Emergent BioSolutions Inc.
Form 10-K
March 08, 2013

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

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

For the fiscal year ended December 31, 2012

OR

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

Commission file number: 001-33137

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

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

2273 Research Boulevard, Suite 400, Rockville, Maryland	20850
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2012 was approximately $367 million based on the price at which the registrant's common stock was last sold on that date as reported on the New York Stock Exchange.

As of February 28, 2013, the registrant had 35,925,891 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2013 annual meeting of stockholders scheduled to be held on May 23, 2013, 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, 2012, 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 2013 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.

EMERGENT BIOSOLUTIONS INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2012
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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 related to BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine, including the timing of deliveries;
- our plans for future sales of BioThrax, including our ability to obtain funding for existing procurement contracts with the U.S. government;
- our ability to successfully execute our growth strategy and achieve our financial and operational goals;
- our plans to pursue label expansions and other improvements for BioThrax;
- our ability to perform under our development contract with the U.S. government for our product candidate 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 ongoing and planned development programs, preclinical studies and clinical trials of our product candidates and post-approval clinical utility of our products;
- our ability to identify and acquire or in-license products and product candidates that satisfy our selection criteria;
- our ability to successfully integrate and develop the products or product candidates, programs, operations and personnel of any entities or businesses that we acquire;
- our ability to selectively enter into new 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; 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 this special note and elsewhere in this annual report, particularly in the "Risk Factors" section in Item 1A of this annual report on Form 10-K, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

PART I

ITEM 1. BUSINESS

Overview

We are a specialty pharmaceutical company seeking to protect and enhance life by developing and offering specialized products to healthcare providers and governments for use in addressing medical needs and emerging health threats. We have two operating divisions: Biodefense and Biosciences. For financial reporting purposes, we operate in two business segments that correspond to these two operating divisions. For information for each of our business segments, see Note 21 to our Consolidated Financial Statements included in Item 8 of this annual report on Form 10-K.

Our Biodefense division is directed to government-sponsored development and supply of countermeasures against potential agents of bioterror or biowarfare and primarily targets the infectious disease anthrax. Our programs in this division include 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, as well as investigational product candidates. Operations in this division include biologics manufacturing, regulatory and quality affairs in support of BioThrax and a product development and manufacturing infrastructure in support of our investigational product candidates.

Our Biosciences division is directed to commercial opportunities and primarily targets oncology indications. Our programs in this division include one clinical stage product candidate for chronic lymphocytic leukemia, or CLL, as well as investigational product candidates and platform technologies. Operations in this division include product development in support of our CLL product candidate and our investigational product candidates, and manufacturing and related infrastructure initiatives in support of our platform technologies.

We have derived substantially all of our product revenues from sales of BioThrax to the U.S. Department of Health and Human Services, or HHS. We expect for the foreseeable future to continue to derive substantially all of our product revenues from the sale of BioThrax to U.S. government customers. Product revenues were $215.9 million in 2012, which consisted of $215.3 million from the Centers for Disease Control and Prevention, or CDC, an operating division of HHS, and $546,000 from international and other domestic customers. Product revenues were $202.4 million in 2011, which consisted of $200.9 million from CDC and HHS and $1.5 million from international and other domestic customers. Product revenues were $251.4 million in 2010, which consisted of $248.5 million from HHS and $2.9 million from international and other customers. We are focused on increasing sales of BioThrax to the U.S. government, expanding the market for BioThrax sales to international and other domestic customers and pursuing ongoing BioThrax enhancements, including initiatives to secure a second label indication for post-exposure prophylaxis, or PEP.

A second significant source of revenue is contracts and grants revenue from governmental and non-governmental organizations, or NGOs. This revenue, which was $66.0 million in 2012, $71.0 million in 2011 and $34.8 million in 2010, partially offsets our development costs. We continue to actively pursue additional sources of and opportunities for external financing of our product development efforts.

Strategy

We have developed a growth strategy based upon expanding our product offerings in the biodefense field and specialty pharmaceutical markets with the intent of increasing and diversifying revenues while maintaining a disciplined approach to spending. This strategy is supported by the following four principles:

§ driving organic growth through maximizing the financial contribution of BioThrax;

- acquiring revenue generating products that complement our existing operations and competencies;
- focusing our product development efforts on promising late-stage candidates that we believe satisfy well defined criteria and seeking to utilize collaborations or non-dilutive funding; and
- continuing to partner with third parties, such as governments and NGOs.

Products and Clinical Programs

Our total research and development expenditure was $120.2 million in 2012, $124.8 million in 2011 and $89.3 million in 2010. Our research and development efforts are primarily conducted by our Biodefense and Biosciences segments.

Our Biodefense segment focuses on vaccines and antibody therapies for use against the infectious disease anthrax. We hold commercial rights to one marketed product, BioThrax, a pre-exposure prophylactic vaccine (general use prophylaxis, or GUP). We are pursuing development and hold commercial rights to the following clinical stage product candidates: BioThrax for the PEP indication, a post-exposure prophylactic vaccine product candidate and NuThrax, a product candidate based on BioThrax combined with the adjuvant CPG 7909.

In addition, we retain commercial rights and are evaluating the future development strategy for the following programs: PreviThrax, a pre/post exposure prophylactic anthrax vaccine product candidate; Anthrivig, a human immune globulin anthrax therapeutic product candidate; and Thravixa, a fully human monoclonal antibody anthrax therapeutic product candidate.

Our Biosciences segment focuses on protein therapies to treat certain types of cancer and vaccines for use against infectious diseases. We are pursuing development and commercial rights to TRU-016, a humanized anti-CD37 ADAPTIR™ (modular protein technology, which was formerly a SMIP/Scorpion therapeutic product candidate) for CLL. We are also developing preclinical product candidates including additional protein therapeutics in our ADAPTIR pipeline, targeted for solid tumors, inflammatory bowel disease, rheumatoid arthritis, and a multivalent, cross-protective human vaccine to protect against influenza caused by a broad range of circulating H5 influenza strains.

We currently hold commercial rights to MVA85A, a tuberculosis vaccine product candidate. In February 2013, we announced the results of a Phase IIb clinical trial evaluating the safety and efficacy of MVA85A in preventing tuberculosis in infants. As a consequence of these results, we are ceasing further development work on MVA85A. We will not participate in or fund any further MVA85A product development efforts and anticipate closing the Oxford-Emergent Tuberculosis Consortium Limited, or OETC, joint venture by year end.

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 applicable regulatory authority, such as the FDA. The results of our completed preclinical tests and Phase I and Phase II clinical trials do not ensure that our ongoing and planned later stage clinical trials for our product candidates will be successful.

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

For vaccines, the immune responses observed in a group of vaccine trial participants can be compared with those observed in other groups of trial participants or with an assumed response rate. Immunogenicity alone does not necessarily establish efficacy for purposes of regulatory approval. Immunogenicity data only provides indications of potential efficacy and are not necessarily required or 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, before Phase II clinical trials may begin.

Anthrax

Disease overview. Anthrax is a potentially fatal disease caused by the spore forming bacterium Bacillus anthracis. Anthrax bacteria are naturally occurring, and spores are found in soil throughout the world. Anthrax spores can withstand extreme heat, cold and drought for long periods. Anthrax infections occur if the spores enter the body through a cut, abrasion or open sore, or by ingestion or inhalation. Once inside the body, anthrax spores germinate into anthrax bacteria that then multiply. Anthrax bacteria secrete three proteins: protective antigen, lethal factor and edema factor. Each of these proteins individually is non-toxic, but if allowed to interact on the surface of human or animal cells, they can form the highly potent toxins known as lethal toxin (protective antigen and lethal factor) or edema toxin (protective antigen and edema factor).

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

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

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

Market opportunity and current treatments. Our current contract with the CDC, provides for the supply of up to 44.75 million doses of BioThrax into the Strategic National Stockpile, or SNS, over a five-year period. The maximum amount that could be paid to us under this contract is approximately $1.25 billion, subject to availability of funding to the CDC, and depending on the expiration dating of BioThrax delivered under the contract. The period of performance under the CDC contract is from September 30, 2011 through September 29, 2016. Funds for the procurement of doses of BioThrax with a value of approximately $477 million have been committed, of which 8.9 million doses representing approximately $235 million have been delivered, as of December 31, 2012.

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

The Project BioShield Act of 2004, or Project BioShield, authorizes expedited procurement of biomedical countermeasures against chemical, biological, radiological and nuclear attacks and related products. Project BioShield initially provided appropriations of $5.6 billion to be expended over ten years into a special reserve fund for

procurement of countermeasures for the SNS. BARDA is one of the government agencies responsible for awarding procurement contracts for biomedical countermeasures. BARDA also provides development funding for advanced research and development in the biodefense arena. This appropriation funding for BARDA has been provided by annual appropriations by Congress. Congress also has appropriated annual funding for the CDC for the procurement of medical assets and countermeasures for the SNS and for NIAID to conduct biodefense research. This appropriation funding has been in addition to amounts available under Project BioShield for chemical, biological, radiological and nuclear countermeasures, and provides funding for activities related to public health emergencies and infectious diseases.

The DoD, primarily through the Military Vaccine Agency, or MilVax, administers various vaccination programs for military personnel 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:

- foreign governments, including both defense and public health agencies;
- non-governmental organizations and multinational companies, including transportation, critical infrastructure services and security companies; 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.

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

BioThrax and BioThrax Related Programs

BioThrax. BioThrax is the only FDA-approved vaccine for the prevention of anthrax disease. It is approved by the FDA as a pre-exposure prophylactic 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 three doses over a six month period with booster doses recommended thereafter. After the initial dose, two additional doses are given at one and six months, with booster doses following at 12 and 18 months and then annually thereafter. BioThrax includes Alhydrogel™ as an

adjuvant. BioThrax is not currently approved as a PEP product. Following the October 2001 anthrax letter attacks, however, the CDC provided BioThrax under an IND protocol for administration as a PEP on a voluntary basis to Capitol Hill employees and certain others who may have been exposed to anthrax.

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

BioThrax Related Programs

- Extended expiry dating. In June 2009, we received approval from the FDA of our supplemental biologics license application, or BLA, to extend the expiry dating of BioThrax from three years to four years, which allows BioThrax to be stockpiled for a longer period of time. In December 2010, we submitted to the FDA a new supplemental BLA to extend the expiry dating of BioThrax from four years to five years, which would further extend the length of time BioThrax may be stockpiled. In February 2011, the FDA issued a complete response letter indicating that the submitted data were not adequate to support a five year expiry.

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

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

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

In November 2010, a Vaccines and Related Biological Products Advisory Committee, or VRBPAC, was convened to discuss the pathway to licensure for protective antigen-based anthrax vaccines for a PEP indication (for the prevention of disease caused by residual Bacillus anthracis spores in exposed individuals who have received full course antibiotics) using the animal rule. The VRBPAC agreed with an FDA-proposed strategy for bridging animal protection data to humans for protective antigen-based anthrax vaccines for a PEP indication using appropriately designed GUP studies. In November 2011, we initiated a pivotal immunogenicity and safety clinical study to evaluate a three-dose vaccination schedule of BioThrax for the PEP indication. Our development efforts to obtain approval of BioThrax as a PEP product are supported in part with funding from BARDA. In June 2012, we entered into an extension of our contract with BARDA through March 2016. The modification provides us with up to $8.4 million in additional funding for a non-interference study of BioThrax as a PEP. We enrolled the first subject in that study in December 2012 and dosed the first subject in January 2013. We believe that the data from our non-clinical efficacy studies such as our GUP studies and proof-of-concept PEP studies, together with pivotal data on human immunogenicity and noninterference of the vaccine with antimicrobials, will be sufficient to support the filing of a BLA supplement with the FDA for marketing approval of BioThrax for the PEP indication.

