course of our business in connection with the manufacture, distribution and use of our products and product candidates. For example, Emergent BioDefense Operations Lansing Inc., or EBOL, was a defendant, along with many other vaccine manufacturers, in a series of lawsuits that have been filed in various state and federal courts in the United States alleging that thimerosal, a mercury-containing preservative allegedly used by the defendants in the manufacture of some vaccines, caused personal injuries, including brain damage, central nervous system damage and autism. The last of the lawsuits in which EBOL was named a defendant, which were pending in California, were dismissed without prejudice in July 2010.

ITEM 4. REMOVED AND RESERVED

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, 2010 and 2009:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year Ended December 31, 2010				
High	$ 17.24	$ 17.30	$ 19.98	$ 23.93
Low	$ 13.22	$ 14.11	$ 14.86	$ 17.10
Year Ended December 31, 2009				
High	$ 27.00	$ 15.31	$ 19.95	$ 18.25
Low	$ 12.23	$ 9.15	$ 12.09	$ 12.36

As of March 4, 2011, the closing price per share of our common stock on the New York Stock Exchange was $21.14 and we had 43 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, 2010, 2009 and 2008 and the consolidated balance sheet data as of December 31, 2010 and 2009 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, 2007 and 2006 and the consolidated balance sheet data as of December 31, 2008, 2007 and 2006 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)	**2010**	**2009**	**2008**	**2007**	**2006**
Statements of operations data:					
Revenues:					
Product sales	$ 251,381	$ 217,172	$ 169,124	$ 169,799	$ 147,995
Contracts and grants	34,790	17,614	9,430	13,116	4,737
Total revenues	286,171	234,786	178,554	182,915	152,732
Operating expenses (income):					
Cost of product sales	47,114	46,262	34,081	40,309	24,125
Research and development	89,295	74,588	59,470	53,958	45,501
Selling, general & administrative	76,205	73,786	55,076	55,555	44,601
Purchased in-process research and development	-	-	-	-	477
Total operating expenses	212,614	194,636	148,627	149,822	114,704
Income from operations	73,557	40,150	29,927	33,093	38,028
Other income (expense):					
Interest income	832	1,418	1,999	2,809	846
Interest expense	-	(7)	(47)	(71)	(1,152)
Other income (expense), net	(1,023)	(50)	134	156	293
Total other income (expense)	(191)	1,361	2,086	2,894	(13)
Income before provision for income taxes	73,366	41,511	32,013	35,987	38,015
Provision for income taxes	26,182	14,966	12,055	13,051	15,222
Net income	$ 47,184	$ 26,545	$ 19,958	$ 22,936	$ 22,793
Net loss attributable to noncontrolling interest	4,514	4,599	724	-	-
Net income attributable to Emergent BioSolutions Inc.	$ 51,698	$ 31,144	$ 20,682	$ 22,936	$ 22,793
Earnings per share — basic	$ 1.63	$ 1.02	$ 0.69	$ 0.79	$ 0.99
Earnings per share — diluted	$ 1.59	$ 0.99	$ 0.68	$ 0.77	$ 0.93
Weighted average number of shares — basic	31,782,286	30,444,485	29,835,134	28,995,667	23,039,794
Weighted average number of shares — diluted	32,539,500	31,375,305	30,458,098	29,663,127	24,567,302

	As of December 31,				
(in thousands)	**2010**	**2009**	**2008**	**2007**	**2006**
Balance Sheet Data:					
Cash and cash equivalents	$ 169,019	$ 102,924	$ 91,473	$ 105,730	$ 76,418
Working capital	167,774	139,113	98,866	88,649	82,990
Total assets	500,319	344,689	290,788	273,508	238,255
Total long-term liabilities	51,039	46,173	37,418	46,688	35,436
Total stockholders' equity	373,561	243,815	199,349	171,159	138,472

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this annual report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this annual report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" 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 antibody 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 focuses on vaccines and antibody therapies for use against biological agents that are potential weapons of bioterrorism or biowarfare. Our products and product candidates in this segment are focused on anthrax. We manufacture and market BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or FDA, for the prevention of anthrax infection. In addition to BioThrax, we are developing PreviThrax™ (Recombinant Protective Antigen Anthrax Vaccine, Purified), Anthrivig™ (Human Anthrax Immunoglobulin), Thravixa™ (Fully Human Anthrax Monoclonal Antibody), NuThrax™ (Anthrax Vaccine Absorbed with CPG 7909 Adjuvant), and a double mutant recombinant protective antigen anthrax vaccine. Operations in this segment include biologics manufacturing, regulatory and quality affairs, marketing and sales in support of BioThrax and a product development infrastructure in support of our investigational product candidates.

Our biosciences segment is directed to commercial opportunities. Our programs in this segment target oncology, including B-cell malignancies of chronic lymphocytic leukemia, or CLL, and non-Hodgkin's lymphoma, or NHL; autoimmune and inflammatory disorders, or AIID, including rheumatoid arthritis, or RA, and systemic lupus erythematosus, or SLE; and other infectious diseases such as tuberculosis, influenza and typhoid. Our programs in this segment include clinical and preclinical stage investigational product candidates. 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 grant funding, but none of our biosciences product candidates has 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. Department of Health and Human Services, or HHS, and the U.S. Department of Defense, or DoD, and 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 $251.4 million, $217.2 million and $169.1 million for the years ended December 31, 2010, 2009 and 2008, 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 awards for the following development programs:

- BioThrax post-exposure prophylaxis;
- NuThrax;
- Large-scale manufacturing for BioThrax;
- PreviThrax;
- Anthrivig;
- Thravixa;
- Double mutant recombinant protective antigen anthrax vaccine;
- Recombinant botulinum vaccine; and
- Typhella

Additionally, our tuberculosis vaccine product candidate is indirectly supported by grant funding provided to The University of Oxford by The Wellcome Trust and Aeras Global Tuberculosis Vaccine Foundation. Our TRU-016 product candidate is being funded via a joint collaboration with Abbott Laboratories, or Abbott, in which we and Abbott share all funding responsibilities equally. Our SBI-087 product candidate is substantially funded by Pfizer Inc., or Pfizer.

We continue to actively pursue additional government sponsored development contracts and grants and to 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. Prior to the award, we incurred costs of approximately $83 million for the building and associated capital equipment, as well as for validation and qualification activities required for regulatory approval and initiation of commercial manufacture of BioThrax.

In November 2009, we purchased a building in Baltimore, Maryland for product development and manufacturing purposes, and have begun renovation and improvement of this facility. 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. As we proceed with this project, we expect the costs to be substantial and will likely seek external sources of funds to finance the project.

We also own two buildings in Frederick, Maryland that we currently expect to sell. Accordingly, we have classified these buildings as assets held for sale in our consolidated balance sheets. We recorded the assets held for sale at fair market value, based on factors that include recent purchase offers, less estimated selling costs, and recorded impairment charges of approximately $1.2 million and $7.3 million for the years ended December 31, 2010 and 2009, respectively. We continue to actively seek to sell these buildings.

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 based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

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

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

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

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 with Pfizer and Abbott. Certain internal and external research and development costs and patent costs are reimbursed in connection with our collaboration agreements. Reimbursed costs under the Pfizer collaboration are recognized as revenue in the period in which the costs are incurred. Our collaboration with Abbott provides for equal cost sharing of development and clinical costs. Each quarter we and Abbott report to the other party the total costs incurred for development costs. 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 may fluctuate depending on which party in the collaboration is incurring 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 of up to $38.7 million to former shareholders and stock option holders of Trubion. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. Because the achievement of these milestones has not occurred as of December 31, 2010, 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 will include a comparison of the fair value of IPR&D to our existing carrying value. We will recognize an impairment for amounts 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.

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 units to the carrying value of the reporting units. If the carrying value of the net assets assigned to the reporting unit's exceeds the fair value of the reporting units, then the second step of the impairment test is performed in order to determine the implied fair value of the reporting units' goodwill. If the carrying value of the reporting units' goodwill exceeds its implied fair value, an impairment loss equal to the difference is recorded and charged to general and administrative expense.

We calculate the fair value of the reporting units utilizing a weighting of the income and market approaches. The income approach utilizes a discounted cash flow model, using a discount rate based on our estimated cost of capital. The market approach utilizes revenue and other metrics from similar publicly traded companies. The results of both fair value calculations are then compared to our reporting unit's carrying value. We have selected October 1st an our annual impairment test date. The acquisition of Trubion occurred on October 28, 2010; therefore we performed an assessment to determine whether goodwill was more likely than not impaired at December 31, 2010, which would require an interim impairment. We determined that no such indicators were present.

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, 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 Strategic National Stockpile, or SNS. This agreement was amended in July 2010 to, among other things, allow us to accelerate the delivery of BioThrax doses into the SNS by approximately three months. The term of the agreement is from September 30, 2008 through September 30, 2011. Delivery of doses under the agreement commenced in September 2009 and are scheduled through June 2011. Funds for the procurement of these doses of BioThrax have been fully committed. The total purchase price for the 14.5 million doses is approximately $400 million. Through December 31, 2010, we have delivered approximately 11.6 million doses under this agreement. We have agreed to provide all shipping services related to delivery of doses into the SNS over the term of the agreement, for which HHS has agreed to pay us approximately $1.9 million. We invoice under the agreement upon acceptance of each delivery of BioThrax doses to the SNS.

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

Product Candidate/Manufacturing	Funding Source	Award Date	Amount (Up to)	Performance Period
Anthrivig	NIAID	9/2007	$9.5 million	9/2007 — 12/2011
Recombinant botulinum vaccine	NIAID	6/2008	$1.8 million	6/2008 — 5/2011
NuThrax	NIAID	7/2008	$2.8 million	7/2008 — 6/2013
Thravixa	NIAID/BARDA	9/2008	$24.3 million	9/2008 — 8/2012
NuThrax	NIAID/BARDA	9/2008	$24.4 million	9/2008 — 9/2011
Double mutant recombinant protective antigen anthrax vaccine	NIAID	9/2009	$4.9 million	9/2009 — 8/2011
Large-scale manufacturing for BioThrax	BARDA	7/2010	$107.0 million	7/2010 — 9/2014
NuThrax	NIAID	7/2010	$28.7 million	8/2010 — 8/2014
PreviThrax	BARDA	9/2010	$186.6 million	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 because of the timing of our fulfilling orders for BioThrax and work done under new and existing contracts and grants.

Cost of Product Sales

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

We determine the cost of product sales for doses sold during a reporting period based on the average manufacturing cost per dose 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:

- § salaries and related expenses for personnel;
- § fees to professional service providers for, among other things, preclinical and analytical testing, independently monitoring our clinical trials and acquiring and evaluating data from our clinical trials 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, including those recently acquired through our acquisition of Trubion, 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, continued participation of our third-party collaborators, 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 with BioThrax conducted by the Centers for Disease Control and Prevention, or 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 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, 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 recently awarded large-scale manufacturing for BioThrax contract and our collaboration 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 costs, and includes increased expenses of $7.7 million on product candidates that are categorized in the biodefense segment, increased expenses of $6.9 million on product candidates and technology platform development activities categorized in the biosciences segment, and increased expenses of $39,000 in other research and development, which are in support of central research and development activities.

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 increase in spending for our double mutant recombinant protective antigen anthrax vaccine product candidate resulted from spending for process manufacturing and assay development. 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 2009 spending for our botulinum vaccine product candidates resulted from conducting non-clinical studies. We expect that spending for our botulinum vaccine candidates will remain minimal in the future, due primarily to reduced funding by the U.S. government for these product candidates.

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 decrease in spending for Typhella was primarily due to the timing of stability and clinical studies. The increase in spending for our influenza vaccine product candidate is related to process and analytical development. 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 diseases and cancer, including RA, SLE, CLL and NHL. The decrease in spending for our hepatitis B therapeutic vaccine product candidate was related to the cessation of the Phase II clinical trial in the United Kingdom and Serbia. We have significantly reduced ongoing spending with regard to this product candidate while we investigate options to sell or outlicense the related technology, and expect that future spending will be reduced. 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 attributable to central research and development activities.

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
Double mutant recombinant protective antigen vaccine	5,938	560
Anthrivig	5,937	6,890
Thravixa	8,148	7,215
Botulinum vaccines	647	4,011
Total biodefense	50,613	42,874
Biosciences:		
Tuberculosis vaccine	13,690	11,710
Typhella	3,398	5,083
Influenza vaccine	4,088	2,822
TRU-016	2,205	-
SBI-087	459	-
Hepatitis B therapeutic vaccine	255	3,522
Other bioscience	8,740	2,769
Total bioscience	32,835	25,906
Other	5,847	5,808
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 $3.3 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.

Year Ended December 31, 2009 Compared to Year Ended December 31, 2008

Revenues

Product sales revenues increased by $48.0 million, or 28%, to $217.2 million for 2009 from $169.1 million for 2008. This increase in product sales revenues was primarily due to payments from HHS of approximately $34.0 million related to the approval of four-year expiry dating for BioThrax, obtained in June 2009, coupled with an 8% increase in the number of doses sold in 2009. Product sales revenues in 2009 consisted of BioThrax sales to HHS of $216.4 million and aggregate international and other sales of $703,000. Product sales revenues in 2008 consisted of BioThrax sales to HHS of $167.6 million and aggregate international and other sales of $1.5 million.

Contracts and grant revenues increased by $8.2 million, or 87%, to $17.6 million in 2009 from $9.4 million in 2008. 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 with Sanofi Pasteur, which was terminated in December 2008. Contracts and grants revenues for 2008 consisted of $4.4 million from the Sanofi Pasteur collaboration, related to recognition upon termination of the collaboration in December 2008 of deferred revenue associated with the upfront payment received in 2006 as well as development service revenue, $3.2 million in development contract and grant revenue from NIAID and other governmental agencies, and $1.8 million from the sale of technology rights and related materials and documentation pertaining to our Pertussis technology.

Cost of Product Sales

Cost of product sales increased by $12.2 million, or 36%, to $46.3 million for 2009 from $34.1 million for 2008. This increase was attributable to the 8% increase in the number of BioThrax doses sold and an increase in average cost per dose sold associated with reduced production yield in the period during which the doses sold were produced.

Research and Development Expenses

Research and development expenses increased by $15.1 million, or 25%, to $74.6 million for 2009 from $59.5 million for 2008. This increase reflects higher contract service costs, and includes increased expenses of $16.6 million on product candidates that are categorized in the biodefense segment, decreased expenses of $6.6 million on product candidates and technology platforms categorized in the biosciences segment, and increased expenses of $5.1 million in other research and development, which are in support of central research and development activities.

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, coupled with increased spending on product candidates that we acquired in 2008. The increase in spending for BioThrax related programs was due to the preparation for and conduct of clinical and non-clinical feasibility, efficacy and stability studies to support applications for marketing approval of these programs, along with formulation development and manufacture of clinical material. The increase in spending for our PreviThrax product candidate was related primarily to costs incurred to respond to a request for proposal from BARDA and the continued advancement of the product candidate. The decrease in spending for our double mutant protective antigen vaccine resulted from the timing of feasibility and stability studies. The increase in spending for our Anthrivig candidate was primarily due to the commencement of clinical and non-clinical studies during 2009. The increase in spending for the Thravixa candidate was primarily for manufacture of a working cell bank, formulation development and the conduct of non-clinical studies. The increase in spending for our botulinum vaccine product candidates resulted from conducting non-clinical studies and the manufacture of master and working cell banks.

The decrease in spending on biosciences product candidates, detailed in the table below, was primarily attributable to the timing of development efforts and to the termination or scaling back of certain programs. The increase in spending for our tuberculosis vaccine product candidate is related to the formation of our joint venture with the University of Oxford in July 2008, the procurement of licenses, and preparation for and conduct of a Phase IIb clinical trial, which commenced in April 2009. The spending for Typhella in 2008 resulted from the manufacture of clinical material and conducting a Phase IIb clinical trial in the United States. These activities did not continue in 2009, resulting in the decrease in spending. The increase in spending for our influenza vaccine product candidate is related to preparation for and conduct of feasibility and immunogenicity studies. The spending for our hepatitis B therapeutic vaccine product candidate was related to our Phase II clinical trial in the United Kingdom and Serbia and other development activities. The decrease in spending for our group B streptococcus vaccine product candidate resulted from our decision not to proceed with Phase I clinical trials for two of the protein components of the vaccine product candidate. The decrease in spending for our chlamydia candidate was related to a decrease in development activities while seeking external funding. The decrease in spending for our meningitis B vaccine product candidate resulted from the termination of our collaboration with Sanofi-Pasteur in December 2008. The increase in spending for our other biosciences programs was related to development activities targeting our technology platforms.

The increase in other research and development expenses was primarily attributable to our central research and development activities.

Our principal research and development expenses for 2009 and 2008 are shown in the following table:

	Year ended December 31,	
(in thousands)	**2009**	**2008**
Biodefense:		
BioThrax related programs	$ 15,748	$ 7,159
PreviThrax	8,450	6,563
Double mutant protective antigen vaccine	560	2,540
Anthrivig	6,890	6,126
Thravixa	7,215	1,062
Botulinum vaccines	4,011	2,871
Total biodefense	42,874	26,321
Biosciences:		
Tuberculosis vaccine	11,711	2,145
Typhella	5,083	15,431
Influenza vaccine	2,822	1,511
Hepatitis B therapeutic vaccine	3,521	3,010
Group B streptococcus vaccine	202	6,539
Chlamydia vaccine	567	1,220
Meningitis B vaccine	158	1,313
Other biosciences	1,842	1,290
Total biosciences	25,906	32,459
Other	5,808	690
Total	$ 74,588	$ 59,470

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $18.7 million, or 34%, to $73.8 million for 2009 from $55.1 million for 2008. This increase includes approximately $5.0 million in increased litigation services and other professional services, a $7.3 million impairment charge associated with our Frederick, Maryland facilities and a $1.4 million charge associated with acquisitions that were in progress but not completed as of December 31, 2008, as well as increased personnel costs related to the growth of our business. The majority of the expense is attributable to the biodefense segment, in which selling, general and administrative expenses increased by $5.9 million, or 14%, to $48.8 million for 2009 from $43.0 million for 2008. Selling, general and administrative expenses related to our biosciences segment increased by $12.8 million, or 105%, to $25.0 million for 2009 from $12.2 million for 2008, reflecting increased litigation services, along with the charges discussed above related to the Frederick facilities and acquisitions in progress.

Total Other Income (Expense)

Total other income decreased by $725,000, or 35%, to $1.4 million for 2009 from $2.1 million for 2008. This decrease resulted primarily from a decrease in interest income of $581,000 primarily as a result of lower investment return on average invested cash balances related to a decline in interest rates.

Income Taxes

Provision for income taxes increased by $2.9 million, or 24%, to $15.0 million for 2009 from $12.1 million for 2008. 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 for 2008 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of $32.7 million and an effective annual tax rate of approximately 37%. The decrease in the effective tax rate was primarily due to the benefit of certain costs capitalized for book purposes that are deductible for tax purposes. The provision for income taxes also reflects research and development tax credits of $835,000 for 2009 and $819,000 for 2008.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest increased by $3.9 million to $4.6 million for 2009 from $724,000 for 2008. The increase resulted from increased development activities and related expenses incurred by our joint venture with the University of Oxford, which was established in July 2008. These amounts represent the portion of the loss incurred by the joint venture for 2009 and 2008, respectively, that is attributable to Oxford.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our cash requirements from inception through 2010 principally with a combination of revenues from BioThrax product sales, debt financings and facilities and equipment leases, development funding from government entities and non-government and philanthropic organizations, 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, 2010.

As of December 31, 2010, we had cash, cash equivalents and investments of $171.0 million. Additionally, at December 31, 2010, our accounts receivable balance was $39.3 million.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2010, 2009 and 2008.

	Year ended December 31,		
(in thousands)	**2010**	**2009**	**2008**
Net cash provided by (used in):			
Operating activities(1)	$ 98,909	$ 29,894	$ 7,588
Investing activities	(23,456)	(33,287)	(30,813)
Financing activities	(9,358)	14,844	8,968
Total net cash provided by (used in)	$ 66,095	$ 11,451	$ (14,257)

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

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 venture with the University of Oxford..

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, a net increase in deferred income taxes related to timing differences of $7.6 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 provided by operating activities of $7.6 million in 2008 resulted principally from our net income of $20.7 million, partially offset by an increase in accounts receivable of $6.0 million due to amounts billed primarily to HHS in December 2008 that were collected in 2009 and a decrease in income taxes payable of $6.7 million due to the timing of payment of our 2007 income tax liability and estimated tax payments related to our 2008 income tax liability.

Net cash used in investing activities of $23.5 million for the year ended December 31, 2010 was primarily due to the 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 Pharmaceuticals, Inc. 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 for the years ended December 31, 2009 and 2008, respectively, resulted principally from the purchase of property, plant and equipment and, in 2008, the issuance of a note receivable in the amount of $10 million. Capital expenditures in 2009 include $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. Capital expenditures in 2008 relate primarily to $13.1 million in construction and related costs for our new manufacturing facility in Lansing, Michigan and approximately $7.7 million in infrastructure investments and other equipment.

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.

Net cash provided by financing activities of $9.0 million in 2008 resulted primarily from $60.0 million in proceeds from borrowings under our revolving line of credit with Fifth Third Bank, $5.0 million from the release of restricted cash related to our continuing compliance with the debt covenants specified in our HSBC term loan, $1.3 million related to excess tax benefits from the exercise of stock options, and $3.4 million in proceeds from stock option exercises, partially offset by $60.8 million in principal payments on indebtedness, including $56.8 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, 2010:

		Payments due by period				
(in thousands)	**Total**	**2011**	**2012**	**2013**	**2014**	**2015**
Contractual obligations:						
Long-term indebtedness including current portion	$ 47,426	$ 17,187	$ 2,331	$ 2,331	$ 25,577	$ -
Operating lease obligations	14,425	3,406	3,511	2,553	2,089	1,800
Total contractual obligations	$ 61,851	$ 20,593	$ 5,842	$ 4,884	$ 27,666	$ 1,800

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 $177 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, 2010, we had $47.4 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;
- § $5.7 million outstanding under a mortgage loan from PNC Bank used to finance the remaining portion of the purchase price for our first Frederick facility;
- § $6.7 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance a portion of the purchase price for our second facility on the Frederick site;
- § $21.2 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;
- § $6.5 million outstanding under a mortgage loan from HSBC Realty Credit Corporation used to finance a portion of the purchase price of our facility in Baltimore, Maryland; and
- § $4.8 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.

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

- Under our loan from the State of Maryland, we are not required to repay the principal amount of the loan if beginning December 31, 2009 and through 2012 we maintain a specified number of employees at the Frederick site, by December 31, 2009 we have invested at least $42.9 million in total funds toward financing the purchase of the buildings on the site and for related improvements and operation of the facility, and we occupy the facility through 2012. 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 as of December 31, 2009. We have reached an agreement with the State of Maryland to repay the loan in full by March 31, 2011, 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 revolving line of credit with Fifth Third Bank, our wholly owned subsidiary, Emergent BioDefense Operations Lansing LLC, or Emergent BioDefense Operations, is required to maintain at all times a ratio of total liabilities to tangible net worth of not more than 2.5 to 1.0.

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

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

Under our mortgage loan from PNC Bank, we began to make monthly principal payments beginning in November 2006. A residual principal payment of approximately $5.3 million is due upon maturity in October 2011. Interest is payable monthly and accrues at an annual rate of 4.075%.

Under our mortgage loan from HSBC Realty Credit Corporation to purchase our second facility in Frederick, Maryland, we are required to make monthly principal payments. A residual principal payment of approximately $6.6 million is due upon maturity in April 2011. Interest is payable monthly and accrues at an annual rate equal to the three month LIBOR plus 3.00%.

Under our term loan with HSBC Realty Credit Corporation, which we refinanced in December 2009, we are required to make monthly principal payments. A residual principal payment of approximately $15.2 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. 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 mortgage loan from HSBC Realty Credit Corporation to purchase our Baltimore facility, we are required to make monthly principal payments. A residual principal payment of approximately $4.7 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 revolving line of credit with Fifth Third Bank, any outstanding principal is due upon maturity in June 2011. The principal amount outstanding at any time under the line of credit may not exceed 75% of total eligible accounts receivable under our HHS contracts.

Tax Benefits

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

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures and debt service requirements from existing cash and cash equivalents, revenues from BioThrax product sales, collaboration funding, development contract and grant funding, and our existing line of credit. 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 debt 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 level of participation of collaborative partners in our development programs, including those recently acquired in our acquisition of Trubion;
- § 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 new manufacturing 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 growth generates increased administrative costs;
- § the extent to which we lend money to, and are able to obtain repayment from, third parties;
- § 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 and technologies;
- § the effect of competing technological and market developments; and
- § the extent to which we become obligated to make cash payments related to the contingent value rights issued to former holders of Trubion common stock in connection with our acquisition of Trubion that are not offset by corresponding cash inflows from our collaborative partners.

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

Effects of Inflation

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

Recent Accounting Pronouncements

In December 2010, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2010-29, which amended Accounting Standards Codification, or ASC, Topic 805 regarding pro forma revenue and earnings disclosure requirements for business combinations. The amendments in ASU No. 2010-29 provide that an entity should disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. This amendment is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010 with early adoption permitted. We adopted this amendment in January 2011. We do not anticipate that this amendment will have a material impact on our financial statements.

In April 2010, the FASB issued ASU No. 2010-17 which amended ASC Topic 605 regarding the milestone method of revenue recognition. The amendments in ASU No. 2010-17 provide guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate along with providing for expanded disclosures. This amendment is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted. We adopted this amendment in January 2011. We do not anticipate that this amendment will have a material impact on our financial statements.

In February 2010, the FASB issued ASU No. 2010-09 which amended ASC Topic 855 regarding subsequent events. The amendments in ASU No. 2010-09 remove the requirement for a Securities and Exchange Commission, or SEC, filer to disclose a date in both issued and revised financial statements. This amendment is effective for financial statements issued for interim and annual periods ending after June 15, 2010. The adoption of this amendment did not have a material impact on our financial statements.

In October 2009, the FASB issued ASU No. 2009-13, which amended ASC Topic 605 regarding multiple-deliverable revenue arrangements. The amendments in ASU No. 2009-13 establish a selling price hierarchy for determining the selling price of a deliverable. In addition, this amendment replaces the term “fair value” in the revenue allocation guidance with “selling price”. ASU No. 2009-13 eliminates the residual method of allocation and require that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method and will require that an entity determine its best estimate of selling price in a manner that is consistent with that used to determine the price to sell the deliverable on a standalone basis. ASU No. 2009-13 will significantly expand the disclosures related to an entity’s multiple-deliverable revenue arrangements. In the year of adoption, entities will be required to disclose information that enables the users of financial statements to understand the effect of adopting ASU No. 2009-13. This amendment is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. If early adoption is elected and the period of adoption is not the beginning of the entity’s fiscal year, the entity will be required to apply the amendments in ASU No. 2009-13 retrospectively from the beginning of the entity’s fiscal year. We adopted this amendment in January 2011. The adoption of this amendment will have an impact on our financial statements to the extent we are a party to multiple-deliverable revenue arrangements.

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 interest on 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 of $2.0 million as of December 31, 2010, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments, but would likely increase the interest expense associated with our debt.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. and Subsidiaries as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2010, 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, 2010, 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 10, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia
March 10, 2011

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

	December 31, 2010	2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 169,019	$ 102,924
Investments	2,029	-
Accounts receivable	39,326	54,872
Inventories	12,722	13,521
Note receivable	-	10,000
Deferred tax assets, net	2,638	1,870
Income tax receivable, net	8,728	2,574
Restricted cash	217	215
Prepaid expenses and other current assets	8,814	7,838
Total current assets	243,493	193,814
Property, plant and equipment, net	152,701	131,834
In-process research and development	51,400	-
Goodwill	5,029	-
Assets held for sale	12,741	13,960
Deferred tax assets, net	33,757	3,894
Other assets	1,198	1,187
Total assets	$ 500,319	$ 344,689
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 25,409	$ 17,159
Accrued expenses and other current liabilities	1,309	1,570
Accrued compensation	23,975	14,926
Indebtedness under line of credit	-	15,000
Long-term indebtedness, current portion	17,187	5,791
Deferred revenue, current portion	7,839	255
Total current liabilities	75,719	54,701
Long-term indebtedness, net of current portion	30,239	44,927
Deferred revenue, net of current portion	4,386	-
Contingent value rights	14,532	-
Other liabilities	1,882	1,246
Total liabilities	126,758	100,874
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2010 and 2009, respectively	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 35,011,423 and 30,831,360 shares issued and outstanding at December 31, 2010 and 2009, respectively	35	31
Additional paid-in capital	197,689	120,492
Accumulated other comprehensive loss	(2,110)	(1,476)
Retained earnings	173,850	122,152
Total Emergent BioSolutions Inc. stockholders' equity	369,464	241,199
Noncontrolling interest in subsidiary	4,097	2,616
Total stockholders' equity	373,561	243,815
Total liabilities and stockholders' equity	$ 500,319	$ 344,689

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

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

	Year Ended December 31,		
	2010	**2009**	**2008**
Revenues:			
Product sales	$ 251,381	$ 217,172	$ 169,124
Contracts and grants	34,790	17,614	9,430
Total revenues	286,171	234,786	178,554
Operating expense:			
Cost of product sales	47,114	46,262	34,081
Research and development	89,295	74,588	59,470
Selling, general and administrative	76,205	73,786	55,076
Income from operations	73,557	40,150	29,927
Other income (expense):			
Interest income	832	1,418	1,999
Interest expense	-	(7)	(47)
Other income (expense), net	(1,023)	(50)	134
Total other income (expense)	(191)	1,361	2,086
Income before provision for income taxes	73,366	41,511	32,013
Provision for income taxes	26,182	14,966	12,055
Net income	47,184	26,545	19,958
Net loss attributable to noncontrolling interest	4,514	4,599	724
Net income attributable to Emergent BioSolutions Inc.	$ 51,698	$ 31,144	$ 20,682
Earnings per share - basic	$ 1.63	$ 1.02	$ 0.69
Earnings per share - diluted	$ 1.59	$ 0.99	$ 0.68
Weighted-average number of shares - basic	31,782,286	30,444,485	29,835,134
Weighted-average number of shares - diluted	32,539,500	31,375,305	30,458,098

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

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

	Year Ended December 31,		
	2010	**2009**	**2008**
Cash flows from operating activities:			
Net income	$ 47,184	$ 26,545	$ 19,958
Adjustments to reconcile to net cash provided by operating activities:			
Stock-based compensation expense	7,063	5,007	2,510
Depreciation and amortization	5,990	4,999	4,964
Deferred income taxes	10,929	7,604	2,006
Non-cash development expenses from joint venture	5,995	7,215	724
Loss (gain) on disposal of property and equipment	(38)	61	(135)
Provision for impairment of long-lived assets	1,218	7,328	-
Provision for impairment of accrued interest on note receivable	1,032	-	-
Excess tax benefits from stock-based compensation	(1,700)	(1,852)	(1,336)
Changes in operating assets and liabilities:			
Accounts receivable	19,094	(30,017)	(6,038)
Inventories	799	6,207	(1,428)
Income taxes	(6,154)	(3,525)	(6,714)
Prepaid expenses and other assets	(653)	(1,230)	(4,949)
Accounts payable	3,623	(1,334)	(457)
Accrued expenses and other liabilities	(223)	(66)	(523)
Accrued compensation	6,207	3,546	1,878
Deferred revenue	(823)	23	(3,143)
Net cash provided by operating activities	99,543	30,511	7,317
Cash flows from investing activities:			
Purchases of property, plant and equipment	(22,101)	(33,287)	(20,813)
Acquisition of Trubion Pharmaceuticals, Inc., net of cash acquired	(17,873)	-	-
Proceed from maturities of investments	6,518	-	-
Repayment/(issuance) of note receivable	10,000	-	(10,000)
Net cash used in investing activities	(23,456)	(33,287)	(30,813)
Cash flows from financing activities:			
Restricted cash release (deposit)	(2)	(7)	4,992
Proceeds from borrowings on long-term indebtedness and line of credit	15,000	57,183	60,000
Issuance of common stock subject to exercise of stock options	7,235	4,464	3,391
Principal payments on long-term indebtedness and line of credit	(33,291)	(48,648)	(60,751)
Excess tax benefits from stock-based compensation	1,700	1,852	1,336
Net cash (used in) provided by financing activities	(9,358)	14,844	8,968
Effect of exchange rate changes on cash and cash equivalents	(634)	(617)	271
Net increase (decrease) in cash and cash equivalents	66,095	11,451	(14,257)
Cash and cash equivalents at beginning of year	102,924	91,473	105,730
Cash and cash equivalents at end of year	169,019	102,924	91,473
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ 2,176	$ 1,627	$ 3,216
Cash paid during the year for income taxes	$ 22,440	$ 15,155	$ 16,788
Supplemental information on non-cash investing and financing activities:			
Issuance of common stock to acquire Trubion Pharmaceuticals, Inc.	$ 61,204	$ -	$ -
Purchases of property, plant and equipment unpaid at year end	$ 3,519	$ 2,749	$ 2,510

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

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

	$0.001 Par Value Common Stock Shares	Amount	Additional Paid-In Capital	Accumulated Other Comp-rehensive Loss	Noncontrolling Interest in Subsidiary	Retained Earnings	Total Stockholders' Equity
Balance at December 31, 2007	29,750,237	$ 30	$ 101,933	$ (1,130)	$ -	$ 70,326	$ 171,159
Exercise of stock options	409,309	-	3,391	-	-	-	3,391
Stock-based compensation expense	-	-	2,510	-	-	-	2,510
Excess tax benefits from exercises of stock options	-	-	1,336	-	-	-	1,336
Net income	-	-	-	-	-	20,682	20,682
Foreign currency translation	-	-	-	271		-	271
Comprehensive income	-	-	-	-	-	-	20,953
Balance at December 31, 2008	30,159,546	$ 30	$ 109,170	$ (859)	$ -	$ 91,008	$ 199,349
Exercise of stock options	671,814	1	4,463	-	-	-	4,464
Stock-based compensation expense	-	-	5,007	-	-	-	5,007
Excess tax benefits from exercises of stock options	-	-	1,852	-	-	-	1,852
Non-cash development expenses from joint venture	-	-	-	-	7,215	-	7,215
Net loss attributable to noncontrolling interest	-	-	-	-	(4,599)	-	(4,599)
Net income	-	-	-	-		31,144	31,144
Foreign currency translation	-	-	-	(617)	-	-	(617)
Comprehensive income	-	-	-		-	-	30,527
	-	-	-	-	-	-	
Balance at December 31, 2009	30,831,360	$ 31	$ 120,492	$ (1,476)	$ 2,616	$ 122,152	$ 243,815
Issuance of stock for the Trubion Pharmaceuticals, Inc. acquisition	3,351,817	3	61,200	-	-	-	61,203
Exercise of stock options	828,246	1	7,234	-	-	-	7,235
Stock-based compensation expense	-	-	7,063	-	-	-	7,063
Excess tax benefits from exercises of stock options	-	-	1,700	-	-	-	1,700
Non-cash development expenses from joint venture	-	-	-	-	5,995	-	5,995
Net loss attributable to noncontrolling interest	-	-	-	-	(4,514)	-	(4,514)
Net income	-	-	-	-		51,698	51,698
Foreign currency translation	-	-	-	(634)	-	-	(634)
Comprehensive income	-	-	-	-	-	-	51,064
Balance at December 31, 2010	35,011,423	$ 35	$ 197,689	$ (2,110)	$ 4,097	$ 173,850	$ 373,561

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

Emergent BioSolutions Inc. and Subsidiaries
Notes to consolidated financial statements

1. Nature of the business and organization

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

As a result of the Reorganization, BioPort became a wholly owned subsidiary of the Company. The Company has renamed BioPort as Emergent BioDefense Operations Lansing Inc. and subsequently converted the entity to Emergent BioDefense Operations Lansing LLC ("Emergent BioDefense Operations"). The Company acquired a portion of its portfolio of vaccine and therapeutic product candidates through an acquisition of Microscience Limited ("Microscience") in a share exchange in June 2005, and acquisitions of substantially all of the assets, for cash, of Antex Biologics Inc. ("Antex") in May 2003 and ViVacs GmbH, Germany ("ViVacs") in July 2006. The Company has renamed Microscience as Emergent Product Development UK Limited. The assets acquired from Antex were incorporated as Emergent Product Development Gaithersburg Inc., and the assets acquired from ViVacs were incorporated as Emergent Product Development Germany GmbH. On October 28, 2010, the Company acquired Trubion Pharmaceuticals, Inc. ("Trubion") for cash, equity and contingent value rights. Concurrent with the acquisition, the Company converted Trubion to Emergent Product Development Seattle LLC.

2. Summary of significant accounting policies

Basis of presentation and consolidation

The accompanying consolidated financial statements include the accounts of Emergent and its wholly-owned and majority-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation. For investments in variable interest entities, the Company consolidates when it is determined to be the primary beneficiary.

Use of estimates

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

Cash and cash equivalents

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

Investments

Investments that are classified as available-for-sale are measured at fair value in the balance sheets, and unrealized holding gains and losses on investments are reported as a separate component of stockholder equity until realized. Realized gains and losses are reported in other income (expense), net, on a specific identification basis.

For debt securities, if the Company intends to either sell or determines that it will more likely than not be required to sell a debt security before recovery of the entire amortized cost basis or maturity of the debt security, the Company recognizes the entire impairment in earnings. If the Company does not intend to sell the debt security but, it determines that it will not be more likely than not required to sell the debt security and it does not expect to recover the entire amortized cost basis, the impairment is bifurcated into the amount attributed to the credit loss, which is recognized in earnings, and all other causes, which are recognized in other comprehensive income. Regardless of the Company's intent to sell a security, it performs additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified when the Company does not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

Fair value of financial instruments

The carrying amounts of the Company's short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair values due to their short maturities. The fair value of the Company's long-term indebtedness is estimated based on the quoted prices for the same or similar issues or on the current rates offered to the Company for debt of the same remaining maturities. The carrying value and fair value of long-term indebtedness were $47.4 million and $47.4 million, respectively, at December 31, 2010 and $50.7 million and $50.0 million, respectively, at December 31, 2009.

Restricted cash

Restricted cash at December 31, 2010 and 2009 includes a certificate of deposit held by a bank as collateral for a letter of credit acting as a security deposit on a loan. As of December 31, 2010 and 2009 the Company had restricted cash of $217,000 and $215,000, respectively.

Significant customers and accounts receivable

For the years ended December 31, 2010, 2009 and 2008, the Company's primary customer was the U.S. Department of Health and Human Services ("HHS"). For the years ended December 31, 2010, 2009 and 2008, revenues from HHS and HHS agencies comprised 97.5%, 99.6% and 95.7%, respectively, of total revenues and is included in the Company's biodefense segment. As of December 31, 2010 and 2009, the Company's receivable balances were comprised of 87.9% and 99.4%, respectively, from this customer. Unbilled accounts receivable, included in accounts receivable, totaling $13.6 million and $3.1 million as of December 31, 2010 and 2009, respectively, relate to various service contracts for which work has been performed, though invoicing has not yet occurred. Substantially all of the unbilled receivables are expected to be billed and collected within the next 12 months. Accounts receivable are stated at invoice amounts and consist primarily of amounts due from HHS as well as amounts due under reimbursement contracts with other government entities and non-government and philanthropic organizations. If necessary, the Company records a provision for doubtful receivables to allow for any amounts which may be unrecoverable. This provision is based upon an analysis of the Company's prior collection experience, customer creditworthiness and current economic trends. As of December 31, 2010 and 2009, an allowance for doubtful accounts was not recorded as the collection history from the Company's customers indicated that collection was probable.

Concentrations of credit risk

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

Inventories

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

Note receivable

In 2008, the Company entered into a loan and security agreement with Protein Sciences Corporation ("PSC") to loan PSC up to $10.0 million in conjunction with an agreement pursuant to which the Company would acquire substantially all of the assets of PSC. The loan was secured by substantially all of PSC's assets, including PSC's intellectual property. On November 2, 2010, the Company and PSC executed a settlement agreement, whereby PSC paid the Company $11.5 million, consisting of full repayment of the original $10.0 million of principal plus $1.5 million in interest. In accordance with the terms of this agreement, all claims arising from the loan and security agreement and related promissory note, and from the original agreement to acquire the assets of PSC, were resolved (see Note 16, Litigation). In connection with this settlement, the Company recorded a charge of approximately $1.0 million in September 2010 to reduce the accrued interest due from PSC. This charge is reflected in the other income (expense) line in the Company's statements of operations.

Property, plant and equipment

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

Buildings	31-39 years
Building improvements	10-39 years
Furniture and equipment	3-7 years
Software	Lesser of 3-5 years or product life
Leasehold improvements	Lesser of the asset life or lease term

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

Income taxes

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

The Company's ability to realize deferred tax assets depends upon future taxable income as well as the limitations discussed below. For financial reporting purposes, a deferred tax asset must be reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax assets will not be realized prior to expiration. The Company considers future taxable income and ongoing tax planning strategies in assessing the need for valuation allowances. In general, if the Company determines that it is more likely than not to realize more than the recorded amounts of net deferred tax assets in the future, the Company will reverse all or a portion of the valuation allowance established against its deferred tax assets, resulting in a decrease to the provision for income taxes in the period in which the determination is made. Likewise, if the Company determines that it is not more likely than not to realize all or part of the net deferred tax asset in the future, the Company will establish a valuation allowance against deferred tax assets, with an offsetting increase to the provision for income taxes, in the period in which the determination is made.

Under sections 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of net operating losses and deductions that are available. The Company believes the use of net operating losses and research and development tax credits acquired in the Trubion acquisition will not be significantly limited. Due to the acquisition of Microscience in 2005 and the Company's initial public offering, the Company believes the use of the operating losses incurred prior to 2007 will be significantly limited.

Revenue recognition

The Company recognizes revenues from product sales if four basic criteria have been met:

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

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

Under previous contracts with HHS, the Company invoiced HHS and recognized the related revenues upon delivery of the product to the government carrier, at which time title to the product passed to HHS. Under the Company's current contracts with HHS, the Company invoices HHS and recognizes the related revenue upon acceptance by the government at delivery site, at which time title to the product passes to HHS.

In December 2005, the Securities and Exchange Commission released an interpretation with respect to the accounting for sales of vaccines and bioterror countermeasures to the federal government for placement into the Strategic National Stockpile ("SNS"). This interpretation provides for revenue recognition for specifically identified products purchased for the SNS in the event that all requirements for revenue recognition are not met. While the Company's contracts with HHS are for qualifying sales of vaccine for placement into the SNS, the Company meets all requirements for revenue recognition upon delivery of product to HHS, and therefore has not applied this guidance.

Collaborative research and development agreements can provide for one or more of upfront license fees, research payments, and milestone payments. Agreements with multiple components ("deliverables" or "items") are evaluated to determine if the deliverables can be divided into more than one unit of accounting. An item can generally be considered a separate unit of accounting if all of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis; (2) there is objective and reliable evidence of the fair value of the undelivered items(s); and (3) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in control of the Company. Items that cannot be divided into separate units are combined with other units of accounting, as appropriate. Consideration received is allocated among the separate units based on their respective fair values or based on the residual value method and is recognized in full when the criteria above are met. The Company deems service to have been rendered if no continuing obligation exists on the part of the Company.

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

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

The Company generates contract and grant revenue from cost-plus-fee contracts. Revenues on reimbursable contracts are recognized as costs are incurred, generally based on allowable costs incurred during the period, plus any recognizable earned fee. The Company considers fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. The Company analyzes cost for contracts and reimbursable grants to ensure reporting of revenues gross versus net is appropriate. For each of the three years in the period ended December 31, 2010, the costs incurred under the contracts and grants approximated the revenue earned.