Additional Anthrax Product Candidates

- NuThrax™ (Anthrax Vaccine Adsorbed containing CPG 7909 Adjuvant). We are developing NuThrax, a product candidate based on BioThrax combined with CPG 7909, an adjuvant that we license from Pfizer Inc., or Pfizer, in part with funding from NIAID and BARDA. We anticipate that NuThrax will, among other things, require fewer doses to produce a sufficient protective immune response and elicit an enhanced immune response. We obtained additional U.S. government funding through an NIAID award in August 2010 to supplement the further development of NuThrax, including activities related to manufacturing and stability studies of Phase II clinical trial lots, process characterization and assay validation, and clinical trial preparation. The award also contains additional optional funding from NIAID for milestone-based activities including continued stability testing of Phase II clinical trial lots, non-clinical studies and a Phase II clinical trial to evaluate safety and immunogenicity of this product candidate. We enrolled and dosed the first subject in the Phase II clinical trial in January 2013.

In collaboration with us, Coley Pharmaceutical Group Inc., or Coley, which was acquired by Pfizer Inc., or Pfizer, in 2008, the owner of CPG 7909, conducted a double-blind Phase I clinical trial of BioThrax combined with CPG 7909 that was funded by DARPA. That trial, which was completed in 2005 and involved 69 healthy volunteers, was designed to evaluate the safety and immunogenicity of this product candidate compared to BioThrax alone and to CPG 7909 alone. In this Phase I trial, the product candidate was administered in three doses by intramuscular injection at two week intervals and elicited an enhanced immune response. The immunogenicity parameters for this trial were the mean peak antibody concentration and the median time to achieve mean peak immune response in trial participants who received BioThrax combined with CPG 7909 as compared to trial participants who received BioThrax alone. In this trial, the mean peak concentration of antibodies to anthrax protective antigen in participants who received the product candidate was approximately 6.3 times higher than in participants who received BioThrax alone. This result was statistically significant, with a p value of less than 0.001. Participants who received BioThrax alone achieved a mean peak geometric anti-PA IgG concentration approximately 42.5 days after first injection. Participants who received BioThrax combined with CPG 7909 achieved this same mean antibody concentration 21 days after the first injection. This result was statistically significant, with a p value of less than 0.001. In this trial, there was a higher frequency of moderate injection site reactions and systemic adverse events in the volunteers who received the product candidate as compared to volunteers who received BioThrax alone or CPG 7909 alone. One volunteer withdrew from this trial because of an adverse event. There were no serious adverse events reported that the trial investigators considered related to the product candidate, to BioThrax or to CPG 7909.

In a multiple site United States parallel arm dose-ranging Phase I clinical trial involving 105 healthy volunteers conducted in 2010 and 2011, the immunogenicity of NuThrax was superior to that of BioThrax.

- PreviThrax™ (Recombinant Protective Antigen Anthrax Vaccine, Purified). We are developing PreviThrax, in part with funding from NIAID and BARDA, a recombinant vaccine product candidate, designed as a pre-exposure prophylaxis against anthrax disease. PreviThrax contains purified recombinant protective antigen, or rPA, and is formulated to induce antibodies that neutralize anthrax toxins in a manner similar to BioThrax. In response to a request from BARDA, we have refocused our development plan to work toward the identification of a new adjuvant for this product and are currently evaluating this vaccine formulated with the new adjuvant.

- Anthrivig™ (Human Anthrax Immune Globulin). We are developing Anthrivig, a human immune globulin, or AIG, a polyclonal antibody therapeutic product candidate, designed as a treatment for patients who have been exposed to anthrax spores and who present with symptoms of anthrax disease. We expect that, if approved, Anthrivig would be prescribed as an intravenous infusion in conjunction with a regimen of antibiotics. We are developing Anthrivig using plasma produced by healthy donors who have been immunized with BioThrax. We have submitted a response to a request for proposal, or RFP, from BARDA for the supply of anthrax antitoxins to the U.S. Government. We are currently evaluating our future development efforts for this product candidate.

- Thravixa™ (Fully Human Anthrax Monoclonal Antibody). We are developing Thravixa, a human monoclonal antibody therapeutic product candidate, designed as an intravenous treatment for patients who present with symptoms of inhalational anthrax disease. Thravixa's development has been funded in part by BARDA and NIAID to support efficacy testing in non-clinical studies, the establishment of a current good manufacturing practices, or cGMP, and initial clinical evaluation. In August 2010, we commenced a randomized, double-blind, placebo-controlled, dose escalation Phase I clinical trial involving 50 healthy volunteers, designed to evaluate the safety and pharmacokinetics of Thravixa. Dosing was completed in 2011. Because the development of this project does not benefit from current external funding from BARDA or NIAID, we are evaluating our future development efforts for this product candidate.

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 or acquire. We may expand our sales and marketing organization as we broaden our sales activities of biodefense products at the state and local level, where we expect there may be interest in these products to protect emergency responders such as police, fire and emergency medical personnel, and other personnel whose occupation may cause them to be at a high risk of exposure to biothreats.

We have established 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.

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

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

- BioThrax. Although BioThrax is the only product approved by the FDA for human use for the prevention of anthrax infection, we face potential future competition for the supply of anthrax vaccines to the U.S. government. Various agencies of the U.S. government are providing funding to our competitors for the development of anthrax vaccines. In addition, the United Kingdom Health Protection Agency, or HPA, manufactures an anthrax vaccine for use by the government of the United Kingdom. Other countries may also have anthrax vaccines for use by or in development for their own internal purposes.

- PreviThrax and NuThrax. PharmAthene, Inc., Vaxin Inc. and Pfenex Inc. are currently developing rPA based anthrax vaccines funded by BARDA.

- Anthrivig and Thravixa. GlaxoSmithKline plc has obtained licensure for ABthrax™, as a therapeutic, which is a monoclonal antibody to Bacillus anthracis protective antigen. Elusys Therapeutics, Inc. is developing Anthim™, for pre-exposure and PEP and as a therapeutic against anthrax.

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

Disease overview. B-cells and T-cells are the two major types of lymphocytes responsible for defending the body against infection. Lymphocytic malignancies arise when these cells multiply uncontrollably. CLL is a type of cancer affecting the blood and bone marrow. It is a slowly progressing disease and in most patients the abnormal proliferating lymphocytes are clonal B-cells arrested in the differentiation pathway between pre-B-cells and mature B-cells. Non-Hodgkin's lymphoma, or NHL, is a diverse group of lymphocytic malignancies, approximately 85% of which are B-cell malignancies.

Prevalence, market opportunity and current treatment. According to the North American Association of Central Cancer Registries 1995-2008 (2012), there are approximately 95,000 adult patients in the U.S. with CLL. In addition, almost 15,000 patients are newly diagnosed with CLL in the U.S. each year. According to the SEER Cancer Statistics Review, 1975-2008 (2011), NHL affects approximately 450,000 people in the U.S. While available CLL and NHL therapies include chemotherapy, radiation therapy, surgery and stem cell transplantation, biologics have become increasingly important in the treatment of these cancers. For the treatment of CLL, there are a number of chemotherapeutics and monoclonal antibodies. Campath® is a CD52-targeted antibody indicated for CLL. Treanda®, a cytotoxic, is also indicated for CLL. Depending upon the nature of the patient's tumor, the chemotherapeutic agent fludarabine in combination with Rituxan®, or the combination of fludarabine, the chemotherapeutic agent cyclophosphamide and Rituxan® are currently the most effective combinations for the treatment of CLL. Biologic therapies for NHL include antibodies such as Rituxan®/Mabthera, Bexxar®, Zevalin® and Arzerra®. These therapies all target CD20 on B-cells.

TRU-016 for treatment of B-cell malignancies. Our TRU-016 program is focused on the development of a novel therapy for B-cell malignancies such as CLL and NHL. Specifically, TRU-016 is a monospecific ADAPTIR protein directed at the CD37 antigen on the surface of both normal and malignant B-cells. CD37 is found at high levels on B-cells and at lower levels on a subpopulation of T-cells and myeloid cells, which could potentially avoid off-target toxicity. Experiments suggest that CD37 plays an important role in B-cell regulation. TRU-016 uses a different mechanism of action than CD20-directed therapies and targets a different cell surface receptor. As a result, we believe its novel design may provide patients with improved therapeutic options and enhanced efficacy when used alone or in combination with chemotherapy or other CD20-directed therapeutics. Preclinical data from in vitro studies with primary CLL cells have demonstrated that TRU-016 induced potent antibody-dependent cell-mediated cytotoxicity, or ADCC, a form of cell death mediated by antibodies, and potent apoptosis, or direct programmed cell death. In addition, combination therapy with a CD37-directed monospecific ADAPTIR protein, a close analogue of TRU-016, and Rituxan® has shown greater preclinical efficacy in decreasing tumor size and prolonging survival than either therapy alone. Previously these products were developed in collaboration with Abbott under a collaboration agreement for the joint development and commercialization of TRU-016 and other protein therapeutics that bind to the CD37 antigen. The collaboration was entered into in August 2009, between Trubion Pharmaceuticals, Inc., or Trubion, predecessor to Emergent, and Facet Biotech Corp., predecessor to Abbott Biotherapeutics Corp., an affiliate of Abbott

Laboratories, or Abbott. Since March 20, 2012, when this collaboration ended, Emergent has developed these products on its own.

A TRU-016 Phase I clinical trial for patients with CLL and NHL completed enrollment in 2012. The open label clinical trial was composed of two parts: a dose escalation study designed to evaluate the safety, tolerability and pharmacokinetics of TRU-016 (Phase I) and an expansion cohort designed to further evaluate safety and to estimate clinical activity of TRU-016 in patients with previously treated CLL or small lymphocytic leukemia (Phase Ib). We amended our study protocol to include treatment of patients with treatment naïve CLL and relapsed/refractory NHL, and patient dosing has been completed. In December 2011, we announced positive data following preliminary analysis from our Phase Ib clinical trial of TRU-016 in patients with treatment naïve CLL and relapsed/refractory NHL. Evidence of biological activity was observed and a maximum tolerated dose was not reached.

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

In January 2011, we initiated a Phase Ib/II clinical trial of TRU-016 for CLL (Protocol 16201). The open-label, multi-center, active-controlled trial is expected to enroll up to 114 bendamustine-sensitive patients with a confirmed diagnosis of relapsed CLL and who have failed up to three previous treatments. The Phase Ib portion of the trial is designed to determine a safe and tolerable dose of TRU-016 in combination with bendamustine in up to 14 patients with relapsed CLL. The primary endpoint for the Phase Ib portion is the incidence of dose-limiting toxicities. The Phase II portion of the trial will evaluate the safety and efficacy of TRU-016 in combination with bendamustine compared with bendamustine alone in a total of 60-100 randomized patients. The primary endpoint for the Phase II portion of the trial is an overall response rate as defined by 2008 International Workshop on Chronic Lymphocytic Leukemia, or IWCLL, criteria. Secondary endpoints include complete and partial response rates as defined by the 2008 IWCLL and the 1996 National Cancer Institute criteria, progression-free survival, duration of response, and improvement in quality of life and disease symptoms. The pharmacokinetics and pharmacodynamics of TRU-016 will be studied in both phases of the study. Enrollment in the Phase Ib portion of the study has been completed and enrollment in the Phase II portion of the study is ongoing. In December 2012, results from the Phase Ib portion of Protocol 16201 were presented at the annual meeting of the American Society of Hematology. There were no dose limiting toxicities and clinical efficacy was observed at both dose levels of TRU-016 studied.

In May 2011, we initiated a Phase Ib/II clinical trial of TRU-016 combined with rituximab and bendamustine in patients with relapsed indolent NHL (Protocol 16011). This open-label, multi-center, active controlled trial is expected to enroll up to 88 patients with a confirmed diagnosis of indolent NHL who have relapsed after at least one prior treatment. The Phase Ib portion of the trial is designed to determine a safe and tolerable dose of TRU-016 in combination with rituximab and bendamustine in up to 12 patients with indolent NHL. The primary endpoint for the Phase Ib portion of the trial is the incidence of dose-limiting toxicities. The Phase II portion of the trial will evaluate the safety and efficacy of TRU-016 in combination with rituximab and bendamustine compared with rituximab and bendamustine alone in up to 76 patients with indolent NHL. The primary endpoint for the Phase II portion of the trial is complete response rate as defined by the disappearance of all evidence of disease. Secondary endpoints include overall response rate, progression-free survival, overall survival, and duration of response. The pharmacokinetics and pharmacodynamics of TRU-016 will be studied in both phases of the study. Enrollment in the Phase Ib portion of the study has been completed. In December 2012, results from the Phase Ib portion of Protocol 16011 were presented at the annual meeting of the American Society of Hematology. There were no dose limiting toxicities and clinical efficacy was observed at both dose levels of TRU-016 studied. The Phase II portion of the study has not been initiated in order to focus our resources on the CLL clinical development program.

In October 2012, we initiated a Phase Ib clinical trial of TRU-016 combined with rituximab in patients with previously untreated CLL (Protocol 16009). This open-label, multi-center trial is expected to enroll up to 24 patients with a confirmed diagnosis of CLL who have never received prior treatment for CLL. The primary objective of the trial is to evaluate the safety and efficacy of TRU-016 in combination with rituximab. The primary efficacy endpoint for the trial is overall response rate as defined by the reduction of disease. Secondary efficacy endpoints include complete response rate, progression-free survival, overall survival, and duration of response. Safety endpoints include the incidence of adverse events, changes in physical exam, vital signs and laboratory measurements. The pharmacokinetics and pharmacodynamics of TRU-016 will be studied. Enrollment is ongoing.

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

Competition. Our oncology therapeutic product candidates will also be subject to significant competition from companies utilizing alternative technologies. If approved for the treatment of CLL, NHL, or other B-cell malignancies, we anticipate that TRU-016 would compete with other B-cell depleting therapies. Non-CD37-directed therapeutics marketed for the treatment of CLL or NHL or both include Rituxan® (Genentech), Zevalin® (Spectrum Pharmaceuticals, Inc. and Bayer Schering AG), Bexxar® (GlaxoSmithKline), Campath® (Genzyme and Bayer Schering AG), Treanda® (Cephalon Oncology) and Arzerra® (GlaxoSmithKline and Genmab). In addition, Boehringer Ingelheim and Immunogen are developing monoclonal antibodies directed to CD37 and AbbVie is developing ABT-199, a Bcl-2 inhibitor, for treatment of CLL in collaboration with Genentech.

Tuberculosis

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. In February 2013, we announced the results of a Phase IIb clinical trial evaluating the safety and efficacy of our MVA85A vaccine candidate in preventing tuberculosis in infants. MVA85A is a TB vaccine candidate designed to boost immune responses already primed by BCG. Data showed that a single dose of MVA85A was not sufficient to confer statistically significant protection against TB disease or infection in infants who had been vaccinated at birth with BCG. As a consequence of the clinical trial results, we are ceasing further development work on MVA85A. We do not intend to participate in or fund any further MVA85A product development efforts, and we anticipate closing our joint venture with the University of Oxford, the OETC, by year end.

Manufacturing

We manufacture BioThrax at our facilities in Lansing, Michigan. In 2009, we completed construction of Building 55, our 50,000 square foot vaccine manufacturing facility at our Lansing campus, and in July 2010 we entered into a contract with BARDA to develop and obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55. The contract award was based on a technical proposal provided to BARDA that projects an annual large-scale manufacturing capacity of approximately 25 million doses of BioThrax in Building 55. The contract award provides funding for activities related to process validation, assay validation, fill/finish, non-clinical studies and, if required, clinical studies as well as regulatory activities in support of the submission to the FDA of a supplemental BLA for BioThrax at the expanded scale. In August 2012, we initiated manufacture of consistency lots of BioThrax in Building 55 for use in animal studies.

In 2009, we purchased a 56,000 square foot manufacturing facility in Baltimore, Maryland. We expect to use this facility to support our future product development, manufacturing and commercialization needs, and in November 2012 we began PreviThrax formulation development activities in the facility. The facility consists of distinct manufacturing suites and uses disposable manufacturing technology, adding to its flexibility. 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 part of the utilization of the Baltimore facility, in June 2012 we entered into a contract with BARDA, which established us as a Center for Innovation in Advanced Development and Manufacturing, or CIADM. This 25-year contract consists of an 8-year base period of performance, valued at approximately $163 million, and additional one-year option periods beginning in the second year of the contract for the duration of the contract. This contract provides for the build out of our Baltimore site. Also under this contract, we were required to secure a pandemic influenza product vaccine candidate. In December 2012, we entered into a license agreement under which we acquired the exclusive right to manufacture and sell a pandemic influenza vaccine candidate in the United States, thereby satisfying the requirement under the CIADM contract.

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

Hollister-Stier Laboratories LLC, or Hollister-Stier, performs contract filling for BioThrax at its FDA-licensed facility located in Spokane, Washington. Hollister-Stier has agreed to meet all of our firm purchase orders for contract filling of BioThrax based on a good faith annual estimate that we provide prior to each calendar year and to accommodate fill requests in excess of our annual estimate, subject to its available production capacity. Under the agreement we executed with Hollister-Stier in December 2010, Hollister-Stier will provide filling services for BioThrax during an initial five-year period that commenced January 1, 2011, which we may extend in our discretion for two additional two-year renewal periods. Additionally, we are obligated to use 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 a second vendor, JHP Pharmaceuticals, LLC, which was licensed by the FDA in November 2011 for the filling of BioThrax.

We are a party to an agreement with Talecris Biotherapeutics, Inc., or Talecris, that provides for plasma fractionation and purification and contract filling of Anthrivig at Talecris' FDA-licensed facilities located in Melville, New York and Clayton, North Carolina. Talecris was acquired by Grifols, S.A. in June 2011 and now operates under the name Grifols Therapeutics Inc., or Grifols. Under our agreement with Grifols, in the event that we request Grifols to produce any quantities of Anthrivig, we and Grifols would be required to negotiate in good faith as to the timing, price, quantity and support, among other terms, of such production, subject to Grifols' right to delay or refuse such request. In the event we are not able to reach an agreement with Grifols on satisfactory product supply terms we may be required to explore other options for our anthrax immune globulin program, which would result in significant costs and project delay and the need for additional clinical trials.

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

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 non-provisional 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.

In September 2011, a new patent statute was enacted into law in the United States, which significantly reforms U.S. patent law. Significant provisions of the new statute, referred to as the America Invents Act, or AIA, came into force in September 2012. Additional new provisions, including the change from a first-to-invent system to first-inventor-to-file system, are scheduled to become effective in March 2013. Changes in the U.S. patent law under the AIA, particularly the new provisions that are scheduled to become effective in March 2013, may adversely affect our ability to patent our inventions. We may deem it necessary to file one or more new patent applications in advance of the implementation of the first-inventor-to-file system.

We have rights in the following patents and patent applications directed to our product candidates. Other than as noted below, our rights arise from ownership by assignment.

Technology	US Patents	Foreign Patents	US Applications	Foreign Applications	Earliest Expiration	Latest Expiration
ADAPTIR Monovalent	-	1	1	11	January 17, 2022	July 7, 2029
ADAPTIR Multivalent	-	1	4	48	June 12, 2027	December 29, 2030
TRU-016	6	56	8	75	January 17, 2022	November 1, 2029
Thravixa	2	2	-	1	November 14, 2023	November 14, 2023
PreviThrax	2	-	2	2	November 23, 2014[1]	June 25, 2032
MVA85A[2]	1	52	-	13	January 5, 2026	January 5, 2026

[1]U.S. patents in-licensed from USAMRIID.
[2]U.S. and foreign patents and applications in-licensed, via OETC, from Isis Innovation and the University of Oxford.

All expiration dates in the table above are calculated with the assumption that all applicable U.S. maintenance fees and foreign patent annuities are timely filed. The effect of terminal disclaimers have not been taken into account. With respect to patent applications that are pending, we cannot predict the availability or length of any patent term adjustment by the U.S. Patent and Trademark Office, which could extend the term of any patent that is ultimately approved as a result of a pending application. In addition, we cannot predict the availability or length of any patent term extension that may be granted by the U.S. Patent and Trademark Office to compensate us for delays in the FDA biologics approval process.

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 license we consider to be significant to our current product portfolio or development pipeline is our agreement with Coley (Pfizer), which is described below.

Coley Pharmaceutical Group agreement. In connection with development of our NuThrax vaccine product candidate, in February 2007, we entered into a license agreement with the Coley pursuant to which we have nonexclusive worldwide rights under the licensed patent technology to develop, manufacture and commercialize product candidates that include Coley's proprietary immunomodulatory oligonucleotide known as CPG 7909 as a vaccine adjuvant for the prevention of anthrax in humans, including GUP and PEP indications.

Under the license agreement, we are required to pay Pfizer an annual license fee, aggregate payments of up to $3 million upon the achievement of specified regulatory and commercial milestones for each licensed product, and mid-single-digit royalties on sales of licensed products. 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 licensed patent in that country.

The license agreement requires us to expend reasonable efforts and resources to carry out the development and marketing of the licensed products 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. Pfizer retains responsibility for the preparation, filing, prosecution, maintenance and enforcement of patent applications and patents included in the licensed patent technology.

Pfizer may terminate the license agreement in the event that we challenge the validity of the licensed patent technology or the secrecy or substantiality of licensed know-how or defend against or oppose any claim brought by Pfizer for royalties due. Either party may terminate in the event of a material breach by the other party, subject to a 30-day cure period, for payment breaches or a 90-day cure period for other material breaches. We may terminate the license agreement at any time upon 30 days advance written notice.

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 also may result in enforcement actions, including withdrawal of approved products, 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 biologics license application, or BLA, in the case of a biologic, which applications contain, 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 institutes a partial or full "clinical hold," and 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 rights and welfare of human subjects involved in research at each medical center proposing to conduct the clinical trials must review and approve any clinical trial.

Furthermore, study subjects must provide informed consent for their participation in a clinical trial. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the study subjects are being exposed to an unacceptable health risk or that the risks of the proposed clinical trials outweigh the potential benefits.

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; and
- A Phase III clinical trial is undertaken if a Phase II clinical trial demonstrates that a dosage range of the drug has the potential to be effective and appears to potentially have an acceptable safety profile. In a Phase III clinical trial, the drug or biologic is administered to an expanded population, often at geographically dispersed clinical trial sites, to further evaluate the dosage amount(s), clinical efficacy, and safety. Prior to commencing Phase III clinical trials, many sponsors elect to meet with FDA officials to discuss the conduct and design of the proposed trial or trials.

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

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

Marketing Approval

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

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

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

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

Fast Track Designation

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

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

Post-Marketing Regulation

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

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

§ advertising and promotion restrictions.

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

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

Drug manufacturers, distributors and their subcontractors are required to register their establishments with the FDA and state agencies. The cGMP requirements for biological products in particular are extensive and compliance with them requires considerable time, resources and ongoing investment. The regulations require manufacturers to establish validated systems to ensure that products meet high standards of sterility, purity and potency. The requirements apply to all stages of the manufacturing process, including the synthesis, processing, sterilization, packaging, labeling, storage and shipment of the biological product. For all drugs and biological products, the regulations require investigation and correction of any deviations from cGMP requirements and impose documentation requirements upon us and any third party manufacturers that we may decide to use. Manufacturing establishments are subject to periodic unannounced inspections by the FDA and state agencies for compliance with all cGMP requirements. The FDA is authorized to inspect manufacturing facilities without a warrant at reasonable times and in a reasonable manner. We or our present or future suppliers may not be able to comply with cGMP and other FDA regulatory requirements.

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

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

BioThrax Lot Release and FDA Review

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

FDA testing.