The Company generates revenues from its collaborations with Pfizer, Inc. ("Pfizer") and Abbott Laboratories ("Abbott"). Certain internal and external research and development costs and patent costs are reimbursed in connection with our collaboration agreements. Reimbursed costs under the Pfizer collaboration are recognized as revenue in the period in which the costs are incurred. The Company's collaboration with Abbott provides for equal cost sharing of development and clinical costs. Each quarter the Company and Abbott report to the other party the total costs incurred for development costs. The total spending by each party is then compared to the spending by to the other party. In the event that our spending for a given quarter exceeds the spending of Abbott, the Company records a net receivable in our financial statements equal to the difference between the Company's spending and 50% of the total spending for the period, and recognizes revenue in this amount. If Abbott's spending for the quarterly period exceeds the Company's spending, the Company records a net payable in its financial statements equal to the difference between the Company's spending and 50% of the total spending, and records additional research and development expenses in this amount. As a result, the Company's revenues and research and development expenses may fluctuate depending on which party in the collaboration is incurring the majority of the development costs in any particular quarterly period.

Contingent value rights

In accordance with the terms of the Company's acquisition of Trubion in October 2010, the Company has committed to make potential future contingent value right ("CVR") payments to former shareholders and stock option holders of Trubion of up to approximately $38.7 million. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. Because the achievement of these milestones has not occurred as of December 31, 2010, the obligation for these contingencies has been recorded in the Company's financial statements at fair value. The fair value model used for the CVR obligations are based on a discounted cash flow model that has been risk adjusted based on the probability of achievement of the milestones.

The Company believes that the inputs it uses for determining the fair value of the CVR obligations are Level 3 fair value measurements. The Company re-evaluates the fair value on a quarterly basis. Changes in the fair value of the CVR obligations can result from adjustments to the discount rates, updates in the assumed timing of achievement of any development milestones or changes in the probability of certain clinical events and changes in the assumed probability associated with approval. 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 obligations will result in a reduction in research and development expense.

Acquired in process research and development

Acquired in-process research and development ("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 drug. 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. The Company determined 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.

The Company believes 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 dates.

If these product candidates are not successfully developed, the sales and profitability of the Company will be adversely affected in future periods. Additionally, the value of the acquired IPR&D may become impaired. The Company believes that the assumptions used in valuing the IPR&D are reasonable. 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. The Company's IPR&D assets will be assessed on an annual basis for impairment or more frequently if indicators of impairment are present.

Goodwill

The Company assesses 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 the Company perform a two-step impairment test. In the first step, the Company compares the fair value of its reporting units to the carrying value of the reporting units. If the carrying value of the net assets assigned to the reporting units exceeds the fair value of the reporting units, then the second step of the impairment test is performed in order to determine the implied fair value of the reporting units goodwill. If the carrying value of the reporting units' goodwill exceeds its implied fair value, an impairment loss equal to the difference is recorded and charged to general and administrative expense.

The Company calculates the fair value of the reporting units utilizing a weighting of the income and market approaches. The income approach utilizes a discounted cash flow model, using a discount rate based on the Company's estimated cost of capital. The market approach utilizes revenue and other metrics from similar publicly traded companies. The results of both fair value calculations are then compared to the Company's reporting units' carrying value. The Company selected October 1st as our annual impairment test date. The acquisition of Trubion occurred on October 28, 2010; therefore the Company performed an assessment to determine whether goodwill was more likely than not impaired at December 31, 2010, which would require an interim impairment. The Company determined that no such indicators were present.

The determination of the fair value of a 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, which requires that the Company makes a number of critical legal, economic, market and business assumptions that reflect best estimates as of the testing date. The Company's assumptions and estimates may differ significantly from actual results, or circumstances could change that would cause the Company to conclude that an impairment now exists or that it previously understated the extent of impairment.

Impairment of long-lived assets

The Company assesses the recoverability of its long-lived assets for which an indicator of impairment exists by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If the Company concludes that the carrying value will not be recovered, the Company measures the amount of such impairment by comparing the fair value to the carrying value. The Company recorded impairment charges of $1.2 million and $7.3 million for the years ended December 31, 2010 and 2009, respectively, related to its two Frederick, Maryland facilities, described more fully in Note 18 — Assets Held for Sale. The Company recorded no impairment losses for the year ended December 31, 2008.

Research and development

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

Comprehensive income

Comprehensive income is comprised of net income and other changes in equity that are excluded from net income. The Company includes gains and losses on intercompany transactions with foreign subsidiaries that are considered to be long-term investments and translation gains and losses incurred when converting its subsidiaries' financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income.

Foreign currencies

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

Capitalized interest

The Company capitalizes interest based on the cost of major ongoing capital projects which have not yet been placed in service. For the years ended December 31, 2010, 2009 and 2008, the Company incurred interest of $1.8 million, $1.8 million and $3.0 million, respectively. Of these amounts, the Company capitalized $1.8 million, $1.8 million and $3.0 million, respectively.

Certain risks and uncertainties

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

Earnings per share

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

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

(in thousands, except share and per share data)	Year Ended December 31, 2010	2009	2008
Numerator:			
Net income	$ 51,698	$ 31,144	$ 20,682
Denominator:			
Weighted-average number of shares—basic	31,782,286	30,444,485	29,835,134
Dilutive securities—equity awards	757,214	930,820	622,964
Weighted-average number of shares—diluted	32,539,500	31,375,305	30,458,098
Earnings per share-basic	$ 1.63	$ 1.02	$ 0.69
Earnings per share-diluted	$ 1.59	$ 0.99	$ 0.68

For the years ending December 31, 2010, 2009 and 2008, outstanding stock options to purchase approximately 1.4 million, 1.4 million and 183,000, respectively, shares of common stock are not considered in the diluted earnings per share calculation because the exercise price of these options is greater than the average per share closing price during the year.

Accounting for stock-based compensation

As of December 31, 2010, the Company has two stock-based employee compensation plans, the Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan") and the Emergent BioSolutions Employee Stock Option Plan (the "2004 Plan" and together with the 2006 Plan, the "Emergent Plans"). The Company has granted options to purchase shares of common stock under the Emergent Plans, and has granted restricted stock units under the 2006 Plan.

The Company determines the fair value of restricted stock units using the closing market price of the Company's common stock on the day prior to the date of grant. The Company utilizes the Black-Scholes valuation model for estimating the fair value of all stock options granted. The fair value of each option is estimated on the date of grant. Set forth below are the assumptions used in valuing the stock options granted and a discussion of the Company's methodology for developing each of the assumptions used:

	Year Ended December 31, 2010	2009	2008
Expected dividend yield	0%	0%	0%
Expected volatility	55%	55%	65%
Risk-free interest rate	0.49-1.46%	1.32-1.72%	1.63-2.75%
Expected average life of options	3.4 years	3.3 years	3.0 years

- Expected dividend yield — the Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.
- Expected volatility — a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company analyzed the volatility of similar companies at a similar stage of development to estimate expected volatility. The volatility of these similar companies ranged from 38% to 77%, with an average estimated volatility of 55%. The Company used a rate of 55% for grants made in 2010, approximately the mid-point of this range.
- Risk-free interest rate — the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date on which the option is granted.
- Expected average life of options — the period of time that options granted are expected to remain outstanding, based primarily on the Company's expectation of optionee exercise behavior subsequent to vesting of options.

Subsequent events

The Company has evaluated subsequent events through the time of filing these financial statements.

Recent accounting pronouncements

In December 2010, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2010-29 which amended Accounting Standards Codification ("ASC") Topic 805 regarding pro forma revenue and earnings disclosure requirements for business combinations. The amendments in ASU No. 2010-29 provide that an entity should disclose revenue and earnings of the combined entity as though the business combination(s) that occurred during the current year had occurred as of the beginning of the comparable prior annual reporting period only. This amendment is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2010 with early adoption permitted. The Company adopted this amendment in January 2011. The Company does not anticipate this amendment will have a material impact on its financial statement.

In April 2010, the FASB issued ASU No. 2010-17 which amended ASC Topic 605 regarding the milestone method of revenue recognition. The amendments in ASU No. 2010-17 provide guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate along with providing for expanded disclosures. This amendment is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted. The Company adopted this amendment in January 2011. The Company does not anticipate this amendment will have a material impact on its financial statement.

In February 2010, the FASB issued ASU No. 2010-09 which amended ASC Topic 855 regarding subsequent events. The amendments in ASU No. 2010-09 remove the requirement for a Securities and Exchange Commission ("SEC") filer to disclose a date in both issued and revised financial statements. This amendment is effective for financial statements issued for interim and annual periods ending after June 15, 2010. The adoption of this amendment did not have a material impact on the Company's financial statements.

In October 2009, FASB issued ASU No. 2009-13, which amended ASC Topic 605 regarding multiple-deliverable revenue arrangements. The amendments in ASU No. 2009-13 establish a selling price hierarchy for determining the selling price of a deliverable. In addition, this amendment replaces the term "fair value" in the revenue allocation guidance with "selling price". ASU No. 2009-13 eliminates the residual method of allocation and require that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method and will require that an entity determine its best estimate of selling price in a manner that is consistent with that used to determine the price to sell the deliverable on a standalone basis. ASU No. 2009-13 will significantly expand the disclosures related to an entity's multiple-deliverable revenue arrangements. In the year of adoption, entities will be required to disclose information that enables the users of financial statements to understand the effect of adopting ASU No. 2009-13. This amendment is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. If early adoption is elected and the period of adoption is not the beginning of the entity's fiscal year, the entity will be required to apply the amendments in ASU No. 2009-13 retrospectively from the beginning of the entity's fiscal year. The Company adopted this amendment in January 2011. The adoption of this amendment will have an impact on the Company's financial statements to the extent the Company is a party to multiple-deliverable revenue arrangements.

3. Acquisition of Trubion Pharmaceuticals, Inc.

On October 28, 2010, the Company acquired 100% of the voting interest in and obtained control of Trubion. Trubion merged with a wholly-owned subsidiary of Emergent in accordance with a merger agreement dated August 12, 2010. This transaction has been accounted for under the acquisition method of accounting, with Emergent as the acquiror. Under the acquisition method of accounting, the assets and liabilities of Trubion have been recorded as of the acquisition date at their respective fair values and combined with those of Emergent. The combined financial condition and results of operations of Emergent after the merger reflects these fair values.

Under the terms and conditions of the merger agreement, each share of Trubion common stock was converted into the right to receive:

- § $1.365 in cash, without interest;
- § 0.1641 of a share of Emergent common stock; and
- § one contingent value right ("CVR") issued by Emergent.

Holders of vested and unvested stock options with an exercise price below $4.55 per share received for each share of Trubion common stock subject to such stock option:

- § a cash payment equal to the difference between $4.55 and the exercise price of the stock option, as applicable; and
- § one CVR issued by Emergent.

Stock options with an exercise price above $4.55 per share were cancelled and extinguished.

Each CVR entitles its holder to receive a pro rata portion of the following payments:

- § $6.25 million upon initiation of dosing in the first Phase III clinical study for the first major indication for a CD20 candidate;
- § $5.0 million upon initiation of dosing in the first Phase III clinical study for the second major indication for a CD20 candidate;
- § $750,000 upon initiation of dosing in the first Phase II clinical study for a product candidate directed towards a non-CD 20 target;
- § $1.7 million upon initiation of the first Phase II clinical study for TRU-016;
- § $15.0 million upon initiation of the first Phase III clinical study in an oncology indication for TRU-016; and
- § $10.0 million upon release of TRU-016 manufactured material for use in clinical studies.

At October 28, 2010, the CVR obligations were recorded at fair value of $14.5 million. The fair value of the CVR obligations are based on management's assessment of the potential future realization of the CVR payments. This assessment is based on inputs that have no observable market (Level 3). The obligation is measured using a discounted cash flow model.

The merger expanded the Company's pipeline of product candidates, broadened the Company's biosciences portfolio, and expanded its manufacturing capabilities. Additionally, the Company expects to realize cost savings and synergies.

The total purchase price is summarized as follows:

(in thousands)	
Amount of cash received by Trubion stockholders and stock option holders	$ 31,743
Value of shares of Emergent common stock issued	61,204
Fair value of CVRs	14,532
Total estimated purchase price	$ 107,479

The table below summarizes the preliminary allocation of the purchase price based upon fair values of assets acquired and liabilities assumed at October 28, 2010. This preliminary allocation is based upon information that was available to management at the time the financial statements were prepared. Accordingly, the allocation may change. The Company has no information that indicates the final purchase price allocation could differ materially from the preliminary estimates noted below other than potential changes associated with the final determination of deferred tax assets acquired and certain accrued liabilities assumed in connection with the acquisition of Trubion.

(in thousands)	
Cash	$ 13,870
Investments	8,547
Accounts receivable	3,548
Prepaid expenses and other assets	1,366
Property, plant and equipment	3,948
Deferred taxes	39,860
Acquired research and development assets	51,400
Goodwill	5,029
Accounts payable and accrued liabilities	(3,857)
Accrued compensation	(2,842)
Deferred revenue	(12,792)
Other long-term liabilities	(598)
Total purchase price	$ 107,479

A substantial portion of the assets acquired from Trubion consisted of intangible assets from in-process research and development programs. As of the date of acquisition, Trubion primarily had two programs in development 1) TRU-016, a novel CD37-directed therapy for B-cell malignancies, such as chronic lymphocytic leukemia and non-Hodgkin's lymphoma; and 2) SBI-087, a next generation, humanized, CD20-directed product candidate for the treatment of rheumatoid arthritis and systemic lupus erythematosus, and other autoimmune and inflammatory diseases. Both of these acquired research and development programs are currently in development and as such are deemed to be indefinite-lived assets and will remain as indefinite−lived assets on the Company's balance sheet until completion or abandonment of the associated research and development efforts. The Company determined the fair value of TRU-016 and SBI-087 using the income approach, which is based on the present value of future cash flows. The fair value measurements are based on significant unobservable inputs, that are developed by the Company using estimates and assumptions of the respective market and market penetration of the Company's developed products. As of the date of acquisition, the Company has recorded approximately IPR&D assets of $41.8 million related to TRU-016 and $9.6 million related to SBI-087. As of December 31, 2010, there were no indicators present that would require the Company to complete an interim impairment assessment.

The value of the deferred tax assets were based on management's assessment of the anticipated future utilization of the tax positions. The estimated fair value of the remaining contractual obligation acquired resulted in a $16.5 million reduction in the carrying balance of historical Trubion deferred revenue at date of acquisition. The fair value of the deferred revenue was determined using unobservable inputs in which no market data exists and is based on the Company's expected future obligations under its collaborations with Abbott and Pfizer. The cost basis of all other assets acquired and liabilities assumed approximates their fair value.

The Company recorded approximately $5.0 million in goodwill related to the Trubion acquisition representing the purchase price paid in the acquisition that was in excess of the fair value of the tangible and intangible assets acquired, which is included in the Company's biosciences segment. None of the goodwill generated from the Trubion acquisition is expected to be deductible for tax purposes.

The Company incurred approximately $2.8 million of transaction costs related to the acquisition, which is included in selling, general and administrative expenses in the Company's consolidated statement of operations.

From the date of the acquisition to December 31, 2010, the Company has recognized revenues of $3.4 million and a net loss attributable to Emergent BioSolutions Inc. of $3.8 million from the operations of the acquired entity.

The unaudited condensed pro forma statements of operations are presented as if the merger had occurred on January 1, 2009, and combines the historical results of operations of Emergent and Trubion for the years ended December 31, 2010 and 2009.

	December 31,	
(in thousands, except per share data)	**2010**	**2009**
Pro forma revenue	$ 303,317	$ 252,789
Pro forma net income	$ 36,973	$ 12,522
Pro forma earnings per share-basic	$ 1.16	$ 0.37
Pro forma earnings per share-diluted	$ 1.14	$ 0.36

The table above includes nonrecurring pro forma additions to pro forma net income directly attributable to the Trubion acquisition totaling $8.3 million and $10.6 million for the years ended December 31, 2010 and 2009, respectively. These adjustments are primarily from the utilization of Trubion's losses by the Company in order to adjust its provision for income taxes.

4. Fair value measurements

The Company measures and records cash equivalents and investment securities considered available-for-sale at fair value in the accompanying financial statements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value include:

Level 1 — Observable inputs for identical assets or liabilities such as quoted prices in active markets;
Level 2 — Inputs other than quoted prices in active markets that are either directly or indirectly observable; and
Level 3 — Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

The following table represents the Company's fair value hierarchy for its financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2010:

(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Investment in money market funds (1)	$ 102,360	$ -	$ -	$ 102,360
U.S. Treasury securities (2)	-	2,029	-	2,029
Total Assets	$ 102,360	$ 2,029	$ -	$ 104,389
Liabilities:				
Contingent value rights	-	-	14,532	14,532
Total Liabilities	$ -	$ -	$ 14,532	$ 14,532

(1) Included in cash and cash equivalents in accompanying consolidated balance sheets.
(2) Included in investments in accompanying consolidated balance sheets

For the year ended December 31, 2009, there were no assets or liabilities measured at fair value.

The fair value of the CVR obligations are based on management's assessment of the potential realization of the CVR payments, which is an input that has no observable market (Level 3). The obligation is measured using a discounted cash flow model.

The following table is a reconciliation of the beginning and ending balance of the liabilities measured at fair value using significant unobservable inputs (Level 3) for the year ended December 31, 2010.

(in thousands)	
Balance at January 1, 2010	$ -
Fair value of CVRs issued	14,532
Increase/(decrease) in fair value	-
Settlements	-
Transfers in/(out) of Level 3	-
Balance at December 31, 2010	$ 14,532

Separate disclosure is required of assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. The assets acquired and liabilities assumed at October 28, 2010 related to the Trubion acquisition were recorded at fair value on a nonrecurring basis. As of December 31, 2010, no assets or liabilities were measured at fair value on a nonrecurring basis.

5. Investments

The Company invests in a variety of highly liquid investment-grade securities. The following is a summary of the Company's available-for-sale securities at December 31, 2010:

(in thousands)	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Market Value
Money market funds	$ 102,360	$ -	$ -	$ 102,360
U.S. Treasury securities	2,030	-	1	2,029
Total	104,390	-	1	104,389
Less: cash equivalents	(102,360)	-	-	(102,360)
Amounts classified as investments	$ 2,030	$ -	$ 1	$ 2,029

The estimated fair value and amortized cost of investments available-for-sale by contractual maturity are due in one year or less. The estimated fair market value amounts have been determined using available market information. Unrealized gains and losses on cash equivalents and available for sale securities are included in accumulated other comprehensive income (loss) in the accompanying consolidated balance sheets. As of December 31, 2010 the unrealized losses on investments were immaterial. As of December 31, 2009, there were no investments in the Company's consolidated balance sheet other than cash equivalents.

6. Accounts receivable

Accounts receivable consist of the following:

	December 31,	
(in thousands)	**2010**	**2009**
Billed	$ 25,751	$ 51,782
Unbilled	13,575	3,090
Total	$ 39,326	$ 54,872

7. Inventories

Inventories consist of the following:

(in thousands)	**2010**	**2009**
Raw materials and supplies	$ 2,311	$ 1,565
Work-in-process	7,917	9,870
Finished goods	2,494	2,086
Total inventories	$ 12,722	$ 13,521

8. Property, plant and equipment

Property, plant and equipment consist of the following:

	December 31,	
(in thousands)	**2010**	**2009**
Land and improvements	$ 3,506	$ 2,932
Buildings, building improvements and leasehold improvements	21,455	18,661
Furniture and equipment	34,797	27,086
Software	10,071	6,833
Construction-in-progress	109,567	98,178
	179,396	153,690
Less: Accumulated depreciation and amortization	(26,695)	(21,856)
Total Property, plant and equipment, net	$ 152,701	$ 131,834

For the years ended December 31, 2010 and 2009, respectively, construction-in-progress included costs related to Building 55, the Company's large-scale manufacturing facility, for which the Company is in the process of receiving regulatory approval, along with costs related to the purchase and renovation of the Company's manufacturing facility in Baltimore, Maryland.

Depreciation and amortization expense was $6.0 million, $5.0 million and $5.0 million for the years ended December 31, 2010, 2009 and 2008, respectively. As of December 31, 2010 and 2009 there was no unamortized internal use software-cost.

9. Long-term debt

The components of long-term debt are as follows:

	December 31,	
(in thousands)	**2010**	**2009**
Term loan dated December 2009; three month LIBOR plus 3.25%, due December 2014	$ 21,233	$ 22,750
Term loan dated November 2009; three month LIBOR plus 3.25%, due November 2014	6,513	6,981
Term loan dated November 2009; three month LIBOR plus 3.25%, due November 2014	4,825	5,134
Term loan dated April 2006; three month LIBOR plus 3.0%, due April 2011	6,686	7,308
Loan dated October 2004; 3.0%, due March 2011	2,500	2,500
Term loan dated October 2004; 4.075%, due October 2011	5,669	6,045
Total long-term indebtedness	47,426	50,718
Less current portion of long-term indebtedness	(17,187)	(5,791)
Noncurrent portion of long-term indebtedness	$ 30,239	$ 44,927

In December 2009, the Company entered into a loan agreement with HSBC, under which HSBC provided the Company with a term loan of $22.8 million. This loan replaced a prior loan arrangement with HSBC under which HSBC agreed to loan the Company $30.0 million. Under the new loan agreement, the Company is required to make monthly payments in the amount of $126,000 in principal plus accrued interest, with a residual principal payment due upon maturity in December 2014. Payment of the loan is secured by substantially all of the assets of Emergent BioDefense Operations, other than accounts receivable under BioThrax supply contracts with HHS and the DoD that are pledged as collateral to secure a $15 million revolving line of credit with Fifth Third Bank. The assets that secure this loan total approximately $150 million at December 31, 2010. The annual interest rate is based on the three month LIBOR plus 3.25% (3.55% as of December 31, 2010).