Legislation and Regulation Related to Bioterrorism Counteragents and Pandemic Preparedness

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

Project BioShield

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

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

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

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

Pandemic and All Hazards Preparedness Act

The Pandemic and All Hazards Preparedness Act, or PAHPA, was enacted by the U.S. congress in December 2006, to improve the Nation's public health and medical preparedness and response capabilities for emergencies, whether deliberate, accidental, or natural. In addition, the PAHPA amended the Public Health Act to establish within HHS a new Assistant Secretary for Preparedness and Response, provided new authorities for a number of programs, including the advanced development and acquisitions of medical countermeasures, and called for the establishment of a quadrennial national health security strategy.

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. Specifically, for the government contractor defense to apply, the government must approve reasonably precise specifications, the product must conform to those specifications and the supplier must warn about known dangers arising from the use of the product. Although sales of BioThrax are subject to the protections of the SAFETY Act, our product candidates may not qualify for the protections of the SAFETY Act or the government contractor defense.

Public Readiness and Emergency Preparedness Act

The Public Readiness and Emergency Preparedness Act, or PREP Act, enacted by Congress in 2005 provides immunity to manufacturers from all claims under state or federal law for "loss" arising out of the administration or use of a "covered countermeasure." However, injured persons may still bring a suit for "willful misconduct" against the manufacturer under some circumstances. "Covered countermeasures" include security countermeasures and "qualified pandemic or epidemic products," including products intended to diagnose or treat pandemic or epidemic disease, such as pandemic vaccines, as well as treatments intended to address conditions caused by such products. For these immunities to apply, the Secretary of HHS must issue a declaration in cases of public health emergency or "credible risk" of a future public health emergency. In October 2008, the Secretary of HHS issued a declaration that BioThrax and Anthrivig have been included as covered countermeasures under the PREP Act. We cannot predict whether the Secretary will renew that declaration when it expires, whether Congress will fund the relevant PREP Act compensation programs, or whether the necessary prerequisites for immunity would be triggered with respect to our product or product candidates.

Changing Legal and Regulatory Landscape

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

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

Foreign Regulation

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

country.

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

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

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

European Union member states generally do not have separate rules or review procedures for biological products and vaccines. Regulators apply broadly consistent principles and standards when reviewing applications, although 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, for a period of one year. The FDA may approve a subsequent application from another applicant, however, if the FDA determines that the

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

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

In the European Union, a product can be designated as an orphan drug if it is intended for either (i) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made; or (ii) a serious and chronic condition in the European Union for which, without incentives, it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the necessary investment. In either case, the applicant must also demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition. The COMP assesses the orphan status at both the time of first designation and also in parallel with the review of every marketing authorization application for an orphan medicine.

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

Anthrivig and Thravixa have been granted orphan drug status in the United States and the European Union, and our TRU-016 product candidate for treatment of CLL 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 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, which is administered through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. The health care reform legislation enacted in 2010, known as the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, contains a number of cost-containment measures. For example, the legislation imposes an annual fee on prescription drug manufacturers, including biologics manufacturers, which is allocated based on market share in the aggregate for certain government programs. In addition, the legislation establishes a program to phase out the coverage gap under Medicare Part D through a combination of manufacturer discounts and federal subsidies, increases the amount of Medicaid rebates, extends Medicaid rebates to utilization by Medicaid managed care organizations, extends the scope of entities eligible for discounts under the 340B program and creates an Independent Payment Advisory Board to recommend changes in Medicare payment rates. Various states have also adopted further mechanisms that seek to control drug prices, including by disfavoring higher priced products and by seeking supplemental rebates from manufacturers. Managed care has also become a potent force in the market place and exerts additional downward pressure on the prices of pharmaceutical products.

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

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

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

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

Vaccine Injury Compensation Program

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

Hazardous Materials and Select Agents

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

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

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

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

Other Regulations

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

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

Personnel

As of December 31, 2012, we had 877 employees, including 323 employees engaged in product development, 351 employees engaged in manufacturing, 8 employees engaged in sales and marketing and 195 employees engaged in general and administrative activities. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

History and Sites

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

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

We have derived and expect for the foreseeable future to continue to derive substantially all of our revenue from sales to the U.S. government of BioThrax, our FDA-approved anthrax vaccine and only marketed product. We are currently party to a contract with the Centers for Disease Control and Prevention, or CDC, for the supply of up to 44.75 million doses of BioThrax for placement into the SNS over a five year period ending in September 2016.

The procurement of doses of BioThrax by the CDC is subject to availability of funding. Our existing contract with the CDC and prior contracts with Health and Human Services, or HHS, and the Department of Defense, or DoD, do not necessarily increase the likelihood that funding for the procurement of doses will be available. If the SNS priorities change, funding to procure doses of BioThrax may be limited or not available, and our business, financial condition and operating results would be materially harmed. The success of our business and our operating results for the foreseeable future are substantially dependent on the terms of our BioThrax sales to the U.S. government, including price per dose, the number of doses and the timing of deliveries.

Our U.S. government contracts require ongoing funding decisions by the U.S. government. Reduced or discontinued funding of these contracts, including funding implications of the federal budget sequestration provisions, 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 or acquire. Additionally, a significant source of our revenue is from U.S. government development contracts and grants. Over its lifetime, a U.S. government program may be implemented through the award of many different individual contracts and subcontracts. The funding for government programs is subject to Congressional appropriations, often made on a fiscal year basis, even for programs designed to continue for several years. These appropriations can be subject to political considerations and stringent budgetary constraints. For example, sales of BioThrax supplied under our multi-year procurement contract with the CDC are subject to available funding, mostly from annual appropriations. Additionally, our government-funded development contracts typically give the U.S. government the right, exercisable in its sole discretion, to extend these contracts for successive option periods following a base period of performance. The value of the services to be performed during these option periods may constitute the majority of the total value of the underlying contract. For example, the development contract we were awarded in September 2010 for development of PreviThrax consists of a two-year base period of performance valued at approximately $51 million and three successive one-year option periods valued at a total of approximately $110 million. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the U.S. government otherwise declines to exercise its options under our contracts with it, our business, revenues and operating results would suffer.

In August 2011, Congress enacted the Budget Control Act of 2011, or BCA, committing the U.S. government to significantly reduce the federal deficit over ten years. The BCA contains provisions commonly referred to as "sequestration" which call for substantial, unspecified automatic federal spending cuts that may continue for a period of ten years. In January 2013, Congress enacted the American Taxpayer Relief Act of 2012, which temporarily postponed enactment of the sequestration provisions until March 1, 2013 to give Congress additional time to evaluate

the amount of deficit reduction under the BCA and reconsider the allocation of spending cuts between government departments. We cannot currently predict the outcome of Congressional negotiations or whether such efforts will result in significant funding delays or cancellation of orders by the U.S. government that may adversely impact our business and results of operations.

The government contracting process is typically a competitive bidding process and involves risks and requirements that are not present in commercial contracting.

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

- the commitment of substantial time and attention of management and key employees to the preparation of bids and proposals for contracts that may not be awarded to us;
- the need to accurately estimate the resources and cost structure that will be required to perform any contract that we might be awarded;
- the possibility that we may be ineligible to respond to a request for proposal issued by the government;
- the submission by third parties of protests to our responses to requests for proposal that could result in delays or withdrawals of those requests for proposal; and
- in the event our competitors protest or challenge contract awards made to us pursuant to competitive bidding, the potential that we may incur expenses or delays, and that any such protest or challenge would result in the resubmission of bids based on modified specifications, or in the termination, reduction or modification of the awarded contract.

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

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.

Compliance with these obligations increases our costs. Failure to comply with these regulations and requirements could lead to suspension or debarment from government contracting or subcontracting for a period of time. The termination of a government contract or relationship as a result of our failure to satisfy any of these obligations could have a negative impact on our operations and harm our reputation and ability to secure other government contracts in the future.

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

Our prior contracts for the supply of BioThrax with HHS and the DoD, as well as our current contract for the procurement of 44.75 million doses of BioThrax by the CDC, are fixed price contracts. We expect that our potential future contracts with the U.S. government for BioThrax, as well as contracts for other biodefense products 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 subject our business to material limitations, restrictions and uncertainties and may have a material adverse impact on or financial condition and operating results.

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

- terminate existing contracts, in whole or in part, for any reason or no reason;
- unilaterally reduce or modify contracts or subcontracts, including by imposing equitable price adjustments;
- cancel multi-year contracts and related orders if funds for contract performance for any subsequent year become unavailable;
- decline to exercise an option to renew a contract;
- exercise an option to purchase only the minimum amount, if any, specified in a contract;
- decline to exercise an option to purchase the maximum amount, if any, specified in a contract;
- claim rights to facilities or to products, including intellectual property, developed under the contract;
- require repayment of contract funds spent on construction of facilities in the event of contract default;
- take actions that result in a longer development timeline than expected;
- change the course of a development program in a manner that differs from the contract's original terms or from our desired development plan, including decisions regarding our partners in the program;
- pursue civil or criminal remedies under the False Claims Act and False Statements Act; and
- control or prohibit the export of products.

Generally, government contracts, including our CDC contract for procurement of BioThrax, contain provisions permitting unilateral termination or modification, in whole or in part, at the U.S. government's convenience. Under general principles of government contracting law, if the U.S. government terminates a contract for convenience, the government contractor may recover only its incurred or committed costs, settlement expenses and profit on work completed prior to the termination. If the U.S. government terminates a contract for default, the government contractor is entitled to recover costs incurred and associated profits on accepted items only and may be liable for excess costs incurred by the government in procuring undelivered items from another source. One or more of our government contracts could be terminated under these circumstances. Some U.S. government contracts grant the U.S. government the right to use, for or on behalf of the U.S. government, any technologies developed by the contractor under the government contract. If we were to develop technology under a contract with such a provision, we might not be able to prohibit third parties, including our competitors, from using that technology in providing products and services to the U.S. government.

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

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

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

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

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

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

Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws could materially damage our relationship with the U.S. government.

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 Foreign Corrupt Practices Act, or FCPA;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

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

Risks Related to Our Financial Position and Need for Additional Financing

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

Although we have been profitable for each of the last five fiscal years, we have not been profitable for every quarter during that time. For example, we incurred a net loss in the first quarter of 2012. Our profitability is substantially dependent on BioThrax product sales, which historically have fluctuated significantly from quarter to quarter and we expect that they will continue to fluctuate significantly based primarily on the timing of our fulfillment of orders from the U.S. government. Additionally, our profitability may be adversely affected as we progress through various stages of ongoing or planned clinical trials for our product candidates. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

Our current indebtedness and any additional debt financing may restrict the operation of our business and limit cash flow available to invest in the ongoing needs of our business.

As of December 31, 2012, we had $62.8 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 would reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
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- increasing the amount of interest that we have to pay on debt with variable interest rates if market rates of interest increase;
- increasing our vulnerability to general adverse economic and industry conditions;
- obligating us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity.

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

We may require significant additional funding and may be unable to raise capital when needed or on acceptable terms, which would harm our business, results of operations and financial condition.

We may require significant additional funding to acquire other companies, in-license and develop additional products, enhance our manufacturing capacity, support commercial marketing activities or otherwise provide additional financial flexibility. We may also require additional funding to support our ongoing operations in the event that our ability to sell BioThrax to the U.S. government is interrupted for an extended period of time, reducing our BioThrax revenues and decreasing our cash balances.

As of December 31, 2012, we had $237.7 million of cash, cash equivalents and accounts receivable. Our future capital requirements will depend on many factors, including:

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

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 or debt offerings, bank loans or collaboration and licensing arrangements. We have an effective shelf registration statement on file with the Securities and Exchange Commission that allows us

to issue up to an aggregate of $180 million of equity, debt and certain other types of securities through one or more future offerings. Current economic conditions may make it difficult to obtain financing on attractive terms or at all. Lenders may be able to impose covenants on us that could be difficult to satisfy, which could put us at increased risk of defaulting on debt. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

Our ability to borrow additional amounts under any line of credit we may establish will likely be subject to our satisfaction of specified conditions. Additional equity or debt financing, development contracts and grants or 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. Public or bank 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 pursuing acquisition opportunities.