In November 2009, the Company acquired a development and manufacturing facility in Baltimore, Maryland for $8.2 million. The Company paid approximately $1.2 million in cash and financed the remaining balance with a term loan from HSBC in the amount of $7.0 million. This loan requires monthly principal payments of $39,000 plus accrued interest from November 2009 through November 2014 with a balloon payment for the remaining unpaid principal and interest due in November 2014. The loan is collateralized by the facility. The annual interest rate is based on the three month LIBOR plus 3.25% (3.55% as of December 31, 2010).

In October 2009, the Company acquired a research and development facility in Gaithersburg, Maryland for $6.4 million. The Company paid $1.2 million in cash and financed the remaining balance with a term loan from HSBC in the amount of $5.2 million. This loan requires monthly principal payments of $29,000 plus accrued interest from November 2009 through November 2014 with a balloon payment for the remaining unpaid principal and interest due in November 2014. The loan is collateralized by the facility. The annual interest rate is based on the three month LIBOR plus 3.25% (3.55% as of December 31, 2010).

In April 2006, the Company aquired a 145,000 square foot facility in Frederick, Maryland for $9.8 million. This facility was previously under a lease which contained an option to purchase the facility. The Company paid $1.3 million in cash and financed the remaining balance with a bank loan with HSBC in the amount of $8.5 million. This loan requires monthly principal and interest payments from May 2006 through April 2011 of $72,000 with a balloon payment for the remaining unpaid principal and interest due in April 2011. The loan is collateralized by the facility. The annual interest rate is based on the three month LIBOR plus 3.0% (3.30% as of December 31, 2010).

Under the terms of the four loans the Company has with HSBC, the Company is required to maintain a book leverage ratio of less than 1.00. This ratio is calculated by dividing total liabilities, excluding deferred revenues specific to contracts with the U.S. government, by total net worth. In addition, the Company is required to maintain a debt coverage ratio of not less than 1.25 to 1.00. This ratio is calculated by dividing earnings before interest, taxes, depreciation and amortization for the most recent four quarters by the sum of current obligations under capital leases and principal obligations and interest expenses for borrowed money, in each case due and payable for the following four quarters. The Company is in compliance with these covenants as of December 31, 2010 and 2009.

In October 2004, the Company entered into a Secured Conditional Loan with the Maryland Economic Development Assistance Fund ("MEDAF") for $2.5 million. The proceeds of the loan were used to reimburse the Company for eligible costs it incurred to purchase a building in Frederick, Maryland. The loan is secured by a $1.3 million letter of credit and a security interest in the building. The Company is required to pay an annual fee of 1.0% to maintain the letter of credit. The borrowing bears interest at 3.0% per annum, and the term of the loan ends March 31, 2013. The terms of the loan call for principal and related accrued interest to be forgiven if specified employment levels are achieved and maintained through December 2012, at least $42.9 million in project costs are expended prior to December 2009, and the Company occupies the building through December 2012. As of December 31, 2010 the Company has not met the requirements for the loan to be forgivable, and has reached an agreement with MEDAF to repay the loan in full by March 31, 2011, with an earlier repayment due upon sale of the building. The full $2.5 million outstanding under this loan is included in current portion of long-term indebtedness at December 31, 2010, and the accrued interest is included in accrued expenses and other current liabilities.

In connection with the 2004 purchase of the building in Frederick, Maryland discussed above, the Company entered into a loan agreement for $7.0 million with a bank to finance the remaining portion of the purchase price. The borrowing accrued interest at 6.625% per annum through October 2006. The Company was required to make interest only payments through that date. Beginning in November 2006, the Company began to make monthly payments of $62,000, based upon a 15 year amortization schedule. In November 2009 and thereafter, the annual interest rate is fixed at 4.075%. All unpaid principal and interest is due in full in October 2011. The Company is required to maintain certain financial and non-financial covenants including a minimum tangible net worth of not less than $5.0 million and a debt coverage ratio of not less than 1.1 to 1. The Company is in compliance with these covenants as of December 31, 2010 and 2009.

Scheduled principal repayments and maturities on long-term debt as of December 31, 2010 are as follows:

(in thousands)	
2011	$ 17,187
2012	2,331
2013	2,331
2014	25,577
2015	-
2016 and beyond	-
Total future payments	$ 47,426

10. Line of credit

In June 2007, the Company entered into a loan agreement with Fifth Third Bank, whereby Fifth Third Bank agreed to extend to the Company a revolving line of credit of up to $15 million. The Company can borrow under this line of credit through June 2011, at which time the agreement expires. The line of credit is secured by accounts receivable under the Company's HHS contract and bears interest at a rate equal to the one month LIBOR plus 2% (2.26% as of December 31, 2010). The Company is subject to certain covenants, including maintenance of specified equity levels on a quarterly basis, and is currently in compliance with those covenants. For the year ended December 31, 2010, there was no outstanding balance under the line of credit. For the year ended December 31, 2009, $15.0 million was outstanding under the line of credit. This amount was repaid in February 2010.

11. Stockholders' equity

Preferred stock

The Company is authorized to issue up to 15,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock"). Any preferred stock issued may have dividend rates, voting rights, conversion privileges, redemption characteristics, and sinking fund requirements as approved by the Company's board of directors. As of December 31, 2010 and 2009 no preferred stock has been issued.

Common stock

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

Stock options and restricted stock units

As of December 31, 2010, the Company has two stock-based employee compensation plans, the 2006 Plan and the 2004 Plan. The Company has granted options to purchase shares of common stock under the Emergent Plans and has granted restricted stock units under the 2006 Plan. The Emergent Plans have both incentive and non-qualified stock option features. The Company no longer grants equity awards under the 2004 Plan.

As of December 31, 2010, an aggregate of 8,678,826 shares of common stock are authorized for issuance under the 2006 Plan, of which a total of 3,314,851 shares of common stock remain available for future awards to be made to plan participants. Awards of restricted stock units are counted against the maximum aggregate number of shares of common stock available for issuance under the 2006 Plan as one and one-half (1.5) shares of common stock for every one restricted stock unit granted. The maximum number of shares subject to awards that may be granted per year under the 2006 Plan to a single participant is 287,700. The exercise price of each option must be not less than 100% of the fair market value of the shares underlying such option on the date of grant. Awards granted under the 2006 Plan have a contractual life of no more than 10 years. The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the Emergent Plans are determined by the Company's compensation committee, which administers the Emergent Plans. Each equity award granted under the Emergent Plans vests as specified in the relevant agreement and no option can be exercised after ten years from the date of grant.

The following is a summary of option award activity under the Emergent Plans:

	2006 Plan		2004 Plan		
	Number of Shares	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2009	3,485,499	$ 12.72	130,082	$ 7.52	$ 11,178,792
Exercisable at December 31, 2009	936,933	$ 9.56	130,082	$ 7.52	$ 4,768,507
Granted	826,553	15.91	-	-	
Exercised	(765,705)	9.07	(62,541)	5.06	
Forfeited	(148,432)	14.64	-	-	
Outstanding at December 31, 2010	3,397,915	$ 14.31	67,541	$ 9.80	$ 32,023,466
Exercisable at December 31, 2010	1,249,749	$ 12.42	67,541	$ 9.80	$ 14,725,004
Options expected to vest at December 31, 2010	1,537,825	$ 10.74	-	$ -	$ 12,996,446

The following is a summary of restricted stock unit award activity under the 2006 Plan:

	Number of Shares	Weighted-Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding at December 31, 2009	-	$ -	$ -
Granted	406,245	16.10	
Vested	-	-	
Forfeited	(10,690)	16.15	
Outstanding at December 31, 2010	395,555	$ 16.09	$ 9,279,720

The weighted average remaining contractual term of options outstanding as of December 31, 2010 and 2009 was 5.3 and 5.6 years, respectively. The weighted average remaining contractual term of options exercisable as of December 31, 2010 and 2009 was 4.6 and 4.8 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2010, 2009 and 2008 was $6.48, $7.16 and $3.53, respectively. The total intrinsic value of options exercised during the years ended December 31, 2010, 2009 and 2008 was $7.5 million, $7.1 million and $4.0 million, respectively. The total fair value of options vested during 2010, 2009 and 2008 was $5.8 million, $3.3 million and $1.9 million, respectively.

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

(in thousands)	December 31, 2010	2009
Cost of sales	$ 324	$ 200
Research and development	1,635	1,103
General and administrative	5,104	3,704
Total stock-based compensation expense	$ 7,063	$ 5,007

During the years ended December 31, 2010, 2009 and 2008, the Company received a tax benefit from stock options exercised of approximately $1.7 million, $1.9 million and $1.3 million, respectively.

12. Income taxes

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

(in thousands)	2010	2009	2008
Current			
Federal	$ 16,664	$ 8,254	$ 11,186
State	187	902	98
International	102	58	101
Total current	16,953	9,214	11,385
Deferred			
Federal	10,003	5,799	(1,174)
State	(774)	(47)	1,844
Total deferred	9,229	5,752	670
Total provision for income taxes	$ 26,182	$ 14,966	$ 12,055

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

(in thousands)	December 31, 2010	2009
Net operating loss carryforward	$ 30,852	$ 10,304
Research and development credit carryforward	2,991	-
Stock compensation	2,623	1,358
Foreign deferrals	60,754	52,059
Deferred revenue	4,183	-
Other	15,703	6,056
Deferred tax asset	117,106	69,777
Fixed assets	(9,150)	(3,104)
Other	(11,971)	(7,713)
Deferred tax liability	(21,121)	(10,817)
Valuation allowance	(59,590)	(53,196)
Net deferred tax asset	$ 36,395	$ 5,764

The Company currently has approximately $60.5 million in net operating loss carryforwards along with $3.0 million in research and development tax credit carryforwards for U.S. federal tax purposes that will begin to expire in 2026 and 2023, respectively. The U.S. federal tax carryforwards are recorded with no valuation allowance. The Company has $180.5 million in state net operating loss carryforwards, primarily in Maryland, that will begin to expire in 2018. During the year ended December 31, 2010, the Company released approximately $62.8 million in valuation allowances for the state net operating losses due to the conversion of Emergent BioDefense Operations. The Company has approximately $186.3 million in net operating losses from foreign jurisdictions that will have an indefinite life unless the foreign entities have a change in the nature or conduct of the business in the three years following a change in ownership. These foreign net operating losses are recorded with a valuation allowance. The use of any of these net operating loss and research and development tax credit carryforwards may be restricted due to changes in the Company's ownership.

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

(in thousands)	Year ended December 31, 2010	2009	2008
US	$ 111,775	$ 74,758	$ 66,326
International	(33,895)	(28,648)	(33,589)
Earnings before taxes on income	77,880	46,110	32,737
Federal tax at statutory rates	$ 27,258	$ 16,138	$ 11,458
State taxes, net of federal benefit	666	(1,172)	(2,118)
Impact of foreign operations	(7,713)	(7,156)	(8,384)
Change in valuation allowance	6,394	9,025	10,835
Effect of foreign rates	(30)	(17)	(11)
Tax credits	(1,754)	(835)	(819)
Other differences	398	(2,056)	185
Permanent differences	963	1,039	909
Provision for income taxes	$ 26,182	$ 14,966	$ 12,055

The effective annual tax rate for the years ended December 31, 2010, 2009 and 2008 was 34%, 32% and 37%, respectively. The increase in the effective rate in 2010 from 2009 is due primarily to the benefit of certain costs capitalized for book purposes that are deductible for tax purposes in 2009 that did not occur in 2010.

In September 2006, the FASB issued guidance for accounting for uncertainty in income taxes. This guidance prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In addition, this guidance requires that the Company recognize in its financial statements the impact of a tax position if that position is more likely than not to be sustained on audit based on the technical merits of the position and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods and disclosure.

The Company recognizes interest in interest expense and recognizes potential penalties related to unrecognized tax benefits in selling, general and administrative expense. The Company accrued approximately $16,000 and $23,000, for the payment of interest and penalties as of December 31, 2010 and 2009, respectively. Of the total unrecognized tax benefits recorded at December 31, 2010 and 2009, $95,000 and $175,000, respectively is classified as a current liability and $855,000 and $85,000, respectively, is classified as a non-current liability on the balance sheet. As of December 31, 2010 and 2009, $25,000 and $126,000, respectively, of unrecognized tax benefits will reverse within the next twelve months.

The table below presents the gross unrecognized tax benefits activity for 2010, 2009 and 2008:

(in thousands)	
Gross unrecognized tax benefits at January 1, 2008	$ 277
Increases for tax positions for prior years	28
Decreases for tax positions for prior years	-
Increases for tax positions for current year	-
Settlements	-
Lapse of statue of limitations	(35)
Gross unrecognized tax benefits at December 31, 2008	270
Increases for tax positions for prior years	15
Decreases for tax positions for prior years	(80)
Increases for tax positions for current year	55
Settlements	-
Lapse of statue of limitations	-
Gross unrecognized tax benefits at December 31, 2009	260
Increases for tax positions for prior years	16
Decreases for tax positions for prior years	(175)
Increases for tax positions for current year	849
Settlements	-
Lapse of statue of limitations	-
Gross unrecognized tax benefits at December 31, 2010	$ 950

When resolved, substantially all of these reserves would impact the effective tax rate.

The Company’s federal and state income tax returns for the tax years 2009 to 2007 remain open to examination. The Company’s tax returns in the United Kingdom remain open to examination for the tax years 2009 to 2002, and tax returns in Germany remain open indefinitely.

In September 2010, the Company was notified by the Internal Revenue Service that the federal income tax return for the 2008 tax year has been selected for audit.

13. Collaboration Agreements

Abbott Laboratories

In August 2009, Trubion entered into a collaboration agreement with Facet Biotech Corporation, now a wholly-owned subsidiary of Abbott, for the joint worldwide development and commercialization of TRU-016, a product candidate in Phase I clinical development for chronic lymphocytic leukemia, or CLL and non-Hodgkin's lymphoma, or NHL. TRU-016 is a CD37-directed Small Modular Immunopharmaceutical, or SMIP, protein therapeutic. The collaboration agreement includes TRU-016 in all indications and all other CD37-directed protein therapeutics. Under the terms of the collaboration agreement, the parties may not develop or commercialize protein therapeutics directed to CD37 outside of the collaboration agreement.

In accordance with the terms of the agreement with Abbott, the Company may receive up to $176.5 million in additional contingent payments upon the achievement of specified development, regulatory and sales milestones. The Company and Abbott share equally the costs of all development, commercialization and promotional activities and all global operating profits. As part of the purchase price accounting related to the acquisition, the deferred revenue related to upfront payment was recorded at fair value and is being recognized proportionally based on the Company's remaining contractual obligations under the collaboration. The Company's current obligations under the collaboration include the performance of non-clinical, clinical, manufacturing and regulatory activities.

At predefined times the parties have the right to opt-out of the collaboration entirely or on a product-by-product basis. Upon a change of control of a party, the other party will have the right to opt-out of the collaboration entirely and if the successor party is conducting a program that competes with the programs under the collaboration agreement, then the successor party must either (i) opt-out of the collaboration entirely or (ii) divest the competing program to a third party. As a result of the acquisition of Trubion by the Company, Abbott has until April 28, 2011 to exercise their opt-out right. If a party exercises its opt-out right with respect to a product, then the parties will no longer share development and commercialization costs for such product and such opting-out party will receive certain royalty payments upon the sale of such product, rather than half of the profits derived from such product. Even if Abbott exercises its opt-out right, its obligation to make milestone payments to the Company continues. In addition, if the party that opts-out is the lead manufacturing party for the opt-out product, then that party must continue to supply the product to the continuing party for up to 18 months following the opt-out.

Abbott can terminate the collaboration agreement at any time, in which event all rights to TRU-016 and other CD37-directed protein therapeutics under the collaboration agreement would revert to the Company. If there is a material breach of the collaboration agreement, then the non-breaching party may either terminate the collaboration agreement or continue the collaboration agreement and force the breaching party to opt-out and accept royalties at a reduced rate. Either party may assign its interest in the collaboration agreement to a third party, provided that the non-assigning party maintains a right of first negotiation over any proposed assignment. In addition, either the Company or Abbott can freely assign the collaboration agreement without the consent of the other party in connection with specified change of control transactions, such as an acquisition.

During the year ended December 31, 2010, the Company has recorded revenue of $1.2 million for research and development services pursuant to the Abbott collaboration, comprised of $831,000 related to the recognition of deferred revenue and $398,000 for collaborative research funding.

Pfizer Inc.

In December 2005, Trubion entered into a collaboration agreement with Wyeth, now a wholly-owned subsidiary of Pfizer, for the development and worldwide commercialization of CD20-directed therapeutics. Pursuant to the agreement, the Company is also collaborating with Pfizer on the development and worldwide commercialization of certain other product candidates directed to a small number of non-CD20 targets. During the period in which the Company will provide research and development services for Pfizer, Pfizer has the right, subject to the Company's reasonable consent, to replace a limited number of these non-CD20 targets. In addition, the Company has the option to co-promote with Pfizer, on customary terms to be agreed, CD20-directed therapies in the United States for niche indications. The Company retains the right to develop and commercialize, on the Company's own or with others, product candidates directed to all targets not included within the agreement. Unless it is terminated earlier, the agreement 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 U.S. 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.

Under the agreement, Trubion provided research services for an initial three-year period ended December 22, 2008 with the option for Pfizer to extend the service period for two additional one-year periods. In June 2008, Pfizer exercised the first option under the terms of the agreement to extend the research period for an additional one-year period through December 22, 2009. In June 2009, Pfizer exercised the second option under the terms of the agreement to extend the research period for an additional one-year period through December 22, 2010. Pfizer has retained a subset of the non-CD20 targets licensed from the Company and released the remaining targets to the Company.

Pfizer's financial obligations include additional amounts for reimbursement of agreed upon external research and development costs and patent costs. Pursuant to the agreement, Pfizer's financial obligations also include payments to the Company of up to $250 million based on the achievement of specified regulatory and sales milestones for CD20-directed therapies and payments to the Company of up to $200 million based on the achievement of specified regulatory and sales milestones for therapies directed to the small number of retained non-CD20 targets. In addition, the Company will receive royalty payments in the event of future licensed product sales. As part of the purchase price accounting related to the acquisition, the deferred revenue related to the upfront payments is recorded at fair value and is recognized proportionally based on the Company's remaining contractual obligations under the collaboration.

For the year ended December 31, 2010, the Company recognized revenue of $992,000 for research and development services pursuant to the Pfizer collaboration, comprised of $9,000 related to the recognition of deferred revenue and $984,000 for collaborative research funding.

14. 401(k) savings plan

The Company has established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers substantially all employees. Under the 401(k) Plan, employees may make elective salary deferrals. The Company currently provides for matching of qualified deferrals up to 50% of the first 6% of the employee's salary. During the years ended December 31, 2010, 2009 and 2008, the Company made matching contributions of approximately $1.3 million, $1.1 million and $827,000 respectively.

15. Leases

The Company leases laboratory and office facilities, office equipment and vehicles under various operating lease agreements. The Company leases office and laboratory space in Munich, Germany under a non-cancelable operating lease that expires in June 2015. The Company leases office and laboratory space in Wokingham, England under two coterminous non-cancelable operating leases that expire in November 2016. The Company is currently in negotiations to modify these leases (see Note 20, Restructuring) The Company leases office space in Rockville, Maryland under two non-cancelable operating leases that contain a 3% annual escalation clause, which expire in December 2016 and the Company has a five-year renewal option at the end of the initial term. The Company leases office and laboratory space under multiple operating lease agreements in Seattle, Washington, which expire in April 2013. Prior to purchasing the building in October 2009, the Company also leased office and laboratory space in Gaithersburg, Maryland. For the years ended December 31, 2010, 2009 and 2008, total rent expense was $2.6 million, $3.2 million and $3.7 million, respectively.

Future minimum lease payments under operating lease obligations as of December 31, 2010 are as follows:

(in thousands)	
2011	$ 3,406
2012	3,511
2013	2,553
2014	2,089
2015	1,800
2016 and beyond	1,066
Total minimum lease payments	$ 14,425

16. Litigation

Litigation against Protein Sciences Corporation. Until reaching settlement with PSC on November 2, 2010, the Company had been pursuing several legal actions against PSC and its senior management arising out of a letter of intent, a loan and security agreement and related promissory note, and an asset purchase agreement between the Company and PSC that were entered into in 2008.

On June 8, 2009, the Company initiated legal proceedings in the Superior Court of the State of Connecticut, Judicial District of New Haven, to acquire possession of the physical assets by foreclosing on PSC's physical assets that secured the loan. On July 9, 2008, the Company initiated legal proceedings against PSC in the Supreme Court of the State of New York including among other claims, claims for fraud, breach of contract, breach of the duty of good faith and fair dealing, unjust enrichment and unfair business practices. On October 3, 2008, the Company initiated legal proceedings in the United States District Court for the District of Connecticut against PSC's executive management team of Daniel D. Adams, PSC's Executive Chairman, and Manon M.J. Cox, PSC's President and Chief Executive Officer alleging, among other things, that these individuals engaged in fraudulent conduct in connection with their efforts to obtain $10 million in bridge financing from the Company. On July 19, 2010, the Company filed a motion for summary judgment in lieu of complaint in the Supreme Court of the State of New York seeking repayment of its loan and interest.

On November 2, 2010, the Company and PSC entered into a settlement and mutual release of claims with respect to the letter of intent, the loan and security agreement and related promissory note and forbearance agreement, the asset purchase agreement and all other claims related thereto. Under the terms of the settlement, PSC paid the Company $11.5 million, consisting of full repayment of the original $10 million of principal plus $1.5 million in interest, and the parties filed stipulations with the relevant courts to dismiss all litigation with prejudice.

Patent Oppositions. The Company's live attenuated modified vaccinia Ankara virus ("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 the Company acquired from the Bavarian State Ministry of the Environment and Public Health. From 2006 to 2008, the Company 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. The Company 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. The Opposition Division set a date of November 27, 2010 for all parties to file appeals, and the Company timely filed its appeal. 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 set due dates of January 29, 2011 and February 7, 2011 for Notices of Appeal to be filed for these Oppositions, and the Company timely filed its Notices of Appeal. The Company's Appeal Briefs are due on March 29, 2011 and April 7, 2011. 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. A due date has not yet been set for the parties to file their appeals. The Company routinely monitors the grant of further Bavarian Nordic European patents to determine whether any additional oppositions should be filed.