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

Risks Related to Manufacturing and Manufacturing Facilities

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

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

Constructing, preparing and maintaining a facility for manufacturing purposes is a significant undertaking. For example, the process for qualifying and validating Building 55 for FDA approval of the large-scale manufacture of BioThrax has been costly and time consuming, may result in unanticipated delays and may cost more than expected due to a number of factors, including regulatory requirements. The costs and time required to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements for sales of our products outside the U.S. may be significant. Start-up costs can be substantial and scale-up entails significant risks related to process development and manufacturing yields. If our qualification, validation and facility licensure activities are delayed, we may not be able to increase the number of doses of BioThrax that we can produce and thereby grow our revenue. In addition, if we experience delays, we may be in breach of the obligations under our government funded development contracts. Costs associated with constructing, qualifying, validating and licensing manufacturing facilities could require us to raise additional funds from external sources, and we may not be able to do so on favorable terms or at all.

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

BioThrax and all of our current 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 ensure that it is reproducible. Problems may arise during manufacturing for a variety of reasons, including problems with raw materials, equipment malfunction and failure to follow specific protocols and procedures. In addition, 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 testing, may result in lot failures or manufacturing shut-down, delays in the release of lots, product recalls, spoilage or regulatory action. Success rates can vary dramatically at different stages of the manufacturing process, which can reduce yields and increase costs. From time to time we may experience deviations in the manufacturing process that may take significant time and resources to resolve and if unresolved may affect

manufacturing output and could cause us to fail to satisfy customer orders or contractual commitments, lead to a termination of one or more of our contracts, lead to delays in our clinical trials, result in litigation or regulatory action against us or cause the FDA to cease releasing product until the deviations are explained and corrected, any of which could be costly to us and negatively impact our business.

FDA approval is required for the release of each lot of BioThrax. We will not be able to sell any lots that fail to satisfy the release testing specifications. We must provide the FDA with the results of certain tests including potency before lots are released for sale. We have one mechanism for conducting this potency testing that is reliant on a unique animal strain for which we currently have no alternative. In developing alternatives, we may face significant regulatory hurdles. In the event of a problem with this strain, if we have not developed alternatives, we would not be able to provide the FDA with required potency testing data and would not be able to release product, and therefore would not be able to sell BioThrax doses until the problem was resolved.

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

Under our current contract with the CDC, we have the option to supply doses of BioThrax in advance of the CDC scheduling the pick-up of these doses. However, if we elect to ship product in advance of the CDC scheduling a pick-up, we are obligated to perform shipping services at no cost to the U.S. government. If we perform these shipping services, we are contractually required to ship BioThrax at a prescribed temperature range, 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.

Under our contract with BARDA for advanced development of chemical, biological, radiological and nuclear medical countermeasures, including domestic pandemic influenza vaccine manufacturing surge capacity, we could be required in a pandemic scenario to produce significant doses of pandemic influenza vaccine in a short period of time. Manufacturing under such circumstances could present technical and logistical challenges. In addition, release of pandemic influenza vaccine lots would require FDA approval. Challenges or delays in producing and releasing pandemic influenza vaccine could result in lost revenues, damage our reputation or otherwise harm our business.

Currently, only our manufacturing facility in Lansing, Michigan has regulatory approval to manufacture BioThrax. A significant interruption of the ability of that facility to manufacture BioThrax would reduce our revenues and materially harm our business, financial condition and operating results.

We currently rely on our manufacturing facility 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 demand of the U.S. government or other BioThrax customers. A number of factors could cause interruptions, including:

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

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

In addition, providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. For example, the U.S. government has designated our Lansing facility as a facility requiring additional security to protect against potential terrorist threats to the facility. However, there can be no assurance that these additional security measures will protect our facility from terrorist efforts determined to disrupt our BioThrax manufacturing activities. Any disruption that impedes our ability to manufacture and ship BioThrax in a timely manner could reduce our revenues and materially harm our business, financial condition and operating results.

The factors listed above could also cause disruptions at our other facilities, including our research and product development facilities and our additional manufacturing facility currently under development in Baltimore, Maryland. Any such disruption, damage, or destruction could result in losses and delays, including delay in the performance of our contractual obligations or delay in our clinical trials, any of which could be costly to us and materially harm our business, financial condition and operating results.

Our business may be harmed if we do not adequately forecast or control production facility needs.

The timing and amount of government or other customer demand can be difficult to predict. If we overestimate government or other customer demand, choose to commercialize products for which the market is smaller than we anticipate or otherwise create or maintain manufacturing facilities that are not efficiently utilized, we could incur significant unrecoverable costs. We also may experience challenges ensuring sufficient production capacity. For example, we may not be able to increase our production capabilities quickly enough to perform new government contracts or fill new customer orders on a timely basis. This could cause us to lose new business and possibly existing business. In addition, if third party manufacturing services are not available on a time frame and cost that is acceptable to us, limited manufacturing capacity in our facilities could lead to delays in some of our product development and commercialization efforts.

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

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

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

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

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

commercialize any products that receive regulatory approval on a timely and competitive basis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Product Development

Our business depends on our success in developing and commercializing our product candidates. If we are unable to commercialize these product candidates, or experience significant delays or unanticipated costs in doing so, our business would be materially and adversely affected.

We have invested significant efforts and financial resources in the development of our vaccines and therapeutic product candidates and the acquisition of additional product candidates. In addition to BioThrax sales, our ability to generate 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 and other commercial entities in providing grant funding for development of certain of our product candidates and on the commercial viability of our developed or acquired product candidates. The commercial success of our product candidates will depend on many factors, including accomplishing the following in an economical manner:

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

If we are delayed or prevented from developing and commercializing a product candidate in an economically acceptable manner, our growth could be materially and adversely affected.

Clinical trials of product candidates are expensive and time-consuming, and their outcome is uncertain. We must invest substantial amounts of time and financial resources to these trials which may not yield viable products.

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 and demonstrate the 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 is uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials or animal efficacy studies will be successful, and interim results of a clinical trial or animal efficacy study do not necessarily predict final results. An unexpected result in one or more of our clinical trials can occur at any stage of testing.

For certain of our Biodefense product candidates, we expect to rely on FDA regulations known as the "animal rule" to obtain approval. The animal rule permits, in certain limited circumstances, the use of animal efficacy studies together with human clinical safety and immunogenicity trials to support an application for marketing approval. These regulations are relatively new, and we have limited experience in the application of these rules to the product candidates that we are developing. It is possible that results from these animal efficacy studies may not be predictive of the actual efficacy of our 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 could 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 toxicology and efficacy testing or clinical trials, or we may abandon projects that we expect to be promising, if our preclinical tests, clinical trials or animal efficacy studies produce negative or inconclusive results;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements;
- regulators may determine that service providers we use in the conduct of a clinical trial are precluded from providing such services;
- we or our collaborative partners may experience delay in beginning the clinical trial;
- we may experience competition in recruiting clinical investigators;
- the cost of our clinical trials could escalate and become cost prohibitive;
- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable;
- regulatory requirements, policy and guidelines could change;
- we may experience limitations in our ability to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials;
- we or our collaborators may fail to adequately manage the increasing number, size and complexity of our clinical trials;
- any or all of our collaborators, the FDA and foreign regulatory agencies may interpret data differently;
- third parties conducting and overseeing the operations of our clinical trials may fail to perform their contractual or regulatory obligations in a timely fashion;
- we may not be successful in recruiting a sufficient number of qualifying subjects for our clinical trials or may experience delays in patient enrollment and variability in the number and types of patients available for clinical trials; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

For example, in February 2013, we announced the results of a Phase IIb clinical trial evaluating the safety and efficacy of MVA85A in preventing tuberculosis in infants. As a consequence of these results, we intend to cease further development work on MVA85A.

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 of 2004, or Project BioShield, 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 of HHS 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 product 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 product 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 products by us or our collaborators may be caused by many factors, including regulatory or patent issues, negative or inconclusive interim or final results of ongoing clinical trials, scheduling conflicts with participating clinics and the rate of patient enrollment in clinical trials and the development priorities of our collaborators. In addition, in preparing these estimates we rely on the timeliness and accuracy of information and estimates reported or provided to us by our collaborators concerning the timing, progress and results of clinical trials or other development activities they conduct under our collaborations with them. If we or our collaborators do not achieve milestones when anticipated, we may not achieve our planned revenue or we may be forced to record an impairment charge to our intangible assets and our stock price could decline. In addition, any delays in obtaining approvals to market and sell products may result in the loss of competitive advantages in being on the market 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 any of our product candidates into viable commercial products, we will be reliant solely on sales of our currently approved product BioThrax for our revenues, thus limiting our growth opportunities and diversification.
We may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates.
We continue to evaluate our business strategy and, as a result, may modify our strategy in the future. In this regard, we may, from time to time, focus our product development efforts on different product candidates or may delay or halt the development of various product candidates. For example, in February 2013, as a consequence of clinical trial results, we determined to cease further development work on our MVA85A tuberculosis vaccine candidate. As a result of changes in our strategy, we may change or refocus our existing product development, commercialization and manufacturing activities. This could require changes in our facilities and personnel and restructuring various financial arrangements. Any product development changes that we implement may not be successful. In particular, we may fail to select or capitalize on the most scientifically, clinically or commercially promising or profitable product candidates. We have limited technical, managerial, and financial resources to determine which of our product candidates should proceed to initial clinical trials, later-stage clinical development, and potential commercialization and, further, we may make incorrect determinations as a result of our limited resources or information available to us at the time of our determination. Our decisions to allocate our research and development, management, and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate product development programs may also be incorrect and could cause us to miss valuable opportunities.
Risks Related to Commercialization

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

An element of our business strategy is to establish a market for the sale of BioThrax to customers in addition to the U.S. government. These potential customers include foreign governments, multinational companies, non-governmental organizations and hospitals, as well as domestic state and local governments, which we anticipate may be interested in BioThrax.

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

Government regulations may make it difficult for us to achieve significant sales of BioThrax to customers other than the U.S. government. For example, many foreign governments require licensure of BioThrax in their jurisdictions before they will consider procuring doses. Additionally, we are subject to export control laws imposed by the U.S. government. Although there are currently only limited restrictions on the export of BioThrax and related technology, the U.S. government may decide, particularly in the current environment of elevated concerns about global terrorism, to increase the scope of export prohibitions. These prohibitions could limit our sales of BioThrax to foreign governments and other foreign customers. In addition, U.S. government demand for an anthrax vaccine may limit our supplies of BioThrax available for sale to non-U.S. government customers. For example, our efforts to further 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.

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

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

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

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

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

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our

failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC may also suspend or bar issuers from listing their securities on United States securities exchanges for violations of the FCPA's accounting provisions.

The commercial success of BioThrax and any additional products that we may develop will depend upon the degree of market acceptance by the government, physicians, patients, healthcare payors and others in the medical community. Any products that we bring to the market may not gain or maintain market acceptance by potential government customers, physicians, patients, healthcare payors and others in the medical community.

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

The U.S. government could conduct clinical trials involving BioThrax in populations or in a manner that may attract negative public attention or otherwise have a detrimental effect on 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, injection site cellulitus and temporary limitation of motion in the inoculated arm, and systemic reactions, such as headache, fever, chills, nausea and general body aches. In addition, some serious adverse events have been reported to the vaccine adverse event reporting system database maintained by the CDC and the FDA with respect to BioThrax, including diabetes, heart attacks, autoimmune disorders, including Guillain-Barre syndrome, lupus, multiple sclerosis, lymphoma and death, which have not been causally linked to the administration of BioThrax. The report of any adverse event to the vaccine adverse event reporting system database is not proof that the vaccine caused such event.

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

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

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

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

Political or social factors may delay or impair our ability to market BioThrax and our product candidates and may require us to spend significant management time and financial resources to address these issues.