Class-action litigation related to Trubion Pharmaceuticals acquisition. On August 17, 2010, two class action lawsuits were filed in the Superior Court of Washington, King County (the "State Court"), against Trubion, its board of directors, and the Company (collectively, the "Defendants"), alleging in summary that, in connection with the proposed merger of Trubion with a subsidiary of the Company (the "Acquisition"), the members of the Trubion board of directors breached their fiduciary duties by conducting an unfair sale process and agreeing to an unfair price. Both complaints also claim that Trubion and the Company aided and abetted the Trubion board of directors in its breach of fiduciary duties. On September 9, 2010, the actions were consolidated (the "State Action"). On October 1, 2010, the plaintiffs in the State Action served on the Defendants a consolidated amended class action complaint (the "Amended Complaint"). The Amended Complaint alleges, among other things and in addition to the matters alleged in the initial complaints, that the Defendants omitted material information from the Proxy Statement/Prospectus.

On October 4, 2010, a class action lawsuit was filed in the U.S. District Court for the Western District of Washington against the Defendants (the "Federal Action" and, collectively with the State Action, the "Actions"), which makes allegations related to the Acquisition that are substantially similar to those matters alleged in the Amended Complaint, includes additional allegations regarding purported violations of the federal securities laws and seeks substantially similar relief.

On October 8, 2010, the Defendants reached agreement in principle with the plaintiffs in the Actions regarding the settlement of the Actions. In connection with the settlement contemplated by that agreement in principle, the Actions will be stayed pending approval of the settlement of the State Action by the State Court. Thereafter, the State Action and all claims asserted therein will be dismissed with prejudice and counsel for the plaintiff in the Federal Action will take all necessary steps to dismiss the Federal Action and all claims asserted therein with prejudice. The terms of the settlement contemplated by that agreement in principle require that Trubion and the Company make certain additional disclosures related to the Acquisition, as set forth in the Company's Current Report on Form 8-K filed on October 8, 2010. The parties also agreed that the plaintiffs in the Actions may seek attorneys' fees and costs in an aggregate amount up to $475,000, to be paid by Trubion if such fees and costs are approved by the State Court. There will be no other payment by Trubion, any of the members of the Trubion board of directors or the Company to the plaintiffs or their respective counsels in connection with the settlement and dismissal of the Actions. The agreement in principle further contemplates that the parties will enter into a stipulation of settlement, which will be subject to customary conditions, including State Court approval following notice to Trubion's shareholders. In the event that the parties enter into a stipulation of settlement, a hearing will be scheduled at which the State Court will consider the fairness, reasonableness and adequacy of the settlement. There can be no assurance that the parties will ultimately enter into a stipulation of settlement, that the State Court will approve any proposed settlement, or that any eventual settlement will be under the same terms as those contemplated by the agreement in principle.

Other. From time to time, the Company is involved in product liability claims and other litigation considered normal in the nature of its business. The Company does not believe that any such proceedings would have a material adverse effect on the results of its operations.

17. Variable interest entities

In July 2008, the Company entered into a collaboration with the University of Oxford ("Oxford") and certain University of Oxford researchers to conduct clinical trials in the advancement of a vaccine product candidate for tuberculosis, resulting in the formation of the Oxford-Emergent Tuberculosis Consortium ("OETC"). The Company has a 51% equity interest in OETC and controls the OETC Board of Directors. In addition, the Company has certain funding and services obligations of up to $20.3 million related to its investment. The Company has evaluated its variable interests in OETC and has determined that it is the primary beneficiary as it has the ability to direct the activities of OETC and will absorb the majority of expected losses. Accordingly, the Company consolidates the entity. As of December 31, 2010 and 2009 respectively, assets of $590,000 and $379,000 and liabilities of $678,000 and $83,000 related to this OETC are included within the Company's consolidated balance sheet. During 2010 and 2009 respectively, the OETC incurred net losses of $8.7 million and $9.4 million of which $4.4 million and $4.8 million is included in the Company's consolidated statement of operations.

In conjunction with the establishment of OETC, the Company granted a put option to Oxford and the Oxford researchers whereby the Company may be required to acquire all of the OETC shares held by Oxford and the Oxford researchers at fair market value of the underlying shares. This put option is contingent upon the satisfaction of a number of conditions that must exist or occur subsequent to the granting by the European Commission of marketing authorization for the OETC-sponsored vaccine product candidate for tuberculosis. The Company accounts for the put option in accordance with the accounting provisions related to derivatives and distinguishing liabilities from equity. In accordance with these provisions, the Company has determined that the put option has a de minimis fair value as of December 31, 2010.

In July 2010, the Company entered into a collaboration to advance the development of monoclonal products for worldwide prophylaxis or treatment of infection caused by existing pandemic influenza strains or anticipated future pandemic influenza strains via a hemagglutinin-based medical countermeasure, resulting in the formation of the EPIC Bio PTE Limited ("EPIC"). The Company has a 60% equity interest in EPIC and controls the EPIC Board of Directors. The Company has evaluated its variable interests in EPIC and has determined that it is the primary beneficiary as it has the ability to direct the activities of EPIC and will absorb the majority of expected losses. Accordingly, the Company consolidates the entity. As of December 31, 2010, assets of $2.2 million and liabilities of $691,000 related to EPIC are included within the Company's consolidated balance sheet. During 2010, EPIC incurred net losses of $682,000 of which $409,000 is included in the Company's consolidated statement of operations.

18. Assets held for sale

The Company currently owns two buildings in Frederick, Maryland that it determined in 2009 would not be placed into service. Accordingly, the Company committed to a plan to sell the buildings, along with associated improvements. These buildings are classified on the Company's balance sheets as assets held for sale. Assets held for sale are recorded at the lower of the carrying amount or fair market value less costs to sell, and are no longer depreciated once classified as held for sale. The Company recorded the assets held for sale at fair market value, based on factors that include recent purchase offers less estimated selling costs, and recorded an impairment charges of $1.2 million and $7.3 million for the years ended December 31, 2010 and 2009, respectively. These charges are classified in the Company's statement of operations as selling, general and administrative expense within the Company's biosciences segment. The Company continues to actively seek to sell these buildings.

19. Related party transactions

The Company entered into an agreement in February 2009 with an entity controlled by family members of the Company's Chief Executive Officer to market and sell BioThrax. The agreement was effective as of November 2008 and requires payment based on a percentage of net sales of biodefense products of 17.5% in Saudi Arabia and 15% in Qatar and United Arab Emirates, and reimbursement of certain expenses. No payments under this agreement have been triggered for the years ended December 31, 2010 and 2009.

The Company entered into a severance agreement in April 2010 with the Company's former Senior Vice President, Legal Affairs and General Counsel, whose employment with the Company terminated in March 2010. Severance payments and other benefits under the agreement are substantially identical to those provided under the provisions of the Company's Severance Plan and Termination Protection Program. One-half of the amounts payable under the severance agreement was paid in September 2010, with the remaining amounts being paid in six equal monthly installments beginning in October 2010.

The Company entered into a consulting agreement in April 2010 with the Company's former Senior Vice President, Legal Affairs and General Counsel. The agreement, which was terminated in July 2010, provided for consulting and support services in connection with the Company's litigation with PSC. During the year ended December 31, 2010, the Company paid approximately $12,000 for services rendered under this agreement, of which no balance remained unpaid in accounts payable at December 31, 2010.

The Company entered into a consulting agreement in September 2010 with an entity controlled by the Company's former Senior Vice President Corporate Affairs, who is also a family member of the Company's Chief Executive Officer. The agreement provides for consulting services in connection with special projects as assigned by the Company's President. During the year ended December 31, 2010, the Company paid approximately $25,000 for services rendered under this agreement, of which $10,000 remained in accounts payable at December 31, 2010.

The Company entered into a transportation arrangement with an entity owned by the Company's Chief Executive Officer. During the years ended December 31, 2010 and 2009, the Company paid approximately $41,000 and $32,000, respectively, under this arrangement for transportation and logistical support, of which $11,000 remained in accounts payable at December 31, 2010. This agreement was terminated in February 2011 with an effective termination date of December 31, 2010.

The Company has entered into a consulting agreement with a member of the Company's Board of Directors. For each of the years ended December 31, 2010 and 2009, the Company paid approximately $180,000 under this agreement for strategic consultation and project support for the Company's marketing and communications group, of which $15,000 remained unpaid in accounts payable at December 31, 2010.

20. Restructuring

On November 30, 2010, the Company adopted a plan to restructure and reprioritize the operations of Emergent Product Development UK Limited ("EPDU"). The key drivers for this restructuring included the following:

- Reprioritization of the Company's product development portfolio;
- Relocation of manufacturing development work for the Company's platform products;
- Centralization of laboratory work in single locations;
- Centralization of resources in key support functions;
- Focus EPDU expertise and activities; and
- Retention of key senior management resources.

The Company has made estimates and judgments regarding the amount and timing of this restructuring expense and liability, including current and future period termination benefits and other exit costs to be incurred when related actions take place. The Company has also assessed the recoverability of certain long-lived assets employed in the business and in certain instances shortened the expected useful life of the assets based on changes in their expected use. When the Company determines that the useful lives of assets are shorter than it had originally estimated, the Company records additional depreciation to reflect the assets' new shorter useful lives. Severance and other related costs and asset-related charges are reflected within the Company's consolidated statement of income as a component of selling, general and administrative expense. Actual results may differ from these estimates. There were no material cash payments from the restructuring made through December 31, 2010.

The restructuring entails a headcount reduction of approximately 40 employees at EPDU, the termination of facilities leases, and the impairment of leasehold improvements and certain other equipment. The Company expects to complete this restructuring in the first half of 2011, and estimates that the total cost of the restructuring will be approximately $6.5 million. These estimated costs are detailed below:

(in thousands)	Incurred in 2010	Total Expected To Be Incurred
Termination benefits	$ 2,418	$ 3,000
Contract termination costs	650	2,800
Other costs	260	700
Total	$ 3,328	$ 6,500

The amount incurred in 2010 of $3.3 million is included in selling, general and administrative expense in the Company's statement of operations, and is included within the biosciences segment.

21. Segment information

For financial reporting purposes, the Company reports financial information for two business segments: biodefense and biosciences. In the biodefense segment, the Company develops, manufactures and commercializes vaccines and antibody therapies for use against biological agents that are potential weapons of bioterrorism or biowarfare. Revenues in this segment relate primarily to the Company's FDA-licensed product, BioThrax. In the biosciences segment, the Company develops vaccines and antibody therapies for use against infectious diseases and other medical conditions that have resulted in significant unmet or underserved public health needs. The "All Other" segment relates to the general operating costs of the Company and includes costs of the centralized services departments, which are not allocated to the other segments, as well as spending on product candidates or activities that are not classified as biodefense or biosciences. The assets in this segment consist primarily of cash and fixed assets.

	Reportable Segments			
(in thousands)	**Biodefense**	**Biosciences**	**All Other**	**Total**
Year Ended December 31, 2010				
External revenue	$ 282,727	$ 3,444	$ -	$ 286,171
Intersegment revenue (expense)	-	-	-	-
Research and development	50,613	32,835	5,847	89,295
Interest revenue	-	-	832	832
Interest expense	-	-	-	-
Depreciation and amortization	4,549	1,368	73	5,990
Net income (loss)	114,826	(55,253)	(7,875)	51,698
In-process research and development assets	-	51,400	-	51,400
Goodwill	-	5,029	-	5,029
Total assets	203,318	112,492	184,509	500,319
Expenditures for long-lived assets	18,168	3,933	-	22,101
Year Ended December 31, 2009				
External revenue	$ 234,574	$ 212	$ -	$ 234,786
Intersegment revenue (expense)	-	-	-	-
Research and development	42,874	25,906	5,808	74,588
Interest revenue	-	-	1,418	1,418
Interest expense	-	-	(7)	(7)
Depreciation and amortization	3,867	1,074	58	4,999
Net income (loss)	88,036	(50,560)	(6,332)	31,144
Assets	211,455	44,897	88,337	344,689
Expenditures for long-lived assets	22,351	10,841	95	33,287

22. Quarterly financial data (unaudited)

Quarterly financial information for the years ended December 31, 2010 and 2009 is presented in the following tables:

	Three months ended			
(in thousands)	**March 31,**	**June 30,**	**September 30,**	**December 31,**
Fiscal year 2010				
Revenue	$ 46,800	$ 62,138	$ 73,986	$ 103,247
Income from operations	3,178	14,811	20,605	34,963
Net income	2,523	9,808	13,120	26,247
Net income per share, basic	0.08	0.32	0.42	0.78
Net income per share, diluted	0.08	0.31	0.41	0.76
Fiscal year 2009				
Revenue	$ 64,519	$ 73,191	$ 43,272	$ 53,804
Income (loss) from operations	17,266	22,710	(3,951)	4,125
Net income	11,119	14,842	949	4,234
Net income per share, basic	0.37	0.49	0.03	0.14
Net income per share, diluted	0.35	0.48	0.03	0.13

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2010. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2010, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2010. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework.* Based on this assessment, our management concluded that, as of December 31, 2010, our internal control over financial reporting is effective based on those criteria.

Management's assessment of and conclusion on the effectiveness of disclosure controls and procedures and internal controls over financial reporting did not include the internal controls related to the operations acquired in the acquisition of Trubion Pharmaceuticals, Inc. which is included in the 2010 consolidated financial statements of Emergent BioSolutions Inc. and constituted total and net assests of $127.6 million and $107.5 million, respectively as of December 31, 2010 and $3.4 million and $3.8 million of revenues and net loss for the year then ended.

Ernst & Young LLP, the independent registered public accounting firm that has audited our consolidated financial statements included herein, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2010, a copy of which is included in this annual report on Form 10-K.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, occurred during the fiscal quarter ended December 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

We have audited Emergent BioSolutions Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Emergent BioSolutions Inc. and Subsidiaries' management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying "Management's Report on Internal Control over Financial Reporting." Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

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

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

As indicated in the accompanying Management's Report on Internal Controls Over Financial Reporting, management's assessment of an conclusions on the effectiveness of internal control over financial reporting did not include the internal controls of the Trubion Pharmaceuticals, Inc. aquisition which is included in the 2010 consolidated financial statements of Emergent BioSolutions, Inc. and Subsidiaries and consituted $127.6 million and $107.5 million total and net assets, respectively, as of December 31, 2010 and $3.4 million and $3.8 million of revenues and net loss, respectively, for the year then ended. Our audit of internal control over financial reporting of Emergent BioSolutions Inc. and Subsidiaries also did not include an evaluation of the internal control over financial reporting of Trubion Pharmaceuticals, Inc..

In our opinion, Emergent BioSolutions Inc. and Subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2010 consolidated financial statements of Emergent BioSolutions Inc. and Subsidiaries, and our report dated March 10, 2011, expressed an unqualified opinion thereon.

/s/Ernst & Young LLP

McLean, Virginia
March 10, 2011

ITEM 9B. OTHER INFORMATION

Executive Compensation

On March 7, 2011, the Compensation Commitee awarded a cash bonus for 2010 performance to Fuad El-Hibri in the amount of $722,570 and to Daniel J. Abdun-Nabi in the amount of $366,692.

Manufacturing

In November 2009, we amended our Product Supply Agreement with Talecris Biotherapeutics, Inc. to delay commencement of commercial manufacturing for our anthrax immune globulin therapeutic product candidate from January 1, 2010 to March 1, 2010 in order to accommodate negotiations for a long-term resolution regarding commercial production of this product candidate. We recently modified this amendment to further extend the commencement date to July 31, 2011, and are currently continuing to negotiate with Talecris.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

Information regarding our directors may be found under the caption "Election of Directors" in the Proxy Statement for our 2011 Annual Meeting of Stockholders. Information regarding our executive officers may be found under the caption “Executive Officers of the Registrant" in the Proxy Statement for our 2011 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Compliance with Section 16(a) of the Exchange Act

Information regarding compliance with Section 16(a) of the Exchange Act by our directors, officers and beneficial owners of more than 10% of our common stock may be found under the caption "Stock Ownership Information—Section 16 (a) Beneficial Ownership Reporting Compliance" in the Proxy Statement for our 2011 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Code of Ethics

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

Director Nominees

Information regarding procedures for recommending nominees to the board of directors may be found under the caption “Corporate Governance—Director Nomination Process” in the Proxy Statement for our 2011 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Audit Committee

We have separately designated a standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Additional information regarding the Audit Committee may be found under the captions “Corporate Governance—Board Committees—Audit Committee” and “Corporate Governance—Audit Committee Report” in the Proxy Statement for our 2011 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Audit Committee Financial Expert

Our board of directors has determined that Zsolt Harsanyi, Ph.D. and Marvin White are “audit committee financial experts” as defined by Item 407(d)(5) of Regulation S-K of the Exchange Act and are “independent” under the rules of the New York Stock Exchange.

ITEM 11. EXECUTIVE COMPENSATION

Information with respect to this item may be found under the caption “Information About Executive and Director Compensation” in the Proxy Statement for our 2011 Annual Meeting of Stockholders. Such information is incorporated herein by reference. The Compensation Committee Report contained in the Proxy Statement for our 2011 Annual Meeting of Stockholders shall be deemed furnished in this annual report on Form 10-K and shall not be deemed “soliciting material” or “filed” with the Securities and Exchange Commission or otherwise subject to the liabilities of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that we specifically request that such information be treated as soliciting material or specifically incorporate such information by reference into a document filed under the Securities Act or the Exchange Act.

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

Information with respect to this item may be found under the captions “Stock Ownership Information” and “Information About Executive and Director Compensation—Securities Authorized for Issuance Under Equity Compensation Plans” in the Proxy Statement for our 2011 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

Information with respect to this item may be found under the captions “Corporate Governance—Transactions with Related Persons” and “Corporate Governance—Board Determination of Independence” in the Proxy Statement for our 2011 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information with respect to this item may be found under the captions “Corporate Governance—Registered Public Accounting Firm's Fees” and “Corporate Governance—Pre-Approval Policy and Procedures” in the Proxy Statement for our 2011 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statements

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

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets at December 31, 2010 and 2009
Consolidated Statements of Operations for the years ended December 31, 2010, 2009 and 2008
Consolidated Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008
Consolidated Statement of Changes in Stockholders’ Equity for the years ended December 31, 2010, 2009 and 2008
Notes to Consolidated Financial Statements

Financial Statement Schedules

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

Exhibits

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

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

By: /s/Fuad El-Hibri

Fuad El-Hibri
Chief Executive Officer and
Chairman of the Board of Directors
Date: March 10, 2011

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

Signature	Title	Date
/s/Fuad El-Hibri Fuad El-Hibri	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 10, 2011
/s/R. Don Elsey R. Don Elsey	Senior Vice President Finance, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 10, 2011
/s/Daniel Abdun-Nabi Daniel Abdun-Nabi	Director	March 10, 2011
/s/Zsolt Harsanyi, Ph.D. Zsolt Harsanyi, Ph.D.	Director	March 9, 2011
/s/Jerome M. Hauer Jerome M. Hauer	Director	March 10, 2011
/s/Dr. John Niederhuber Dr. John Niederhuber	Director	March 9, 2011
/s/Ronald B. Richard Ronald B. Richard	Director	March 9, 2011
/s/Louis W. Sullivan, M.D. Louis W. Sullivan, M.D.	Director	March 10, 2011
/s/Marvin White Marvin White	Director	March 9, 2011
/s/Dr. Sue Bailey Dr. Sue Bailey	Director	March 9, 2011

Exhibit Index

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated August 12, 2010, among the Registrant, Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc.), 35406 LLC, and 30333 Inc. (Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on August 13, 2010)
2.2	Amendment No. 1 to Agreement and Plan of Merger, dated September 29, 2010, among the Registrant, Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc.), 35406 LLC, and 30333 Inc. (Incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on September 30, 2010)
3.1	Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-139190 filed on December 8, 2006)
3.2	Amended and Restated By-laws of the Registrant, as amended (Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2007 (File No. 001-33137))
4.1	Specimen Certificate Evidencing Shares of Common Stock (Incorporated by reference to Exhibit 4.1 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on October 20, 2006)
4.2	Registration Rights Agreement, dated September 22, 2006, among the Registrant and the entities listed on Schedule 1 thereto (Incorporated by reference to Exhibit 4.3 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
4.3	Rights Agreement, dated November 14, 2006, between the Registrant and American Stock Transfer & Trust Company (Incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-8 (File No. 333-139190) filed on December 8, 2006)
9.1	Voting and Right of First Refusal Agreement, dated October 21, 2005, between the William J. Crowe, Jr. Revocable Living Trust and Fuad El-Hibri (Incorporated by reference to Exhibit 9.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.1*	Employee Stock Option Plan, as amended and restated (Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.2*	Form of Director Stock Option Agreement (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.3*	Amended and Restated 2006 Stock Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009 (File No. 001-33137))
10.4*	Form of Incentive Stock Option Agreement under 2006 Stock Incentive Plan (Incorporated by reference to Exhibit 10.4 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on October 30, 2006)
10.5*	Form of Nonstatutory Stock Option Agreement under 2006 Stock Incentive Plan (Incorporated by reference to Exhibit 10.5 to Amendment No. 5 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on October 30, 2006)
10.6*	Form of Restricted Stock Unit Agreement under Amended and Restated 2006 Stock Incentive Plan (Incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009 (File No. 001-33137))
10.7*	Annual Bonus Plan for Executive Officers (Incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009 (File No. 001-33137))
10.8*	Director Compensation Program (Incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2007 (File No. 001-33137))
10.9† *	Severance Plan and Termination Protection Program (Incorporated by reference to Exhibit 10.6 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on October 20, 2006)
10.10*	Election of Fuad El-Hibri to Participate in the Severance Plan and Termination Protection Program (Incorporated by reference to Exhibit 10.35 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
10.11	Form of Indemnity Agreement (Incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.12†	Contract No. HHSO100200700037C, dated September 25, 2007, between Emergent BioDefense Operations Lansing Inc., and the Department of Health and Human Services (Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 (File No. 001-33137))
10.13†	Contract No. HHS0100200800091C between the Department of Health and Human Services and Emergent BioDefense Operations Lansing Inc. dated September 30, 2008 (Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (File No. 001-33137))
10.14†	Filling Services Agreement, dated March 18, 2002, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Hollister-Stier Laboratories LLC, as amended (Incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.15	Amendment No. 5 to the Filling Services Agreement, effective May 14, 2007 between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Hollister-Stier Laboratories LLC (Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137))
10.16†	Exclusive Commercial License of Technology by and among Oxford-Emergent Tuberculosis Consortium Limited, Emergent Product Development UK Limited, Emergent BioSolutions Inc. and Isis Innovation Limited dated July 18, 2008 (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (File No. 001-33137))
10.17†	Product Supply Agreement, dated June 12, 2006, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics, Inc. (Incorporated by reference to Exhibit 10.34 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on October 20, 2006)
10.18†	Amendment No. 1 to Product Supply Agreement, effective December 19, 2006, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics Inc. (Incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009 (File No. 001-33137))
10.19	Amendment No. 2 to Product Supply Agreement, effective June 25, 2007, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics Inc. (Incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009 (File No. 001-33137))
10.20†	Amendment No. 3 to Product Supply Agreement, effective August 29, 2007, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics Inc. (Incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009 (File No. 001-33137))
10.21	Amendment No. 4 to Product Supply Agreement, effective November 17, 2009, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics Inc. (Incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009 (File No. 001-33137))
10.22	Amendment No. 5 to Product Supply Agreement, dated November 3, 2010, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics, Inc. (Incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010 (File No. 001-33137)
10.23†	First Addendum to Product Supply Agreement, effective September 1, 2009, between Emergent Product Development Gaithersburg Inc. and Talecris Biotherapeutics Inc. (Incorporated by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009 (File No. 001-33137))
10.24†	Agreement, dated June 16, 2005, between the Free State of Bavaria and Emergent Product Development UK Limited, formerly ViVacs GmbH (Incorporated by reference to Exhibit 10.43 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on October 20, 2006)
10.25†	License Agreement between U.S. Army Medical Research Institute of Infectious Diseases and the Registrant dated October 7, 2003 (Incorporated by reference to Exhibit 10.21 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008 (File No. 001-33137), filed on March 6, 2009)
10.26	Investment Agreement relating to Microscience Holdings plc, dated March 18, 2005, among the Wellcome Trust, Microscience Investments Limited, formerly Microscience Holdings plc, and Emergent Product Development UK Limited, formerly Microscience Limited, as amended (Incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.27	Consulting Services Agreement, effective April 1, 2009, between the Registrant and The Hauer Group (Incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009 (File No. 001-33137))
10.28	Amended and Restated Marketing Agreement entered into on February 10, 2009 between Emergent BioDefense Operations Lansing Inc.and Intergen N.V. (Incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the year ended December 31,2008 (File No. 001-33137), filed on March 6, 2009)
10.29	Lease (540 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire), dated December 13, 1996, between Slough Properties Limited and Azur Environmental Limited, as assigned to Emergent Product Development UK Limited, formerly Microscience Limited (Incorporated by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.30	Lease (545 Eskdale Road, Winnersh Triangle, Wokingham, Berkshire), dated December 13, 1996, between Slough Properties Limited and Azur Environmental Limited, as assigned to Emergent Product Development UK Limited, formerly Microscience Limited (Incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.31	Lease Agreement, dated May 10, 2007, among Slough Estates (Winnerish) Limited, Emergent Product Development UK Limited and the Registrant (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137))
10.32	Lease Agreement, dated June 27, 2006, between Brandywine Research LLC and the Registrant (Incorporated by reference to Exhibit 10.24 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
10.33	Loan and Security Agreement, dated October 14, 2004, among the Registrant, Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., Antex Biologics Inc., Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Mercantile Potomac Bank (Incorporated by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.34	Promissory Note, dated October 14, 2004, from Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., to Mercantile Potomac Bank (Incorporated by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.35	Loan Agreement, dated October 15, 2004, between Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., and the Department of Business and Economic Development (Incorporated by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.36	Deed of Trust Note, dated October 14, 2004, between Emergent Commercial Operations Frederick Inc., formerly Advanced BioSolutions, Inc., and the Department of Business and Economic Development (Incorporated by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.37	Bond Purchase Agreement, dated March 31, 2005, between the County Commissioners of Frederick County, Emergent Commercial Operations Frederick Inc., formerly Emergent Biologics Inc., and Mercantile Potomac Bank (Incorporated by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.38	Loan Agreement, dated April 25, 2006, among the Registrant, Emergent Frederick LLC and HSBC Realty Credit Corporation (USA) (Incorporated by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on August 14, 2006)
10.39	Promissory Note, dated April 25, 2006, from Emergent Frederick LLC to HSBC Realty Credit Corporation (USA) (Incorporated by reference to Exhibit 10.39 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-136622) filed on September 25, 2006)
10.40	Loan Agreement, dated December 30, 2009, among the Registrant, Emergent BioDefense Operations Lansing Inc., and HSBC Realty Credit Corporation (USA) (Incorporated by reference to Exhibit 10.40 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009 (File No. 001-33137))
10.41	Promissory Note, dated December 30, 2009, from Emergent BioDefense Operations Lansing Inc. to HSBC Realty Credit Corporation (USA) (Incorporated by reference to Exhibit 10.41 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009 (File No. 001-33137))
10.42	Loan Agreement, dated June 8, 2007, between Emergent BioDefense Operations Lansing Inc., formerly BioPort Corporation, and Fifth Third Bank (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 (File No. 001-33137))
10.43	Amendment to Loan Agreement between Emergent BioDefense Operations Lansing, Inc. and Fifth Third Bank dated August 15, 2008 (Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (File No. 001-33137))
10.44	Revolving Credit Note made by Emergent BioDefense Operations Lansing, Inc. in favor of Fifth Third Bank dated August 15, 2008 (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 (File No. 001-33137))
10.45*	Employment Agreement dated September 21, 2007, between Emergent Product Development UK Ltd and Dr. Stephen Lockhart (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K dated December 10, 2009 (File No. 001-33137))
10.46	Contingent Value Rights Agreement, dated August 12, 2010, among the Registrant, Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc.) and Mellon Investor Services LLC, as rights agent (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on August 13, 2010)
10.47	Form of Support Agreement, dated August 12, 2010, between the Registrant and certain former holders of common stock of Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc.) (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on August 13, 2010)
10.48	Form of Lock-up Agreement, dated August 12, 2010, between the Registrant and certain former holders of common stock of Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion

	Pharmaceuticals, Inc.) (Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-33137) filed with the SEC on August 13, 2010)
10.49#	Supply Agreement, dated January 1, 2011, between Emergent BioDefense Operations Lansing LLC and Hollister-Stier Laboratories LLC
10.50 #	Modification No. 2 of Contract No. HHSO100201000034C, dated December 30, 2010, between Emergent BioDefense Operations Lansing LLC, formerly known as Emergent BioDefense Operations Lansing Inc., and Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services
10.51†	Contract No. HHSO100201000034C, dated July 13, 2010, between Emergent BioDefense Operations Lansing LLC, formerly known as Emergent BioDefense Operations Lansing Inc., and the Department of Health and Human Services (Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010 (File No. 001-33137)
10.52†	Modification No. 9 to Contract No. 200-2009-30162, dated July 16, 2010, between Emergent BioDefense Operations Lansing LLC, formerly known as Emergent BioDefense Operations Lansing Inc., and the Centers for Disease Control and Prevention (Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010 (File No. 001-33137)
10.53†	Contract No. HHSO100201000059C, dated September 17, 2010, between Emergent Product Development Gaithersburg Inc. and the Department of Health and Human Services (Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010 (File No. 001-33137)
10.54	Modification No. 7 to Contract No. HHSO100200700037C, dated September 22, 2010, between Emergent BioDefense Operations Lansing LLC, formerly known as Emergent BioDefense Operations Lansing Inc., and the Department of Health and Human Services (Incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010 (File No. 001-33137)
10.55	Lease Agreement between Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc.) and Selig Real Estate Holdings Eight, dated April 28, 2003 (Incorporated by reference to Exhibit 10.8 to Trubion Pharmaceuticals, Inc. Registration Statement on Form S-1 (File No. 333-134709) filed with the SEC on June 2, 2006)
10.56	Amendment to Lease Agreement between Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc.) and Selig Real Estate Holdings Eight, dated December 8, 2004 (Incorporated by reference to Exhibit 10.9 to Trubion Pharmaceuticals, Inc. Registration Statement on Form S-1 (File No. 333-134709) filed with the SEC on June 2, 2006)
10.57	Amendment to Lease Agreement between Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc.) and Selig Real Estate Holdings Eight, dated February 1, 2006 (Incorporated by reference to Exhibit 10.10 to Trubion Pharmaceuticals, Inc. Registration Statement on Form S-1 (File No. 333-134709) filed with the SEC on June 2, 2006)
10.58	Amendment to Lease Agreement between Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc.) and Selig Real Estate Holdings Eight, L.L.C, dated February 2, 2007 (Incorporated by reference to Exhibit 10.1 to Trubion Pharmaceuticals, Inc. Quarterly Report on Form 10-Q (File No. 001-33054) filed with the SEC on August 7, 2008)
10.59	Collaboration and License Agreement between Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc.) and Wyeth, acting through Wyeth Pharmaceuticals Division, dated December 19, 2005 (Incorporated by reference to Exhibit 10.11 to Trubion Pharmaceuticals, Inc. Registration Statement on Form S-1 (File No. 333-134709) filed with the SEC on October 5, 2006)
10.60†	Amendment No. 1 to the Collaboration and License Agreement between Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc.) and Wyeth, acting through Wyeth Pharmaceuticals Division, dated November 30, 2006 (Incorporated by reference to Exhibit 10.12 to Trubion Pharmaceuticals, Inc. Annual Report on Form 10-K (File No. 001-33054) filed with the SEC on March 26, 2007)
10.61	Common Stock Purchase Agreement between Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc.) and Wyeth, dated December 19, 2005 (Incorporated by reference to Exhibit 10.12 to Trubion Pharmaceuticals, Inc. Registration Statement on Form S-1 (File No. 333-134709) filed with the SEC on June 2, 2006)
10.62†	Collaboration and License Agreement between Emergent Product Development Seattle, LLC (as successor-in-interest to Trubion Pharmaceuticals, Inc.) and Facet Biotech Corporation, dated August 27, 2009 (exhibit 10.1) (Incorporated by reference to Exhibit 10.1 to Trubion Pharmaceuticals, Inc. Quarterly Report on Form 10-Q (File No. 001-33054) filed with the SEC on November 5, 2009)
21.1#	Subsidiaries of the Registrant
23.1 #	Consent of Independent Registered Public Accounting Firm
31.1#	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)
31.2#	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)
32.1#	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Filed herewith

† Confidential treatment granted by the Securities and Exchange Commission as to certain portions. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

†† Confidential treatment requested by the Securities and Exchange Commission as to certain portions. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

* Management contract or compensatory plan or arrangement filed herewith in response to Item 15(a) of Form 10-K.

Exhibit 21.1

List of Subsidiaries

Name of Subsidiary	Jurisdiction of Incorporation or Organization
Emergent BioDefense Operations Lansing LLC	Delaware
Emergent Product Development Gaithersburg Inc.	Delaware
Emergent Commercial Operations Frederick Inc.	Maryland
Emergent Frederick LLC	Maryland
Emergent Sales and Marketing US LLC	Delaware
Emergent International Inc.	Delaware
Emergent Europe Inc.	Delaware
Emergent Manufacturing Operations Meriden LLC	Delaware
Emergent Product Development UK Limited	England
Oxford-Emergent Tuberculosis Consortium Limited	England
Emergent Sales and Marketing Germany GmbH	Germany
Emergent Product Development Germany GmbH	Germany
Emergent BioSolutions Malaysia SDN. BHD.	Malaysia
Emergent Sales and Marketing Singapore Pte. Ltd.	Singapore
Emergent Holding Asia Pte. Ltd.	Singapore
Emergent Manufacturing Operations Baltimore LLC	Delaware
EPIC Bio Pte. Limited	Singapore
Emergent Product Development Seattle, LLC	Delaware
Emergent Sales and Marketing Australia Pty Limited	Australia
Emergent Global Health Foundation Limited	England

Exhibit 23.1

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-155311) of Emergent BioSolutions Inc. and Subsidiaries,

(2) Registration Statement (Form S-8 No. 333-139190) pertaining to the Employee Stock Option Plan, as amended and restated, the 2006 Stock Incentive Plan and individual director options agreements of Emergent BioSolutions Inc. and Subsidiaries,

(3) Registration Statement (Form S-8 No. 333-161154) pertaining to the Employee Stock Option Plan, as amended and restated, and the 2006 Stock Incentive Plan of Emergent BioSolutions, Inc., and

(4) Registration Statement (Form S-4 No. 333-169351) of Emergent BioSolutions Inc. and Subsidiaries.

of our reports dated March 10, 2011, with respect to the consolidated financial statements of Emergent BioSolutions Inc. and Subsidiaries, and the effectiveness of Emergent BioSolutions Inc. and Subsidiaries' internal control over financial reporting, included in this Annual Report (Form 10-K) for the year ended December 31, 2010.

/s/ Ernst & Young LLP

McLean, Virginia
March 10, 2011

CERTIFICATION

I, Fuad El-Hibri certify that:

1. I have reviewed this Annual Report on Form 10-K of Emergent BioSolutions Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to he designed tinder our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information, and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date:March 10, 2011

/s/Fuad El-Hibri
Fuad El-Hibri
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, R. Don Elsey certify that:

1. I have reviewed this Annual Report on Form 10-K of Emergent BioSolutions Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to he designed tinder our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information, and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date:March 10, 2011

/s/R. Don Elsey
R. Don Elsey
Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Emergent BioSolutions Inc. (the "Company") for the year ended December 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Fuad El-Hibri, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2011

/s/Fuad El-Hibri
Fuad El-Hibri
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Emergent BioSolutions Inc. (the "Company") for the year ended December 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, R. Don Elsey, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2011

/s/R. Don Elsey
R. Don Elsey
Chief Financial Officer

Exhibit 10.49

SUPPLY AGREEMENT

This Agreement is made effective as of the first day of January 2011 (the "Effective Date") by and between Hollister-Stier Laboratories LLC, having a principal place of business at 3525 North Regal Street, Spokane, Washington, 99207-5788 ("Hollister-Stier") and Emergent BioDefense Operations Lansing LLC, having a principal place of business at 3500 North Martin Luther King Jr. Blvd., Lansing, Michigan 48906 ("EBOL"). Both Hollister-Stier and EBOL are referred to herein individually as "Party" and collectively as the "Parties."

WITNESSETH THAT:

WHEREAS, EBOL has agreed to provide to the United States Government (the "Government") certain amounts of its licensed pharmaceutical product pursuant to Contract No. 200-2009-30162 between EBOL and the Centers for Disease Control and Prevention dated as of September 30, 2008 (the "2008 CDC Contract") and any follow-on contracts to the 2008 CDC Contract (each, a "CDC Follow-On Contract" and together with the 2008 CDC Contract, the "CDC Contracts"); and

WHEREAS, EBOL has a commercial interest in the manufacture of the Filled Product (as hereafter defined) and requests the services of Hollister-Stier in the manufacturing of the Filled Product pursuant to the terms and conditions contained herein, and Hollister-Stier desires to manufacture the Filled Product on behalf of EBOL pursuant to the terms and conditions contained herein;

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

1. Certain terms are defined in the text of this Agreement. In addition, as used in this Agreement, the following definitions shall apply:

1.1. "Act" shall mean the U.S. Food, Drug and Cosmetic Act of 1938 (21 U.S. C. § 301 et seq.) and the regulations promulgated thereunder, as the same may be amended from time to time.

1.2. "Affiliate" shall mean any individual, firm, corporation or other legal entity that directly or indirectly controls, is controlled by, or is under common control with, a Party. As used in the preceding sentence, "control" means possession, whether direct or indirect, of the power to direct or cause the direction of the management and policies of such entity, whether pursuant to the ownership of voting securities, by contract or otherwise.

1.3. "AVA" shall mean BioThrax® (Anthrax Vaccine Adsorbed).

1.4. "Bulk Lot" shall mean each separate and distinct quantity of Bulk Product designated as a single batch or lot by EBOL and designated by lot number

1.5. "Batch" or "Lot" shall mean each separate and distinct quantity of Bulk Product manufactured under continuous conditions and designated by EBOL with a formulated anthrax vaccine (FAV) batch or lot number.

1.6. "Bulk Product" shall mean AVA in bulk form as manufactured by EBOL.

1.7. "Bulk Product Specification(s)" shall mean the specifications for the composition, testing, packaging and labeling of the Bulk Product

1.8. "cGMP Regulations" shall mean the applicable current Good Manufacturing Practices as promulgated by the FDA from time to time under the Act, as presently codified in 21 CFR Parts 210 and 211.

1.9. "Certificate of Analysis" or "COA" shall mean a document executed by Hollister-Stier to certify that a Batch or Lot of Filled Product meets all specifications agreed to by Hollister-Stier and EBOL.

1.10. "Components" shall mean the raw materials listed in Exhibit A and having the specifications described in Exhibit A, necessary or desirable to manufacture Filled Product which shall be provided by EBOL to Hollister-Stier at EBOL's expense .

1.11. "Confidential Information" shall mean any nonpublic information of Hollister-Stier or EBOL including without limitation, trade secrets, business methods, operating procedures, manufacturing methods and processes, prices, and customer information, whether of a written, oral, or visual nature.

1.12. "FDA" shall mean the United States Food and Drug Administration.

1.13. "Filled Lot" shall mean each separate and distinct quantity of Filled Product manufactured under continuous conditions from a 120-liter Bulk Lot and that is designated as a single batch or lot by HOLLISTER-STIER and designated by a lot number.

1.14. "Filled Product" shall mean vials filled by HOLLISTER-STIER with Bulk Product in accordance with all Filling Process Specifications and other requirements of this Agreement.

1.15. "Filling Process Specification(s)" shall mean the requirements and statement of procedures for filling, testing, packaging, labeling and storage prior to shipping, as set forth in HS001-00-FPS, as altered or amended by mutual written agreement of the Parties. The Filling Process Specifications do not include matters covered by the Bulk Product Specifications

1.16. "Intellectual Property" shall mean patents, trade secrets, copyrights, trademarks, trade names, service marks, licenses and other intellectual property rights of a Party.

1.17. "Lot Production Fee" has the meaning set forth in Section 3.8.3.

1.18. "Master Batch Record" shall mean a written description of the procedure to be followed by Hollister-Stier in manufacturing of a Batch or Lot of Filled Product, which description shall include, but not be limited to, a complete list of all active and inactive ingredients, components, weights and measures used in manufacturing the Filled Product within the meaning of 21 CFR part 211.186, or its successor as in effect from time to time.

1.19. "Percentage Yield" shall mean the ratio of the Yield to the Theoretical Yield with respect to a particular Bulk Lot, expressed as a percentage.

1.20. "Quality Systems Agreement" shall mean the executed agreement attached as Exhibit B, as may be amended by the Parties in writing from time to time.

1.21. "Regulatory Authority" shall mean a regulatory authority having jurisdiction over the manufacture or sale of Bulk Product or Filled Product, including but not limited to the Canadian Health Protection Branch, the European Medicines Evaluation Agency, the FDA and any other relevant national regulatory agency in any nation, and "Regulatory Authorities" shall mean collectively all such regulatory authorities.

1.22. "Theoretical Yield" shall mean the number of vials of Filled Product that could be filled from a particular Bulk Lot based on the total amount of Bulk Product in such Bulk Lot, as documented in the Master Batch Record.

1.23. "Third Party" shall mean any party other than EBOL or Hollister-Stier and their respective Affiliates.

1.24. "Yield" shall mean the number of acceptable vials of Filled Product shipped to EBOL that were filled from a particular lot of Bulk Product.

ARTICLE 2

REPRESENTATIONS AND WARRANTIES

2. The Parties agree to the following representations and warranties:

2.1. Each Party represents and warrants to the other as follows:

2.1.1. It has full power and authority to enter into this Agreement and perform its obligations hereunder.

2.1.2. It has such permits, licenses, and authorizations of Regulatory Authorities and any other government agency, authority or body having jurisdiction under applicable law, including Regulatory Authorities with jurisdiction over the Filled Product, Bulk Product and AVA, as are necessary to own its respective properties, conduct its business and perform its obligations hereunder.

2.1.3. It is not currently debarred, suspended, or otherwise excluded by the FDA or any other Regulatory Authority from conducting business and shall not knowingly use in connection with this Agreement the services of any person debarred by the FDA.

2.1.4. It is not currently debarred, suspended, or otherwise excluded by the United States from receiving Federal contracts.

2.1.5. Each Party shall provide immediate written notice to the other Party in the event that Party is debarred, suspended, or otherwise excluded by the FDA or any other Regulatory Authority from conducting business.

2.1.6. Each Party shall provide immediate written notice to the other Party in the event that Party is debarred, suspended, or otherwise excluded by the United States from receiving Federal contracts.

2.1.7. Each Party shall provide to each other copies of all correspondence from Regulatory Authorities related to the Bulk Product or Filled Product, including all inspection reports issued by a Regulatory Authority during the term of this Agreement. Hollister-Stier shall provide informal notice to EBOL within 24 hours by telephone of any such inquiry or inspection. All documents related to the Bulk Product or Filled Product provided by Hollister-Stier to any Regulatory Authority shall be provided to EBOL, in advance, if feasible, and in no case shall such documents be provided to EBOL later than three (3) business days after such documents are provided to any Regulatory Authority. Hollister-Stier shall promptly notify EBOL of all Regulatory Authority inspections concerning its filling processes, the Bulk Product or Filled Product, whereupon, EBOL shall have the right to be present for such inspection. Notwithstanding the foregoing a Party may redact portions of correspondence from or to Regulatory Authorities that would reveal confidential information of other clients.