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

In addition, substantial delays or cancellations of purchases could result from protests or challenges from third parties. Lawsuits brought against us by third parties or activists, even if not successful, could require us to spend significant management time and financial resources defending the related litigation. 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 our license for BioThrax and 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 created negative publicity about BioThrax. Additional lawsuits, publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of BioThrax and thereby limit the demand for BioThrax and any of our other biodefense product candidates, which could adversely affect our operating results.

We have a small sales and marketing group that is focused on Biodefense products, including BioThrax. 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 acquire or develop. This small sales group would not be capable of supporting sales efforts for our Biosciences product candidates. If we do not enter into collaborative agreements with respect to our biosciences product candidates with third parties with appropriate commercialization capabilities, we may need to further expand our sales, marketing and distribution infrastructure to effectively commercialize these product candidates.

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

- potential difficulties in recruiting, training and retaining adequate numbers of effective sales and marketing personnel;
- the potential that the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities could be delayed, resulting in us incurring related expenses too early relative to the product launch and causing personnel retention issues;
- our limited experience in the commercialization of pharmaceutical products other than BioThrax;
- difficulties in establishing an effective distribution network, including entering into marketing and distribution agreements with third parties on acceptable terms;
- the inability of sales personnel to obtain access to or persuade adequate numbers of potential government customers to purchase our products and physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and maintaining a sales and marketing organization.

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

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

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid technological advances. We may face future competition from biopharmaceutical companies worldwide. Potential competitors also include biodefense companies, academic institutions, government agencies and other public and private research institutions that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Our competitors may develop products that are safer, more effective, have fewer side effects, are more convenient or are less costly than any products that we may develop or market. Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours. They may also devote greater resources to market or sell their products, adapt more quickly to new technologies and scientific advances, initiate or withstand substantial price competition more successfully than we can, more effectively negotiate third-party licensing and collaborative arrangements and

take advantage of acquisition or other opportunities more readily than we can. Any therapeutic product candidate that we successfully develop and commercialize is likely to compete with currently marketed products and with other product candidates currently in development for the same indications. In many cases, the currently marketed products have well-known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. In particular, any new product candidate that competes with a generic market-leading product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome severe price competition and be commercially successful.

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

We believe that our most significant competitors in the area of biodefense and commercial vaccines are a number of pharmaceutical companies that have vaccine programs, including Merck & Co., GlaxoSmithKline, Sanofi Pasteur, Pfizer and Novartis, as well as smaller, more focused companies engaged in vaccine and immune therapeutics development, such as Soligenix, Dynport Vaccine Company, Elusys, Bavarian Nordic and PharmAthene. With respect to the protein therapeutics we are developing, we are aware of existing products and products in research or development by others that address the diseases we are targeting. Any of these products may compete with our product candidates.

Any reduction in demand for our products as a result of a competing product could lead to reduced revenues, reduced margins, reduced levels of profitability and loss of market share for our products. These competitive pressures would adversely affect our business and operating results.

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

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

The 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. The Secretary of HHS has issued PREP Act declarations identifying BioThrax, Anthrivig and pandemic Influenza A vaccines as covered countermeasures. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct. Upon a declaration by the Secretary of HHS, a compensation fund is created to provide "timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." The "covered injuries" to which the program applies are defined as serious physical injuries or death. Individuals are permitted to bring a willful misconduct action against a manufacturer only after they have exhausted their remedies under the compensation program. Therefore, a willful misconduct action could be brought against us, thereby exposing us to liability, if any individuals exhaust their remedies under the compensation program.

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

We face product liability exposure, which could cause us to incur substantial liabilities and negatively affect our business, financial condition and results of operations.

We face an inherent risk of product liability exposure related to the sale of BioThrax and any other products that we successfully develop and the testing of our product candidates in clinical trials. For example, we have been a

defendant in lawsuits filed on behalf of military personnel who alleged that they were vaccinated with BioThrax by the DoD and claimed damages resulting from personal injuries allegedly suffered because of the vaccinations. The plaintiffs in these lawsuits claimed different injuries and sought varying amounts of damages. Although we successfully defended these lawsuits, we cannot ensure that we will be able to do so in the future.

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

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

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

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

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

Our revenues and profits from any products that we successfully develop, other than with respect to sales of our Biodefense products under government contracts, will depend heavily upon the availability of adequate reimbursement for the use of such products from governmental and other third party payors, both in the U.S. and in other markets. Reimbursement by a third party payor may depend upon a number of factors, including the third party payors 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, contain 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. Until many of the provisions are fully implemented the specific impact of the legislation cannot be known. Our results of operations could be adversely affected by current and potential future healthcare reforms.

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.

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

Our success depends on our continued ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel. We consider Fuad El-Hibri, executive chairman of our Board of Directors and our former chief executive officer, and Daniel J. Abdun-Nabi, a member of our Board of Directors and our president and

chief executive officer, to be key to our BioThrax operations and our efforts to develop and commercialize our product candidates. Mr. Abdun-Nabi succeeded Mr. El-Hibri as our chief executive officer on April 1, 2012. Mr. El-Hibri continues to serve as executive chairman of the Board of Directors. Both of these key employees are at will employees and can terminate their employment at any time. We do not maintain "key person" insurance on any of our employees.

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

Risks Related to Our Acquisition Strategy

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

Our business strategy includes growing our business through acquisition and in-licensing transactions. We may not be successful in identifying, effectively evaluating, acquiring or in-licensing, and developing additional products on appropriate terms. Competition for attractive product opportunities is intense, and may require us to devote substantial resources, both managerial and financial, to a product opportunity. A number of more established companies are also pursuing strategies to acquire or in-license products in our targeted field. These 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 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. Even if we are successful in acquiring a product or company, it may not result in a successfully developed or commercialized product. Moreover, the cost of acquiring other companies or in-licensing products could be substantial and in order to acquire companies or new products, we may need to incur substantial debt or issue dilutive securities. If we are unsuccessful in our efforts to acquire other companies or in-license and develop additional products, or if we acquire or in-license unproductive assets, it could have a material adverse effect on the growth of our business.

Our failure to successfully integrate acquired assets into our operations could adversely affect our business.

Issues that could delay or prevent successful integration of an acquired business include:

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

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

If we are unable to successfully integrate our acquisitions with our existing business, we may not obtain the advantages that the acquisitions were intended to create, which may adversely affect our business and our ability to develop and introduce new products.

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 product candidates and have been advancing pre-clinical and multiple clinical stage product candidates. We plan to continue adding products and late stage product candidates through acquisition and in-licensing over the next several years and to continue developing our existing product candidates that demonstrate the requisite efficacy and safety to advance into and through clinical trials. To manage the existing and planned future growth and the increasing breadth and complexity of our activities, we have grown our employee base substantially and will need to continue making additional investments in personnel, infrastructure, information management systems and resources. Our ability to develop and advance the commercialization of our products and product candidates, achieve our research and development objectives, add and integrate new products, and satisfy our commitments under our collaboration and acquisition agreements depends on our ability to respond effectively to these demands and expand our internal organization and infrastructure to accommodate our growth and additional anticipated growth. If we are unable to manage and advance these activities effectively, our ability to operate our business successfully and maximize the value of our product or our product candidates could suffer, which could materially and adversely affect our business, financial condition and prospects for future growth.

Risks Related to Regulatory Approvals

Our long term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize product candidates, and if we are not successful, our business and operating results may suffer.

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

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

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

known as the FDA's "animal rule".

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

The process of obtaining these 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.

Even after regulatory approval is received, if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our approved products, they could be subject to restrictions, penalties or withdrawal from the market.

Any vaccine or 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 prior notice at reasonable times and in a reasonable manner.

The FDA conducts periodic inspections of our Lansing facilities, most recently in August 2011. Following each of these inspections, the FDA has issued inspectional observations, all of which have been resolved, but some of which were significant. 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 penalties or other actions, including:

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

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

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

If one of our competitors obtains orphan drug exclusivity for an indication for a product that competes with one of the indications for one of our product candidates before we obtain orphan drug designation, and if the competitor's product is the same drug as ours, the FDA would be prohibited from approving our product candidate for the same orphan indication unless we demonstrate that our product is clinically superior or the FDA determines that the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the drug. We have obtained orphan drug status from the FDA for Anthrivig, Thravixa and TRU-016 (CLL indication), and in the European Union for Anthrivig and Thravixa. None of our other products or product candidates have been designated as an orphan drug and there is no guarantee that the FDA will grant such designation in the future. Even if we obtain orphan drug exclusivity for one or more indications for one of our product candidates, we may not be able to maintain it. For example, if a competitive product that is the same drug or biologic as our product is shown to be clinically superior to our product, any orphan drug exclusivity we may have obtained will not block the approval of that competitive product.

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

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

Failure to obtain regulatory approval in international jurisdictions could prevent us from marketing our products abroad and could harm the growth of our business.

We intend to have some or all of our products marketed outside the United States. To market our products in the European Union and many other foreign jurisdictions, we may need to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. With respect to some of our product candidates, we expect that a future collaborator may have responsibility to obtain regulatory approvals outside the United States, and in that case, we would depend on our collaborator to obtain these approvals. The approval procedure varies among countries and can involve additional clinical trials 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. 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 establishing and maintaining collaborations to leverage our capabilities to develop and commercialize our product candidates.

For each of our product candidates, we plan to evaluate the merits of retaining commercialization rights or entering into collaboration arrangements with leading biopharmaceutical companies or non-governmental organizations. We expect to selectively pursue collaboration arrangements in situations in which the collaborator has particular technology, expertise or resources for the development or commercialization of our 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 partners for our product candidates. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish, implement and maintain collaborations or other alternative arrangements, or the arrangements that we establish may not turn out to be productive or beneficial for us. The terms of any collaboration or other arrangements that we establish may not be favorable to us.

Any collaboration that we enter into may not be successful and 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 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 collaborators may prefer regulatory strategies that differ from those we prefer, complicating the process of obtaining marketing approvals and releasing products;
- our collaboration agreements are likely to be for fixed terms and may be subject to termination by our collaborators;
- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if our collaborators do not do so, our ability to maintain and defend our intellectual property rights may be compromised by our collaborators' acts or omissions;
- our collaborators may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;
- our collaborators may decide not to pursue further development and commercialization of products and product candidates resulting from the collaboration, or may elect to discontinue research and development programs, which could delay development, result in impairment charges or write offs 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.

For example, our previous collaborative partner Pfizer Inc. terminated its collaboration with us for the development of SBI-087 following a portfolio reprioritization process. As a result, we experienced a charge of $9.6 million attributable to impairment of our SBI-087 in-process research and development asset. Similarly, our previous collaborative partner Abbott Laboratories terminated its collaboration with us for the development of TRU-016 following a similar portfolio reprioritization process.

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

We depend on third parties to conduct our clinical and non-clinical trials. If these third parties 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 and non-clinical trials required to obtain regulatory approval for our product candidates. 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 our clinical trials are conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as current Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

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

In addition, in certain cases, we encourage government entities and non-government organizations to pursue development and conduct studies of our product candidates. For example, we expect to rely on data from clinical trials conducted by such entities in seeking marketing approval for certain of our product candidates, including our BLA supplement for a label expansion of BioThrax for a regimen of fewer doses, which is based on the results of a clinical trial conducted by the CDC. These government entities and non-government organizations have no obligation or commitment to us to conduct or complete any of these studies or clinical trials and may choose to discontinue these development efforts at any time. Furthermore, government entities depend on annual Congressional appropriations to fund their 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

If we are unable to protect our proprietary rights, our business could be harmed.