2.2. Hollister-Stier represents and warrants to EBOL as follows:

2.2.1. Hollister-Stier shall process the Bulk Product in compliance with the Quality Systems Agreement, the Master Batch Record, the Filling Process Specifications, the Act and the cGMP Regulations.

2.2.2. The Filled Product when delivered shall comply with the Filling Process Specifications; provided, however, that Hollister-Stier shall have no liability to EBOL or any Third Party for any breach of the foregoing representation and warranty to the extent that any such breach is caused in whole or in part by EBOL, in compliance with the Filling Process Specifications or by any materials provided by EBOL.

2.2.3. The manufacturing facilities for the Filled Product shall conform to the standards of those Regulatory Authorities with jurisdiction over such facilities, including, but not limited to, those set forth in the cGMP Regulations.

2.2.4. No material changes to the Filling Process Specifications, Hollister-Stier's manufacturing facilities, manufacturing process(es) equipment, testing procedures, validation, suppliers of raw materials and components, or documentation systems relating to the filling of Bulk Product shall be made without the prior written consent of EBOL. Material changes for the purposes of this Agreement are those changes that may potentially have an impact on product quality, regulatory status or submissions.

2.2.5. Hollister-Stier's performance of the filling services shall not violate or misappropriate any patent, copyright, trademark, trade secret or other intellectual property right of any Third Party.

2.2.6. All product contact parts used to manufacture Filled Product shall be dedicated solely to Filled Product or disposed after each use.

2.2.7. Hollister-Stier shall not fill any penicillin-based antibiotics or live viral vaccines at its facility in Spokane, WA.

2.2.8 The filling services under this Agreement shall be conducted at its facility in Spokane, Washington.

2.3. EBOL represents and warrants to Hollister-Stier as follows:

2.3.1. EBOL has all necessary rights to enable Hollister-Stier to manufacture the Filled Product in accordance with the terms and conditions of this Agreement.

2.3.2. All laboratory, scientific, technical and/or other data submitted by or on behalf of EBOL relating to the Bulk Product shall be complete and correct and shall not contain any falsification, misrepresentation or omission.

2.3.3. The Bulk Product shall conform to the Bulk Product Specifications and all other Components supplied by or on behalf of EBOL for use in manufacturing the Filled Product shall conform to such Components' specifications as provided by EBOL to Hollister-Stier.

2.3.4. Neither the Bulk Product nor the Filled Product or the manufacture of Bulk Product infringe or misappropriate the Intellectual Property rights of any Third Party.

2.4 THE WARRANTIES SET FORTH HEREIN ARE THE SOLE AND EXCLUSIVE WARRANTIES MADE BY EITHER PARTY UNDER THIS AGREEMENT, AND NEITHER PARTY MAKES ANY OTHER WARRANTIES EXPRESS OR IMPLIED OR ARISING BY LAW, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE OR ARISING FROM THE COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OF TRADE.

2.5 EXCEPT AS NECESSARY TO SATISFY A THIRD PARTY CLAIM INDEMNIFIED UNDER ARTICLE 6 OF THIS AGREEMENT, EBOL'S SOLE AND EXCLUSIVE REMEDY, AND HOLLISTER-STIER'S SOLE AND EXCLUSIVE LIABILITY AND OBLIGATION FOR ANY BREACH OF A REPRESENTATION AND WARRANTY SET FORTH IN SECTION 2.2 SHALL BE FOR HOLLISTER-STIER TO PERFORM ITS OBLIGATIONS UNDER SECTIONS 3.8.4, 4.1 OR 4.2, AS THE CASE MAY BE.

2.6 WITHOUT LIMITING HOLLISTER-STIER'S OBLIGATIONS UNDER SECTION 3.8.4 OR EBOL'S OBLIGATIONS UNDER SECTION 3.1, AND EXCEPT AS NECESSARY TO SATISFY A THIRD PARTY CLAIM INDEMNIFIED UNDER ARTICLE 6 OF THIS AGREEMENT, AND/OR IN THE EVENT OF A BREACH OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH IN ARTICLE 9 OF THIS AGREEMENT, UNDER NO CIRCUMSTANCES WILL EITHER PARTY BE LIABLE TO THE OTHER UNDER ANY CONTRACT, TORT, STRICT LIABILITY, NEGLIGENCE OR OTHER LEGAL OR EQUITABLE THEORY, FOR THE COST OF COVER OR FOR ANY INDIRECT, INCIDENTAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS) IN CONNECTION WITH THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING, WITHOUT LIMITATION, THE FILLED PRODUCT, BULK PRODUCT OR ANY SERVICES PROVIDED IN CONNECTION WITH SUCH PRODUCT, EVEN IF A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

2.7 EXCEPT AS NECESSARY TO SATISFY A THIRD PARTY CLAIM INDEMNIFIED UNDER ARTICLE 6 OF THIS AGREEMENT, AND/OR IN THE EVENT OF A BREACH OF ITS CONFIDENTIALITY OBLIGATIONS SET FORTH IN ARTICLE 9 OF THIS AGREEMENT, UNDER NO CIRCUMSTANCES SHALL HOLLISTER-STIER'S TOTAL LIABILITY TO EBOL IN CONNECTION WITH THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING, WITHOUT LIMITATION, THE FILLED PRODUCT OR ANY SERVICES PROVIDED IN CONNECTION WITH THE FILLED PRODUCT, EXCEED THE AMOUNT SET FORTH IN SECTION 3.8.4 OF THIS AGREEMENT.

2.8 NOTHING SET FORTH IN THIS AGREEMENT SHALL RESTRICT OR LIMIT HOLLISTER-STIER'S RIGHT TO RECOVER DIRECT DAMAGES, INCLUDING LOST PROFITS, FOR ANY BREACH BY EBOL OF ITS OBLIGATION TO PAY THE PRICE FOR DELIVERED FILLED PRODUCT IN ACCORDANCE WITH ARTICLE 3.

ARTICLE 3

SUPPLY AND MANUFACTURE OF FILLED PRODUCT; FORECASTS,

PURCHASE ORDERS AND PAYMENT

3. The Parties agree to the following supply and manufacturing provisions:

3.1. EBOL hereby engages Hollister-Stier, on a non-exclusive basis, and Hollister-Stier hereby accepts such engagement, to provide EBOL with filling services to produce Filled Product in accordance with the Filling Process Specification(s) and the other terms and conditions set forth in this Agreement, as ordered by EBOL in accordance with this Agreement. Each calendar year during the Term, EBOL will purchase at least 75% of its aggregate requirements of filled AVA from Hollister-Stier ("Requirements Obligation").

Notwithstanding the above or anything else to the contrary in this Agreement, in the event of a "Supply Failure" (as defined below), no purchase order shall be considered firm and during the pendency of the Supply Failure (as further described below) EBOL shall be released from its Requirements Obligation such that filled AVA obtained from other suppliers during the pendency of the Supply Failure shall not be considered in calculating whether the Requirements Obligation has been met during a calendar year. "Supply Failure" shall mean that in any given rolling six (6) month period, two (2) or more Filled Lots have each had a Percentage Yield of less than 80%. For purposes of this definition:(i) any Filled Product properly rejected by EBOL pursuant to the provisions of Sections 4.1 and 4.2 (subject to the ruling of an independent laboratory or consultant) shall be included in the calculation of the Percentage Yield for such Filled Lot; and (ii) any Filled Lot or Bulk Lot (otherwise suitable to manufacture a Filled Lot) made unusable or destroyed through the fault of Hollister-Stier (or otherwise because it does not meet the Filling Process Specifications and such failure is unrelated to the Bulk Product failing to meet the Bulk Product Specifications or Components failing to meet their specifications) as further described in Section 3.8.4 shall be deemed to be a Filled Lot having a Percentage Yield of less than 80%. A Supply Failure shall terminate and no longer be pending at such time that Hollister-Stier and EBOL agree in writing that Hollister-Stier has remedied such Supply Failure and is able to manufacture Filled Product in compliance with its representations and warranties set forth in Section 2.2.1 of this Agreement. Such writing shall specifically list the duration of the Supply Failure for purposes of being able to determine whether the Requirements Obligation has been met during a calendar year. Upon EBOL's written request, Hollister-Stier shall provide EBOL with reasonable documentation or other appropriate evidence of Hollister-Stier's remedy of such Supply Failure.

EBOL shall maintain accurate and complete books and records of purchases of Filled Product and purchases of filled AVA product from Hollister-Stier and Third Parties in such form and in such reasonable detail as to enable EBOL and its Affiliates to verify they have met the Requirements Obligation. Upon the written request of Hollister-Stier, EBOL shall permit an independent certified public accounting firm or consultant selected by Hollister-Stier and reasonably acceptable to EBOL to have access during normal business hours to such of the records of EBOL as may be reasonably necessary to verify that EBOL has met the Requirements Obligation for any calendar year ending not more than three full years prior to the date of such request. If such accounting firm or consultant concludes that EBOL did not meet the Requirements Obligation (or if without an audit the parties agree the Requirements Obligation was not met) then EBOL shall pay Hollister-Stier for any Filled Lots not provided by Hollister-Stier that would have been provided by Hollister-Stier had EBOL met the Requirements Obligation (ie the Lot Production Fee for such Filled Lots). The fees and expenses charged by such accounting firm or consultant shall be paid by Hollister-Stier. However, if the audit discloses that the Hollister-Stier is owed at least $10,000 for the periods under audit, then EBOL shall pay the fees, costs and expenses charged by the accounting firm or consultant.

3.2. Hollister-Stier shall be solely responsible for securing and maintaining approval of Hollister-Stier's facility as a registered FDA facility.

3.3. Bulk Product and Components: EBOL will supply to Hollister-Stier's facility, at its expense, (i) sufficient quantities of Bulk Product at least one (1) business day prior to the scheduled fill date and (ii) sufficient Components at least thirty (30) days prior to the scheduled fill date set forth in any purchase order, to enable Hollister-Stier to meet its obligations hereunder. All such Bulk Product shall conform to the Bulk Product Specifications and all Components will correspond to their respective specifications. Title to Bulk Product shall remain at all times with EBOL. Except as expressly provided otherwise in Section 3.8.3, risk of loss of the Bulk Product shall remain at all times with EBOL.

3.4. EBOL shall be responsible for release of Filled Product for sale or distribution.

3.5. EBOL shall be responsible for any stability testing program for the Filled Product required by the Act and the cGMP Regulations.

3.6. EBOL shall be responsible for maintaining any retention samples of the Filled Product required by the Act and the cGMP Regulations.

3.7. EBOL shall have the right, upon reasonable advance notice to Hollister-Stier, to conduct an annual audit to observe and inspect Hollister-Stier's facilities and procedures for manufacturing Filled Product. Such annual inspections will be made by no more than four (4) EBOL representatives and shall be conducted in accordance with the confidentiality provisions as set forth in Article 9. Each annual inspection shall last no more than two (2) business days. During such inspection, EBOL's representatives shall (a) be accompanied by a representative of Hollister-Stier, (b) follow such security and facility access procedures as are reasonably requested by Hollister-Stier, and (c) use good faith efforts to avoid disrupting Hollister-Stier's operations. In addition, EBOL shall have the right to perform reasonable "for cause" audits in addition to any scheduled annual audit. The specific goals of such audit, the proposed date of such audit, and the names of the individuals who will conduct the audit shall be provided to Hollister-Stier by EBOL in advance of such audit.

3.8. Forecasts, Purchase Orders, Price, Price Adjustment, Waste/Disposal, Terms of Payment:

3.8.1. Forecasts: Within thirty (30) days following execution of this Agreement, EBOL shall supply Hollister-Stier with an initial written, rolling twelve (12) month forecast of EBOL's estimated requirements for Filled Product during such 12 month period (the "Forecast"). Every 90 days thereafter, EBOL will update and extend the Forecast to cover the 12 months beginning with the date of such updated Forecast. Each Forecast shall include an estimated number of Batches and requested delivery dates for the 12 months covered by such Forecast. Amounts set forth in a Forecast are good faith estimates, to be used for planning purposes only, and Forecasts shall not constitute purchase orders.

3.8.2. Purchase Orders: EBOL will provide Hollister-Stier with a firm purchase order at least sixty (60) days prior to the earliest delivery date specified in such purchase order. All purchase orders will be sent by facsimile or electronic mail to the address specified by Hollister-Stier.

3.8.2.1. Each purchase order and any acknowledgment thereof shall be governed by the terms of this Agreement. In the event a Party uses forms or documents to place or accept purchase orders that contain terms and conditions that are in addition to or contrary to those in this Agreement, the Parties agree and acknowledge that such forms or documents will be used for convenience only, and that unless agreed by both Parties in writing no terms or conditions set forth therein, except with respect to quantity and date of delivery on the face of the purchase order, shall be of any force or effect. Hollister-Stier shall be deemed to have accepted a purchase order unless it objects in writing within ten business days after receiving a purchase order. Hollister-Stier may refuse to accept a purchase order only in the event it cannot accommodate the delivery date requested in the purchase order in which case the Parties shall agree on an alternative delivery schedule. Once a purchase order is accepted or deemed accepted by Hollister-Stier, Hollister-Stier shall be required to use commercially reasonable efforts to meet the delivery dates(s) set forth in such purchase order; *provided however*, that Hollister-Stier's efforts shall not be deemed commercially reasonable if, following Hollister-Stier's acceptance of a purchase order as provided in this Section 3.8.2.1, other than as a result of a force majeure event or the requirement of a Regulatory Authority, Hollister-Stier suspends or cancels the manufacture of Filled Product in order to manufacture a Third Party product and, as a result, Hollister-Stier is unable to meet the delivery date for the Filled Product specified in the applicable purchase order and *further provided*, that the scheduled fill date shall not be changed without EBOL's prior written approval not to be unreasonably withheld.

3.8.2.2. EBOL reserves the right to cancel or postpone any purchase order after acceptance by Hollister-Stier. However, should EBOL cancel or postpone any purchase order within fourteen (14) calendar days prior to the scheduled fill date, EBOL shall pay Hollister-Stier a cancellation fee equivalent to 25% of the purchase price for the Filled Product described in the purchase order.

3.8.3. Price and Shipping: EBOL shall pay Hollister-Stier, in U.S. dollars, the price specified in Exhibit C annexed hereto ("Lot Production Fee") for each Bulk Lot filled during each respective year. The price excludes all taxes, duties, shipping, insurance and other expenses. Bulk Product shall be delivered FCA Hollister-Stier's facility, Spokane, Washington, freight prepaid. Following Hollister-Stier's processing of Bulk Product, Hollister-Stier shall deliver Filled Product to EBOL's carrier at Hollister-Stier's site and risk of loss shall pass to EBOL when the Filled Product is tendered to the carrier for shipment to EBOL. Shipment and insurance of Bulk Product and Filled Product during shipment shall be arranged by EBOL and the price and liability of such shipment shall be borne by EBOL.

3.8.4. Price Adjustment/Loss of Filled Lot: In instances where the Percentage Yield for accepted Filled Product is less than ninety percent of the Theoretical Yield EBOL shall AS ITS SOLE REMEDY THEREFOR, be entitled to a prorata price adjustment to reflect the shortfall below the threshhold. As an example, if the Theoretical Yield for a given Filled Lot is 18,000 vials and fifteen thousand, three hundred (15,300) vials of Filled Product from a Filled Lot are accepted by EBOL (subject to Article 4 hereof), the Percentage Yield for this Filled Lot is 85%. The Lot Production Fee for such Filled Lot would therefore be reduced by 5%.

If an entire Filled Lot or the Bulk Product is made unusable or is destroyed through the fault of Hollister-Stier (or otherwise because it does not meet the Filling Process Specifications and such failure is unrelated to the Bulk Product failing to meet the Bulk Product Specifications), Hollister-Stier shall promptly so inform EBOL or EBOL shall promptly so inform Hollister-Stier, as the case may be, together with an explanation of the circumstances and Hollister-Stier shall not charge EBOL for that Filled Lot. AS EBOL'S SOLE REMEDY THEREFOR, Hollister-Stier shall (i) conduct the filling services for two (2) replacement Bulk Lots without charge, provided that EBOL at its risk and expense shall supply the replacement Bulk Product and all necessary Components; (ii) conduct a non-conforming materials run without charge to EBOL, if reasonably so requested by EBOL; and (iii) conduct, without charge to EBOL, appropriate additional training of personnel, development work and/or technical studies to address the causes underlying the failed fill as EBOL and Hollister-Stier agree in good faith after consultation are called for under the circumstances.

3.8.5. Waste/Disposal of Rejected Bulk Product or Filled Product: The expense for disposal or reclamation of rejected defective Bulk Product or Filled Product shall be borne by EBOL, provided, however, that normal inspection (manufacturing fallout through visual inspection by Hollister-Stier of an otherwise acceptable lot) rejects or other associated Filled Product or Bulk Product lost during the filling process at Hollister-Stier shall not be deemed subject to this subsection 3.8.5 and EBOL shall have no responsibility for disposal, reclamation or any costs associated therewith.

3.8.6. Terms of Payment: Invoices shall be payable to Hollister-Stier at the later of forty-five (45) calendar days after EBOL's acceptance or deemed acceptance of Filled Product as set forth in Article 4 or receipt of invoice. All amounts not paid when due shall bear interest from the due date at the rate of one and one-half percent (1.5%) per month.

3.8.6.1. Invoices shall be sent to the following address:

Emergent BioDefense Operations Lansing LLC

Attention: Accounts Payable

3500 N. Martin Luther King Jr., Blvd.

Lansing, MI 48906

3.8.6.2. All payments due hereunder to Hollister-Stier shall be sent by wire transfer of funds via the Federal Reserve Wire Transfer System to:

ACH ABA# 323070380

WIRE ABA# 026009593

Beneficiary: Hollister-Stier Laboratories LLC

Account # 004850802409

Swift Code BOFAUS3N

Or by check via mail to:

Hollister-Stier Laboratories LLC

14110 Collections Center Drive

Chicago, IL 60693-4110

ARTICLE 4

INSPECTION AND REJECTION OF FILLED PRODUCT; QUALITY CONTROL

4. The Parties agree to the following provisions for acceptance or rejection of Filled Product and certain matters relating to quality control:

4.1. Each Batch of Filled Product delivered to EBOL hereunder shall be accompanied by a Certificate of Analysis signed by a duly authorized representative of Hollister-Stier. EBOL shall have 30 days from the date of

receipt of the Certificate of Analysis to inspect and reject acceptance by written notice to Hollister-Stier; provided, however, that any such notice shall set forth EBOL's reasons for rejection in reasonable detail and provided, further, that EBOL may reject Filled Product only if: (i) EBOL claims a material breach of Hollister-Stier's representations and warranties in Section 2.1 or 2.2 of this Agreement with respect to such Filled Product; or (ii) Hollister-Stier has failed to deliver a Certificate of Analysis for such Filled Product. If Hollister-Stier does not receive EBOL's written notice of rejection within such 30 day period, EBOL shall be deemed to have accepted Filled Product.

4.2. In the event EBOL provides Hollister-Stier with a timely notice of rejection as set forth in Section 4.1, Hollister-Stier shall have thirty (30) days to review the reason for the rejection. If Hollister-Stier disagrees with EBOL's decision to reject the Filled Product, the Parties shall use their best efforts to resolve the dispute amicably and promptly. If the Parties are unable to reach a resolution within 60 days after EBOL's notice of rejection, the matter shall be referred to any independent laboratory or consultant mutually acceptable to the Parties, whose decision as to the acceptance of such Filled Product shall be final and binding. The Party against whom the dispute is decided shall pay any charges for such laboratory or consultant. If the laboratory or consultant determines that the returned Filled Product did not conform to the acceptance criteria set forth in Section 4.1 hereof, EBOL shall be entitled to the remedies set forth in Section 3.8.4 hereof.

4.3. In addition to any safety requirements set forth in the Quality Systems Agreement or the Master Batch Record, Hollister-Stier shall develop, adopt and enforce safety procedures for manufacturing Filled Product in compliance with the Act and the cGMP Regulations.

4.4. In the event (a) any Regulatory Authority issues a request, directive or order that any of the Filled Product be recalled, withdrawn, or corrected, (b) a court of competent jurisdiction orders such an action, or (c) either Party reasonably determines that any Filled Product should be recalled, withdrawn or corrected, the Parties shall take all appropriate corrective actions as they reasonably mutually determine, and shall cooperate in any governmental investigations relating to the Filled Product. As between Hollister-Stier and EBOL, EBOL shall be solely responsible for initiating, conducting, and managing any recall, withdrawal or correction effort. EBOL shall be solely responsible for all related expenses, except that Hollister-Stier shall be liable for such expenses to the extent that the recall, withdrawal or correction resulted solely from a breach by Hollister-Stier of any of its representation and warranties set forth in Section 2.1 or 2.2 of this Agreement.

4.5. EBOL shall provide to Hollister-Stier copies of all material regulatory submissions that relate to Hollister-Stier's services under this Agreement, which copies shall be provided reasonably in advance of submission. Hollister-Stier shall consult with EBOL in responding to questions from the Regulatory Authorities regarding manufacturing of the Filled Product. Each Party shall notify the other promptly after receipt of any notice of any Regulatory Authority inspection, investigation or other inquiry regarding the Filled Product. The Parties shall cooperate with each other during any such inspection, investigation or other inquiry including, but not limited to, allowing, upon reasonable request, a representative of the other to participate during such inspection, investigation or other inquiry, and providing copies of all relevant documents.

4.6. The Parties agree to the following provisions regarding adverse events and complaints:

4.6.1. EBOL shall be responsible to (a) report adverse events involving the Filled Product to the FDA and other Regulatory Authorities, and (b) respond to quality complaints and medical and technical inquiries, respecting the Filled Product.