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

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

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. In addition, we know that other entities have filed patent applications in various jurisdictions that relate to several areas in which we are developing products. Some of these patent applications have already resulted in patents and some are still pending. If use of technology incorporated into or used to produce our product candidates is challenged, or if our processes or product candidates conflict with the 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 derivation proceedings in the U.S. Patent and Trademark Office to determine inventorship, which could result in substantial costs to us and an adverse decision as to the inventorship, and therefore ownership, of our inventions. An unfavorable outcome in a derivation proceeding could require us to cease using the technology or to license rights from prevailing third parties. There can be no assurance 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 financial resources. Intellectual property lawsuits are expensive and unpredictable and would consume time and other resources, including the attention of our management, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also a risk that, even if the validity of a patent were upheld, a court would refuse to stop the other party from using the invention(s), including on the grounds that its activities do not infringe the patent. If any of these events were to occur, our business, financial condition and operating results could be materially and adversely affected.

Our collaborators and licensors may not adequately protect our intellectual property rights. These third parties may have the first right to maintain or defend our intellectual property rights and, although we may have the right to assume the maintenance and defense of our intellectual property rights if these third parties do not do so, our ability to maintain and defend our intellectual property rights may be compromised by the acts or omissions of these third parties. For example, we license an oligonucleotide adjuvant, CPG 7909, for use in NuThrax from Pfizer. One of the

licensed U.S. patents related to CPG 7909 has been revoked by the U.S. Patent and Trademark Office, as a result of a patent interference between Pfizer and a third party.

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

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

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

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

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

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

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

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

Third parties may choose to file patent infringement claims against us. Defending ourselves from such allegations would be costly, time-consuming, distracting to management and could be materially adverse to 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 may have substantially greater financial resources than us and could bring claims against us 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, we could be forced to stop or delay development, manufacturing or sales of the product or product candidate that is the subject of the suit. Intellectual property litigation in the biopharmaceutical industry is common, and we expect this trend to continue.

As a result of patent infringement or other similar claims, or to avoid potential claims, we 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 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 are unable to enter into licenses on acceptable terms or if an injunction is granted against us, which could harm our business significantly.

Risks Related to Information Technology

We rely significantly on information technology systems and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively or result in data leakage of proprietary and confidential business and employee information.

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

In addition, our systems are potentially vulnerable to data security breaches—whether by employee error, malfeasance or other disruption—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information, including sensitive personal information, of our employees, clinical trial patients, customers, and others.

A significant business disruption or a breach in security resulting in misappropriation, theft or sabotage with respect to our proprietary and confidential business and employee information could result in financial, legal, business or reputational harm to us, any of which could adversely affect our business, financial condition and operating results.

Risks Related to Our Common Stock

Fuad El-Hibri, executive chairman of our Board of Directors, has significant influence over us through his substantial beneficial ownership of our shares, including his ability to significantly influence the election of the members of our Board of Directors, or delay or prevent a change of control.

Mr. El-Hibri has the ability to significantly influence the election of the members of our Board of Directors due to his significant beneficial ownership of our shares. As of February 28, 2013, Mr. El-Hibri was the beneficial owner of approximately 24% of our outstanding common stock. Because of Mr. El-Hibri's significant beneficial ownership 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.

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 of candidates for election as 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 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 the corporation's voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of us.

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

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

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

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

Our stock price has been, and is likely to continue to be, volatile. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through February 28, 2013, our common stock has traded as high as $27.00 per share and as low as $4.40 per share. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price of our common stock may be influenced by many factors, including, among others:

- 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), or delay in achievement of milestones;
- announcements of technological innovations or new therapeutic products or methods by us or others;
- acts or omissions of our licensees, suppliers, or any collaborators;
- 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.

Because we have no current intention to pay dividends in the foreseeable future, investors will benefit from an investment in our common stock only if it appreciates in value.

Although our Board of Directors has authorized a share repurchase program under which we may repurchase our shares from time to time, we currently intend to retain our resulting future earnings, if any, to fund the development and growth of our business and do not anticipate paying dividends on our common stock. Our current and any future debt agreements that we enter into may limit our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

A significant portion of our shares may be sold into the market at any time. This could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales or the perception in the market that the holders of a large number of shares intend to sell shares could reduce the market price of our common stock. Moreover, holders of an aggregate of approximately 6.8 million shares of our common stock outstanding as of February 28, 2013 have the right to require us to register these shares of common stock under specified circumstances. In 2012, we registered 3.0 million of these shares to be sold by these holders from time to time.

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	Amount Approximate square feet	Owned/leased
Lansing, Michigan	Manufacturing operations facilities, office space and laboratory space	Biodefense	214,000	Owned
Baltimore, Maryland	Manufacturing facilities and office and laboratory space	Biodefense	56,000	Owned
Gaithersburg, Maryland	Office and laboratory space	Biodefense	48,000	Owned
Seattle, Washington	Office and laboratory space	Biosciences	51,000	Leases expire 2015
Rockville, Maryland	Office space	Biodefense/Biosciences	41,000	Lease expires 2016
Munich, Germany	Office and laboratory space	Biosciences	16,000	Lease expires 2015

Lansing, Michigan. We own a multi-building campus on approximately 12.5 acres in Lansing, Michigan that includes facilities for current and future bulk manufacturing of BioThrax, including fermentation, filtration and formulation, as well as for raw material storage and in-process and final product warehousing. The campus is secured through perimeter fencing, limited and controlled ingress and egress and 24-hour on-site security personnel.

Baltimore, Maryland. We own a 56,000 square foot manufacturing facility in Baltimore, Maryland. We are using this facility to support our future product development and manufacturing needs, including those of our pipeline product candidates, as well as to meet the requirements under the Center for Innovation in Advanced Development and Manufacturing contract. Our future use of this facility will be dependent on the progress of our existing development programs and the outcome of our efforts to acquire new product candidates.

Other. We own or lease three separate product development facilities. Our facility in Gaithersburg, Maryland is approximately 48,000 square feet and contains a combination of laboratory and office space. Our facility in Seattle,

Washington is approximately 51,000 square feet and contains a combination of laboratory and office space. Our facility in Munich, Germany is approximately 16,000 square feet and contains a combination of laboratory and office space. In addition, our facility in Rockville, Maryland contains approximately 41,000 square feet of office space, including our executive offices.

In January 2013, we entered into a purchase agreement with certain conditions precedent, for an office building for $27.5 million. We plan to utilize a portion of the new building for our headquarters operations and continue to lease the remaining space under existing lease agreements with third parties. We anticipate the purchase will be completed during the first quarter of 2013.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information and Holders

Our common stock trades on the New York Stock Exchange under the symbol "EBS". The following table sets forth the high and low sales prices per share of our common stock during each quarter of the years ended December 31, 2012 and 2011:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year Ended December 31, 2012				
High	$18.34	$16.32	$15.87	$16.15
Low	$14.22	$13.30	$13.49	$12.50
Year Ended December 31, 2011				
High	$25.07	$26.41	$22.84	$19.77
Low	$18.32	$20.44	$14.90	$15.14

As of February 28, 2013, the closing price per share of our common stock on the New York Stock Exchange was $15.49 and we had 33 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend Policy

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds

Not applicable.

Purchases of Equity Securities

The table below presents information regarding shares of our common stock that we repurchased during the year ended December 31, 2012.

Issuer Purchases of Equity Securities

Period	Total number of shares (or units) purchased	Average price paid per share (or unit)	Total number of shares (or units) purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs
September 1 to September 30, 2012 [1]	97,600	$ 14.93	97,600	$ 33,542,832
October 1 to October 31, 2012 [1]	300,881	14.54	300,881	$ 29,168,022
December 1 to December 31, 2012 [2]	4,677	15.81	-	$ 29,168,022
Total	403,158	$ 14.64	398,481	$ 29,168,022

(1) On May 21, 2012, we publicly announced that our board of directors authorized the repurchase of up to $35.0 million of our common stock through a share repurchase program. The repurchase program was authorized on May 17, 2012 and terminates on December 31, 2013. We did not repurchase any shares of our common stock under this repurchase program prior to September 2012.

(2) In December 2012, in a form of stock option transaction provided for under the terms of our stock incentive plan and the stock option agreement, we engaged in a transaction with our chief executive officer in which we acquired 4,677 shares of common stock as payment of the exercise price for 7,300 stock options.

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, 2012, 2011 and 2010 and the consolidated balance sheet data as of December 31, 2012 and 2011 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, 2009 and 2008 and the consolidated balance sheet data as of December 31, 2010, 2009 and 2008 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)	2012	2011	2010	2009	2008
Statements of operations data:					
Revenues:					
Product sales	$215,879	$202,409	$251,381	$217,172	$169,124
Contracts and grants	66,009	70,975	34,790	17,614	9,430
Total revenues	281,888	273,384	286,171	234,786	178,554
Operating expenses:					
Cost of product sales	46,077	42,171	47,114	46,262	34,081
Research and development	120,226	124,832	89,295	74,588	59,470
Selling, general & administrative	76,018	74,282	76,205	73,786	55,076
Impairment of in-process research and development	9,600	-	-	-	-
Total operating expenses	251,921	241,285	212,614	194,636	148,627
Income from operations	29,967	32,099	73,557	40,150	29,927
Other income (expense):					
Interest income	134	105	832	1,418	1,999
Interest expense	(6)	-	-	(7)	(47)
Other income (expense), net	1,970	(261)	(1,023)	(50)	134
Total other income (expense)	2,098	(156)	(191)	1,361	2,086
Income before provision for income taxes	32,065	31,943	73,366	41,511	32,013
Provision for income taxes	13,922	15,830	26,182	14,966	12,055
Net income	$18,143	$16,113	$47,184	$26,545	$19,958
Net loss attributable to noncontrolling interest	5,381	6,906	4,514	4,599	724
Net income attributable to Emergent BioSolutions Inc.	$23,524	$23,019	$51,698	$31,144	$20,682
Earnings per share — basic	$0.65	$0.65	$1.63	$1.02	$0.69
Earnings per share — diluted	$0.65	$0.64	$1.59	$0.99	$0.68
Weighted average number of shares — basic	36,080,495	35,658,907	31,782,286	30,444,485	29,835,134
Weighted average number of shares — diluted	36,420,662	36,206,052	32,539,500	31,375,305	30,458,098

	As of December 31,				
(in thousands)	2012	2011	2010	2009	2008
Balance Sheet Data:					
Cash and cash equivalents	$141,666	$143,901	$169,019	$102,924	$91,473
Working capital	201,440	183,364	167,774	139,113	98,866
Total assets	564,230	546,864	500,319	344,689	290,788
Total long-term liabilities	60,195	59,083	51,039	46,173	37,418
Total stockholders' equity	442,128	416,727	373,561	243,815	199,349

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 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 on Form 10-K 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

Emergent BioSolutions is a specialty pharmaceutical company seeking to protect and enhance life by developing and offering specialized products to healthcare providers and governments for use in addressing medical needs and emerging health threats. For financial reporting purposes, we operate in two business divisions or segments, Biodefense and Biosciences.

Our Biodefense division is directed to government-sponsored development and supply of countermeasures against potential agents of bioterror or biowarfare and primarily targets the infectious disease anthrax. Our programs in this division include 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, as well as investigational product candidates. Operations in this division include biologics manufacturing, regulatory and quality affairs in support of BioThrax and a product development and manufacturing infrastructure in support of our investigational product candidates.

Our Biosciences division is directed to commercial opportunities and primarily targets oncology indications. Our programs in this division include one clinical stage product candidate for chronic lymphocytic leukemia, or CLL, as well as investigational product candidates and platform technologies. Operations in this division include product development in support of our CLL product candidate, our investigational product candidates, and manufacturing and related infrastructure initiatives in support of our platform technologies.

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

Product Sales

We have derived substantially all of our product sales revenues from BioThrax sales to the U.S. government. We are currently a party to a contract with the Centers for Disease Control and Prevention, or CDC, an operating division of the U.S. Department of Health and Human Services, or HHS, to supply up to 44.75 million doses of BioThrax for placement into the Strategic National Stockpile, or SNS, over a five-year period. We expect for the foreseeable future to continue to derive substantially all of our product sales revenues from our sales of BioThrax to the U.S. government. Our total revenues from BioThrax sales were $215.9 million, $202.4 million and $251.4 million for the years ended December 31, 2012, 2011 and 2010, respectively. We are focused on increasing sales of BioThrax to U.S. government customers, expanding the market for BioThrax to other customers domestically and internationally and pursuing label expansions and improvements for BioThrax.