4.6.2. In the event Hollister-Stier (a) receives information regarding any adverse event relating to the Filled Product, (b) receives any complaints relating to the Filled Product, (c) receives any medical or technical inquiry relating to the Filled Product, or (d) discovers or is notified of any defect in the Filled Product, it shall (i) promptly notify EBOL and (ii) conduct an investigation in accordance with its normal procedures for complaints, inquiries or discoveries of that nature and promptly report the results of such investigation to EBOL. The Parties shall reasonably cooperate with and assist each other in connection with any such matter.

ARTICLE 5

INTELLECTUAL PROPERTY RIGHTS

5. The Parties agree to the following provision regarding Intellectual Property:

5.1. Limitation of Use: Except as expressly stated in this Agreement, no Intellectual Property rights of any kind or nature are conveyed by this Agreement and neither Party shall have any right, title or interest in or to the other Party's Intellectual Property rights for any purpose whatsoever without such other Party's prior written consent. Upon termination of this Agreement for whatever reason, neither Party shall use or exploit in any manner whatsoever any Intellectual Property rights of the other Party.

ARTICLE 6

INDEMNIFICATION FOR THIRD PARTY CLAIMS

6. The Parties agree to the following clauses regarding indemnification for Third Party claims:

6.1. Indemnification by EBOL: EBOL shall indemnify, defend and hold Hollister-Stier, its Affiliates and their respective directors, officers, employees, agents, successors and assigns harmless from and against any and all damages, losses, judgments, claims, suits, actions, liabilities, costs and expenses (including, but not limited to, reasonable attorneys' fees and costs) (collectively, "Liabilities") resulting from any Third Party claims or suits to the extent arising out of (1) the ownership or handling of the Filled Product,by parties other than Hollister-Stier, or the use, distribution, marketing or sale of the Filled Product, (2) EBOL's sale of filled AVA products manufactured by Third Parties; (3) EBOL's material breach of any of its warranties or representations, or failure to perform any of its obligations, hereunder, (4) EBOL's negligent acts or omissions or willful misconduct; or failure of the Bulk Product or Components to meet their respective specifications; or (5) infringement of any Third Party Intellectual Property by the Bulk Product or the Filled Product or manufacture of the Bulk Product or any misappropriation of Third Party Intellectual Property by EBOL.

6.2. Indemnification by Hollister-Stier: Hollister-Stier shall indemnify, defend and hold EBOL, its Affiliates and their respective directors, officers, employees, agents, successors and assigns harmless from and against any and all Liabilities resulting from any Third Party claims to the extent arising out of (1) Hollister-Stier's failure to manufacture Filled Product in accordance with the Filling Process Specifications, (2) Hollister-Stier's material breach of any of its warranties or representations, or failure to perform any of its obligations, hereunder; (3) Hollister-Stier's negligent acts or omissions or willful misconduct; or (4) Hollister-Stier's infringement or misappropriation of any Third Party Intellectual Property in performing the filling services.

6.3. Indemnification Procedures:

6.3.1. Any Party hereto seeking indemnification hereunder (in this context the "Indemnified Party") shall notify the other Party (in this context the "Indemnifying Party") in writing reasonably promptly after the assertion against the Indemnified Party any claim by a Third Party (a "Third Party Claim") in respect of which the Indemnified Party intends to base a claim for indemnification hereunder.

6.3.2. (1) The Indemnifying Party shall have the right, upon written notice given to the Indemnified Party within thirty (30) calendar days after receipt of the notice from the Indemnified Party of any Third Party Claim, to assume the defense and handling of such Third Party Claim, at the Indemnifying Party's sole expense, in which case the provisions of Section 6.3.2(2) below shall govern.

(2) The Indemnifying Party shall select counsel reasonably acceptable to the Indemnified Party in connection with conducting the defense and handling of such Third Party Claim, and the Indemnifying Party shall defend or handle the same in consultation with the Indemnified Party, and shall keep the Indemnified Party apprised of the status of the Third Party Claim. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, which consent will not be unreasonably withheld, agree to a settlement of any Third Party Claim that could directly or indirectly lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to indemnification hereunder. The Indemnified Party shall cooperate with the Indemnifying Party and shall be entitled to participate in the defense or handling of such Third Party Claim with its own counsel at its own expense.

6.3.3. (1) If the Indemnifying Party does not give written notice to the Indemnified Party, within thirty (30) calendar days after receipt of the notice from the Indemnified Party of any Third Party Claim, of the Indemnifying Party's election to assume the defense or handling of such Third Party Claim, the provisions of Section 6.3.3(2) below shall govern.

(2) The Indemnified Party may, at the Indemnifying Party's expense, select counsel in connection with conducting the defense or handling of such Third Party Claim and defend or handle such Third Party Claim in such manner as it may deem appropriate, provided, however, that the Indemnified Party shall keep the Indemnifying Party timely appraised of the status of such Third Party Claim and shall not settle such Third Party Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld. If the Indemnified Party defends or handles such Third Party Claim, the Indemnifying Party shall cooperate with the Indemnified Party and shall be entitled to participate in the defense or handling of such Third Party Claim with its own counsel and at its own expense.

6.3.4. The indemnification remedies in this Article 6, shall constitute the sole and exclusive remedies of the Parties with respect to any Third Party Claims arising under or relating to this Agreement.

6.4. Limitation of Liability: Notwithstanding any other provisions of this Agreement, except with respect to claims for bodily injury and/or death, Hollister-Stier's aggregate (not per claim) indemnification liability to EBOL and its Affiliates for Third Party Claims pursuant to this Article 6 shall not exceed one Lot Production Fee, and in no event will Hollister-Stier be liable for EBOL's cover damages to Third Parties. With respect to claims of indemnification or contribution for bodily injury or death, Hollister-Stier's liability for indemnification and/or contribution shall be strictly limited to the insurance proceeds (excluding defense costs) it receives or which are paid on its behalf.

ARTICLE 7

INSURANCE

Each of EBOL and Hollister-Stier shall obtain and maintain by no later than the scheduled delivery date for the first Batch of Filled Product delivered under this Agreement, either itself or through one or more of its Affiliates, with reputable carriers, the following insurance:

(a) Product Liability insurance with limits of not less than Ten Million United States Dollars (US $10,000,000) per claim/annual aggregate;

(b) Workers Compensation as required by all applicable laws;

(c) Employer's Liability insurance with a policy limit of not less than $1,000,000; Commercial General Liability Insurance including contractual liability with minimum limits of $1,000,000 for each occurrence and $2,000,000 general aggregate; and

(d) Umbrella insurance with minimum limits of $5,000,000 each occurrence and in the aggregate.

Upon request, each Party shall furnish the other Party with a certificate of insurance evidencing the insurance coverage required to be maintained herein and provide at least thirty (30) days prior written notice of cancellation. Such policies shall be provided by unrelated third party insurance companies rated A-VII or better in the most current edition of Best's Key Rating Guide.

ARTICLE 8

TERM AND TERMINATION

8. The Parties agree to the following clauses regarding the term and termination of this Agreement:

8.1. Term: This Agreement shall remain in full force and effect for five (5) years after the Effective Date (the "Term"), unless terminated earlier in accordance with 8.2 or 8.3. This Agreement shall automatically renew for up to two (2) additional two (2) year terms (each a "Renewal Term") unless EBOL provides notice of non-renewal to Hollister-Stier not less than ninety (90) days prior to the expiration of the Term or the Renewal Term, as the case may be.

8.2. Termination for Default: This Agreement may be terminated by either Party in the event of material breach or default by the other Party of the terms and conditions hereof; provided, however, the other Party shall first give to the defaulting Party written notice of the proposed termination or cancellation of this Agreement, specifying the grounds therefor. Upon receipt of such notice, with respect to such defaults as are capable of being cured, the defaulting Party shall have ninety (90) calendar days to respond by curing such default. If the breaching Party does not respond or fails to work diligently and to cure such breach within such ninety (90) day period, then the other Party may terminate this Agreement.

8.3. Bankruptcy or Insolvency:

8.3.1. Either Party may terminate this Agreement upon the occurrence of any of the following with respect to the other Party:

8.3.1.1. The filing of an involuntary petition under the U.S. Bankruptcy Code, or any other similar law, which is not dismissed within sixty (60) days after the filing date; or

8.3.1.2. The filing of a voluntary petition by such other Party for relief under the U.S. Bankruptcy Code or other similar law which is not dismissed within sixty (60) days after the filing date.

8.4. Rights and Duties Upon Termination:

8.4.1. Termination of this Agreement for whatever reason, shall not affect the obligations of either Party, including payment of obligations which have accrued prior to such termination, and EBOL's obligation to purchase Filled Product subject to binding purchase orders. Articles 1, 2, 3, 4, 5, 6, 9, 10, 11 and 12 and Section 8.4 shall survive the termination.

ARTICLE 9

CONFIDENTIALITY

9. In carrying out their respective obligations under this Agreement, it is recognized by Hollister-Stier and EBOL that each may disclose to the other Confidential Information of the disclosing Party, and they hereby agree as follows with respect to any such disclosure:

9.1. Form of Disclosure: Confidential Information may be disclosed in oral, written or electronic form.

9.2. Obligations: The receiving Party shall hold Confidential Information in confidence and use it only for the purpose of performing its obligations under this Agreement or otherwise complying with applicable laws, rules or regulations. Except as provided below, the receiving Party shall not disclose, disseminate or distribute any such Confidential Information to any Third Party unless prior written authorization has been obtained from the disclosing Party. These obligations shall not apply to:

9.2.1. Information which, at the time of disclosure, is generally known to the public;

9.2.2. Information which, after disclosure, becomes generally known to the public by publication or otherwise, except by breach of this Agreement by the receiving Party;

9.2.3. Information which the receiving Party can demonstrate by its written records was in the receiving Party's possession at the time of the disclosure, and which was not acquired directly or indirectly, from the disclosing Party under an obligation of confidentiality;

9.2.4. Information which is lawfully disclosed to the receiving Party on a non-confidential basis by a Third Party who is not obligated to the disclosing Party or any other Third Party to retain such information in confidence;

9.2.5. Information which results from independent research and development by the receiving Party, as shown by competent evidence; or

9.2.6 Information which is required to be disclosed by law, regulation or legal process; provided that the Party so disclosing such Confidential Information timely informs the other Party and uses commercially reasonable efforts to limit the disclosure and maintain its confidentiality to the extent possible. EBOL and/or Hollister-Stier may, and may permit its Affiliates to, disclose the existence, terms and text of this Agreement to the extent it deems necessary to comply with the rules or regulations of a relevant stock exchange or similar governing body (including the U.S. Securities and Exchange Commission).

9.3. Each Party covenants and agrees that it has and shall use commercially reasonable efforts to prevent the unauthorized use, disclosure, copying, dissemination or distribution of the other Party's Confidential Information. Without limiting the foregoing, the receiving Party shall make Confidential Information of the other Party available only to those of its employees, agents and other representatives who have a need to know the same for the purpose carrying out this Agreement or to fulfill their obligations to a Party as accountants, lawyers, or in other advisory roles and who have been informed that the Confidential Information belongs to the disclosing Party and is subject to this Agreement, and who have agreed or are otherwise obligated to comply with the confidentiality provisions of this Agreement.

ARTICLE 10

FORCE MAJEURE/DISPUTE RESOLUTION

10. The Parties agree to the following:

10.1. Effect of Force Majeure: Neither Party shall be held liable or responsible for any loss or damages resulting from any failure or delay in its performance due hereunder (other than payment of money) caused by force majeure. As used herein, force majeure shall be deemed to include any condition beyond the reasonable control of the affected Party including, without limitation, strikes or other labor disputes, war, riot, earthquake, tornado, hurricane, flood or other natural disasters, fire, civil disorder, explosion, accident, sabotage, lack of or inability to obtain adequate fuel, power, materials, labor, containers, transportation, supplies or equipment, compliance with governmental requests, laws, rules, regulations, orders or actions; inability despite good faith efforts to renew operating permits or licenses from local, state or federal governmental authorities; breakage or failure of machinery or apparatus; national defense requirements; or supplier strike, lockout or injunction.

10.2. Notice of Force Majeure: In the event either Party is delayed or rendered unable to perform due to force majeure, the affected Party shall give notice of the same and its expected duration to the other Party promptly after the occurrence of the cause relied upon, and upon the giving of such notice the obligations of the Party giving the notice will be suspended during the continuance of the force majeure; provided, however, such Party shall take commercially reasonable steps to remedy or mitigate the force majeure with all reasonable dispatch. The requirement that force majeure be remedied with all reasonable dispatch shall not require the settlement of strikes or labor controversies by acceding to the demands of the opposing party.

10.3 Dispute Resolution: The Parties hereto agree to perform the terms of this Agreement in good faith, and to attempt to resolve any controversy, dispute or claim arising hereunder in good faith. Any dispute regarding the validity, construction, interpretation, or performance of this Agreement (other than provisions hereof relating to any Intellectual Property rights, or the confidentiality obligations contained in Article 9 hereof for which immediate injunctive relief may be sought) shall be resolved as follows:

(a) A Party shall provide written notice of the dispute to the other Party.

(b) Each Party shall designate one senior executive to represent it in a meeting to resolve the dispute. Within fifteen (15) days of receipt of notice of a dispute, the designated executive officers shall meet, in person or by telephone, to attempt to resolve the dispute. The designated executive officers shall negotiate in good faith to achieve a resolution to the dispute referred to them within thirty (30) days after such meeting.

(c) If the designated executive officers are unsuccessful in resolving the dispute as provided above, either may recommend that the dispute be submitted to non-binding mediation. If both executive officers agree that the matter be submitted to mediation, within twenty (20) days the Parties shall select a mutually acceptable licensed mediator to conduct the mediation. Mediation shall take place within sixty (60) days of retaining the licensed mediator at a location selected by the mediator. For so long as both Parties agree to such mediation, the Parties shall participate in good faith in the mediation effort.

(d) If the matter is not submitted to mediation, the Parties have not selected a mediator within the twenty (20) day period or the dispute has not been resolved within forty-five (45) days after the initiation of mediation, each Party shall then have the right to pursue remedies available to it at law or in equity, subject to the terms of this Agreement.

(e) The Parties shall equally share the fees and reasonable expenses of the licensed mediator. The Parties shall each be responsible for all of their own costs of mediation and/or other dispute resolution.

ARTICLE 11

NOTICES

Except as otherwise specifically set forth in Section 3.8.2 with respect to purchase orders, all notices and other communications provided herein shall be in writing and shall be deemed to be delivered when deposited in the United States mail, postage prepaid and certified, or hand-delivered, or sent by express service courier, charges prepaid, to the address of the other Party designated below:

EBOL	Hollister-Stier
Emergent BioDefense Operations Lansing LLC 3500 North Martin Luther King Jr. Blvd., Lansing, Michigan 48906 Attention: Supply Chain	Hollister-Stier Laboratories LLC 3525 North Regal Street Spokane, WA 99207 Attention: Sitakant Chaudhury

The addresses and persons provided above may be changed by either Party by providing the other Party with written notice of such change.

ARTICLE 12

MISCELLANEOUS

12. The Parties agree to the following miscellaneous clauses:

12.1. Entire Agreement: This Agreement and attached exhibits contain the entire understanding between the Parties with respect to the subject matter hereof, and may be modified only by a written instrument duly executed by each Party's authorized representative. Any existing confidentiality agreements between the Parties shall remain in full force and effect, and in the event of conflicts between such agreements and this Agreement, the more restrictive provision shall control.

12.2. Independent Contractors: The Parties are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint venturers. Neither Party shall have power or right to bind or obligate the other, nor hold itself out as having such authority.

12.3. Publicity: Except as explicitly set forth below in Section 12.4, any press release, publicity or other form of public written disclosure related to this Agreement prepared by one Party shall be submitted to the other Party prior to release for written approval, which approval shall not be unreasonably withheld or delayed by such other Party.

12.4. Use of Party's Name: Except as expressly provided or contemplated hereunder and except as otherwise required by applicable law, no right is granted pursuant to this Agreement to either Party to use in any manner the trademarks or name of the other Party, or any other trade name, service mark, or trademark owned by or licensed to the other Party in connection with the performance of the Agreement. To the extent required by applicable law, the Parties shall be permitted to use the other Party's name and disclose the existence and terms of this Agreement in connection with required public regulatory filings, public securities filings and private placement memoranda and documentation, using reasonable commercial efforts to protect the confidentiality of the terms of this Agreement.

12.5. Severability: If any provision of this Agreement or any Exhibit is held to be invalid or unenforceable to any extent, then (a) such provision shall be interpreted, construed or reformed to the extent reasonably required to render it valid, enforceable and consistent with the Parties' original intent underlying such provision and (b) such invalidity or unenforceability shall not affect any other provision of this Agreement or any other agreement between the Parties.

12.6. Assignment: This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, either Party may, without such consent, assign this Agreement

(a) in connection with the transfer or sale of all or substantially all of the assets of such Party or the

line of business of which this Agreement forms a part, or

(b) in the event of a merger or consolidation of a Party.

Any purported assignment in violation of the preceding shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve either Party of responsibility for the performance of any obligation which accrued prior to the effective date of such assignment.

12.7. Governing Law: This Agreement shall be governed by and construed in accordance with the laws of the state of Washington, irrespective of any conflicts of law rule which may direct or refer such determination of applicable law to any other state, and if this Agreement were performed wholly within the state of Washington.

12.8. Headings: Paragraph headings and captions used herein are for convenience of reference only and shall not be used in the construction or interpretation of this Agreement.

12.9. Waiver: Neither Party's waiver of any breach or failure to enforce any of the terms and conditions of this Agreement at any time, shall in any way affect, limit or waive such Party's right thereafter to enforce and compel strict compliance with every term and condition of this Agreement. Any such waiver shall be made in writing.

12.10. Construction: This Agreement has been jointly prepared on the basis of the mutual understanding of the Parties and shall not be construed against either Party by reason of such Party's being the drafter hereof or thereof.

12.11. Exhibits: Any and all exhibits referred to herein form an integral part of this Agreement and are incorporated into this Agreement by this reference.

12.12. Counterparts: This Agreement may be executed in counterparts, each of which shall be deemed an original and both of which together shall constitute a single instrument.

12.13. PRIME CONTRACT FLOW DOWN

(a) The services being provided by Hollister-Stier under this Agreement represent subcontracted work under EBOL's 2008 CDC Contract. Certain provisions of that contract, the titles of which are set forth in Exhibit D hereto (the **"**Flow-Down Provisions") are hereby incorporated by reference into this Agreement and made a part hereof except that where not inappropriate in the context of the clauses, "Government" shall mean "EBOL", "Contracting Officer" shall mean "EBOL's representative", "Contractor" shall mean "Hollister-Stier" and other terms shall be appropriately revised to reflect that this Agreement is a subcontract. Notwithstanding the foregoing with respect to FAR 52.249-2, Government shall mean EBOL, and Contractor shall mean Hollister-Stier, only if the Government terminates EBOL's prime contract for convenience. In addition these FAR and HHSAR provisions shall only be applicable with respect to CDC Contracts and shall not give EBOL any additional rights under any contracts which are not CDC Contracts.

(b) Upon EBOL's entry into a Follow-On Contract, Exhibit D shall automatically be amended and the provisions of any required additional Flow-Down Provisions shall be incorporated by reference into the Agreement and made a part hereof with no further action required by the Parties, except that EBOL shall provide written notice to Hollister-Stier of the amendment of Exhibit D with reference the specific Flow-Down Provisions added to the Agreement. Where not inappropriate in the context of the clauses, "Government" shall mean "EBOL", "Contracting Officer" shall mean "EBOL's representative", "Contractor" shall mean "Hollister-Stier" and other terms shall be appropriately revised to reflect that this Agreement is a subcontract.

(c) To the extent a Flow-Down Provision is determined to be inapplicable to Hollister-Stier under the terms of this Agreement, Exhibit D shall automatically be amended and such provisions will automatically be deleted with no further action required by the Parties.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, this Agreement has been executed by the Parties as of the Effective Date.

FOR: HOLLISTER-STIER LABORATORIES LLC

/s/Marcelo Morales
Signature

Marcelo Morales
Printed Name

CEO
Title

December 15, 2010
Date Signed

FOR: EMERGENT BIODEFENSE OPERATIONS LANSING LLC

/s/Adam Havey
Signature

Adam Havey
Printed Name

President
Title

December 9, 2010
Date Signed

Exhibit 10.50

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 I 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
0002	12/01/2010		

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	ASPR-BARDA	ASPR-BARDA 330 Independence Ave,SW, Rm G640 Washington DC 20201	ASPR-BARDA02

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP code)		9A. AMENDMENT OF SOLICITATION NO.
EMERGENT BIODEFENSE OPERATIONS LANSING INC 330303 EMERGENT BIODEFENSE OPERATIONS LANS 1500 N MARTIN LUTHER KING JR BLVD # MI LANSING 489062933	(X)	
		9B. DATED (SEE ITEM 11)
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. HHSO100201000034C
		10B. DATED (SEE ITEM 13) 07/13/2010
CODE 330303	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth In Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ Is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which Includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)
X	Bilateral Modification: Pursuant to the Mutual Agreement of Both Parties.

E. IMPORTANT: Contractor ☐ Is not. ☐ IS required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: 38-3412788
DUNS Number: 026489018

This modification serves three purposes.
1. Extend milestone #01 plan due date from 2 December 2010 until 21 January 2011 at no cost.

2. Article C.3. Add Francine L. Hemphill, contracts specialist as the primary recipient for submission of reports and documents and Ethan J. Mueller, contracting officer as the alternate.

3. Article G.5. Add e-mail address for invoice submission as follows:
Francine.hemphill@hhs.gov.
Continued

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Daniel J. Abdun-Nabi, Vice President		ETHAN J. MUELLER	
15B. CONTRACTOR/OFFEROR /s/Daniel J. Abdun-Nabi	15C. DATE SIGNED DEC 3, 2010	16B. UNITED STATES OF AMERICA 16C. /s/Ethan J. Mueller	16D. DATE SIGNED 12/3/10
(Signature of person authorized to sign)		(Signature of Contracting Officer)	

STANDARD FORM 30 (REV. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: 07/19/2010 to 07/18/2012				