Contracts and Grants

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

§ Anthrivig;
§ BioThrax as a post-exposure prophylaxis, or PEP;
§ NuThrax;
§ Large-scale manufacturing for BioThrax;
§ PreviThrax;
§ Thravixa; and
§ Tuberculosis vaccine.

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

Manufacturing Infrastructure

We conduct our primary vaccine manufacturing operations at a multi-building campus on approximately 12.5 acres in Lansing, Michigan. To augment our existing manufacturing capabilities, we have constructed Building 55, a 50,000 square foot large-scale manufacturing facility on our Lansing campus. In July 2010, we entered into an agreement with the Biomedical Advanced Research and Development Authority, or BARDA, to finalize development of and obtain regulatory approval for large-scale manufacturing of BioThrax in Building 55.

In 2009, we purchased a building in Baltimore, Maryland for product development and manufacturing purposes, and have completed renovation, improvement and equipment acquisitions at this facility. We have entered into two loan agreements with PNC Bank totaling up to $42.0 million to fund these renovations, improvements and equipment acquisitions. In June 2012, we entered into a contract with BARDA, which established us as a Center for Innovation in Advanced Development and Manufacturing, or CIADM. We expect to use this facility to support our future product development and manufacturing needs. Our specific plans for this facility will be contingent on the progress of our existing development programs and the outcome of our efforts to acquire new product candidates.

Critical Accounting Policies and Estimates

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

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

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

Revenue Recognition

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

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

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

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

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. 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 an annual 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.

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. 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 cost projections used to value acquired IPR&D are, as applicable, reduced based on the probability of successfully developing a new product. Additionally, the projections consider 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 are 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 the likelihood and timing of 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, and as a result, the value of the acquired IPR&D assets may become impaired. Our annual assessment includes a comparison of the fair value of IPR&D to our existing carrying value. We recognize an impairment when the carrying value is greater than the determined fair value. We believe that the assumptions used in valuing the

IPR&D are reasonable and are based upon our best estimate of likely outcomes of our clinical development. The underlying assumptions and estimates used to value these IPR&D assets are subject to change in the future, and actual results may differ significantly from the assumptions and estimates. We assess our IPR&D assets for impairment on an annual basis or more frequently if indicators of impairment are present. We have selected October 1st as our annual impairment test date.

Goodwill

We assess the carrying value of our 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. We have selected October 1st as our annual impairment test date. The provisions of the relevant accounting guidance require that we perform a two-step impairment test. In the first step, we compare the fair value of our reporting unit to the carrying value of the reporting unit. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, then the second step of the impairment test is performed in order to determine the implied fair value of the reporting unit's goodwill. If the carrying value of the reporting unit's goodwill exceeds its implied fair value, an impairment loss equal to the difference is recorded and charged to general and administrative expense.

We calculate the fair value of the reporting unit utilizing the income approach. The income approach utilizes a discounted cash flow model, using a discount rate based on the reporting unit's estimated weighted-average cost of capital. The results of the fair value calculations are then compared to our reporting unit's carrying value.

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

We entered into a contract with the CDC effective as of September 30, 2011 to supply up to 44.75 million doses of BioThrax to the CDC over a five-year period. The period of performance under the award is from September 30, 2011 through September 29, 2016. The maximum amount that could be paid to us under the contract is up to $1.25 billion,

subject to availability of funding by the U.S. government. To date, the U.S. government has committed approximately $477 million for the procurement of BioThrax doses under this contract. Through December 31, 2012, we have delivered and, upon CDC acceptance, recognized revenue on approximately 8.9 million doses, representing approximately $235 million under this contract.

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

Development Programs	Funding Source	Award Date	Performance Period
Post-Exposure Prophylaxis indication for BioThrax	BARDA	9/2007	9/2007 — 3/2016
Recombinant botulinum vaccine	NIAID	6/2008	6/2008 — 5/2012
NuThrax	NIAID	7/2008	7/2008 — 6/2013
Thravixa	NIAID/BARDA	9/2008	9/2008 — 8/2012
NuThrax	NIAID/BARDA	9/2008	9/2008 — 7/2012
Double mutant recombinant protective antigen anthrax vaccine	NIAID	9/2009	9/2009 — 8/2012
Large-scale manufacturing for BioThrax	BARDA	7/2010	7/2010 — 7/2015
NuThrax	NIAID	7/2010	8/2010 — 8/2014
PreviThrax	BARDA	9/2010	9/2010 — 9/2015
Tuberculosis vaccine	NIAID	3/2012	3/2012 — 2/2017

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

Cost of Product Sales

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

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

Research and Development Expenses

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

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

We intend to focus our product development efforts on promising late-stage candidates that we believe satisfy well defined criteria and see to utilize collaborations or non-dilutive funning. We plan to limit earlier stage development activities unless funded by external sources and continuing to partner with third parties, such as governmental NGOs for the funding of all our product development programs. We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development, number of product candidates under development, the size, structure and duration of any follow-on clinical programs that we may initiate, costs associated with manufacturing our product candidates on a large-scale basis for later-stage clinical trials, and our ability to use or rely on data generated by government agencies, such as studies involving BioThrax conducted by the CDC.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and other related costs for personnel serving the executive, sales and marketing, business development, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales or research and development expense and professional fees for legal, accounting and auditing 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 acquire additional product candidates or if we receive marketing approval for our product candidates, 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 2012, a business interruption insurance recovery. We earn interest income on our cash and cash equivalents, 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.

Income taxes

In January 2013, Congress passed the American Taxpayer Relief Act of 2012, which among other things extended the research and development tax credit through December 31, 2013. We expect this legislation to have a favorable impact on our 2013 effective tax rate.

In-process research and development and goodwill

We have determined that the IPR&D assets and goodwill reside in our Biosciences therapeutics reporting unit, a component of our Biosciences segment. During the year ended December 31, 2012, Pfizer terminated its development programs with respect to our SBI-087 product candidate. We considered the termination as a potential indicator of impairment of the related SBI-087 IPR&D asset, and as a result performed an interim assessment. As part of the assessment, we considered the impact of Pfizer's decision, along with our decision to no longer pursue further development of this asset due to reduced overall probability of success and increased development costs for the product candidate. As a result, we recorded an impairment charge of $9.6 million during the year ended December 31, 2012, which represented the entire carrying value of the SBI-087 IPR&D asset. This charge is classified in our statement of operations as impairment of in-process research and development, within our Biosciences segment.

We performed our annual impairment analysis of our IPR&D assets and goodwill on October 1, 2012 and 2011, respectively, and determined there was no impairment of these assets. On December 21, 2011, Abbott terminated our collaboration on TRU-016 effective March 20, 2012. In light of this termination, we performed an interim assessment and determined that there was no impairment of the TRU-016 IPR&D asset or goodwill as of December 31, 2011.

Results of Operations

Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

Revenues

Product sales revenues increased by $13.5 million, or 7%, to $215.9 million for 2012 from $202.4 million for 2011. This increase in product sales revenues was primarily due to a 15% increase in the number of doses of BioThrax delivered, partially offset by a 7% decrease in the average sales price per dose. The increase in the number of doses delivered was primarily attributable to the timing of deliveries to the SNS. The decrease in the sales price per dose was due to a slightly lower price per dose under the current CDC contract compared to our prior contract with HHS. Product sales revenues in 2012 consisted of BioThrax sales to the CDC of $215.3 million and aggregate international and other sales of $546,000. Product sales revenues in 2011 consisted of BioThrax sales to HHS and the CDC of $200.9 million and aggregate international and other sales of $1.5 million.

Contracts and grants revenues decreased by $5.0 million, or 7%, to $66.0 million in 2012 from $71.0 million in 2011. The decrease in contracts and grants revenues was primarily due to decreased revenues from our agreements with Abbott and Pfizer and decreased activity and associated revenue from our development contracts with BARDA and NIAID for our Anthrivig, NuThrax and Thravixa product candidates, partially offset by increased revenues from our contracts with BARDA for large-scale manufacturing for BioThrax and development of PreviThrax, along with milestone payments received related to our PEP indication for BioThrax. Contracts and grants revenues in 2012 consisted of $60.5 million in development contract and grant revenue from NIAID and BARDA, $3.9 million from Abbott and Pfizer and $1.5 million from the sale of patent and trademark rights and related materials pertaining to our spi-VEC platform technology. Contracts and grants revenues in 2011 consisted of $48.6 million in development contract and grant revenue from NIAID and BARDA, $22.1 million from Abbott and Pfizer and $250,000 from the Wellcome Trust.

Cost of Product Sales

Cost of product sales increased by $3.9 million, or 9%, to $46.1 million for 2012 from $42.2 million for 2011. This increase was attributable to the 15% increase in the number of BioThrax doses delivered partially offset by lower cost doses sold in 2012 associated with an adjustment to certain BioThrax testing specifications that allowed us to sell doses that were previously expensed.

Research and Development Expense

Research and development expenses decreased by $4.6 million, or 4%, to $120.2 million for 2012 from $124.8 million for 2011. This decrease primarily reflects lower contract service costs, and includes decreased expenses of $17.0 million for product candidates and technology platform development activities categorized in the Biosciences segment, increased expenses of $10.7 million for product candidates and manufacturing development categorized in the Biodefense segment, and increased expenses of $1.6 million in other research and development, which are in support of central research and development activities. Net of development contract and grant reimbursements along with the net loss attributable to noncontrolling interests, we incurred research and development expenses of $48.8 million and $47.0 million, respectively, during 2012 and 2011.

Our principal research and development expenses for 2012 and 2011 are shown in the following table:

	Year ended December 31,	
(in thousands)	2012	2011

Biodefense:		
Large-scale manufacturing for BioThrax	$18,908	$13,138
BioThrax related programs	10,934	6,961
PreviThrax	19,805	14,404
NuThrax	8,591	11,632
Pandemic influenza[(1)]	2,500	-
Thravixa	1,362	3,460
Anthrivig	257	2,608
Other Biodefense	6,222	5,630
Total biodefense	68,579	57,833
Biosciences:		
Tuberculosis vaccine	15,736	19,032
TRU-016	13,585	13,503
T-Scorp	4,673	-
ES-301 (formerly DRACO)	2,047	7,165
Zanolimumab	1,057	4,821
Influenza vaccine	391	2,520
Typhella	295	1,271
Other biosciences	6,804	13,254
Total biosciences	44,588	61,566
Other	7,059	5,433
Total	$120,226	$124,832

(1) Represents an upfront payment for an exclusive license and the rights to manufacture and sell pandemic influenza products in support of our contract with BARDA to establish a CIADM.

The increase in spending on Biodefense product candidates, detailed in the table above, was primarily attributable to the timing of development efforts on several programs as we completed various studies and prepared for subsequent studies and trials. The increase in spending for our large-scale manufacturing for BioThrax program was primarily due to non-clinical studies and preparation for and initiation of consistency lot manufacturing. The increase in spending for BioThrax related programs was related to clinical and non-clinical studies to support applications for label expansion for BioThrax. The increase in spending for PreviThrax was primarily due to model optimization. The decrease in spending for NuThrax was primarily due to the timing of clinical and non-clinical trial activities. The increase in pandemic influenza is related to an upfront payment for an exclusive license to the rights to manufacture and sell pandemic influenza products. The decrease in spending for Thravixa was primarily due to the timing of clinical trial activities. The decrease in spending for Anthrivig was primarily due to the completion of clinical trial activities. We anticipate spending for our Anthrivig and Thravixa product candidates will be minimal in the future in light of reduced government funding for these product candidates. The increase in spending for our other Biodefense activities was primarily due to increased spending related to manufacturing development, partially offset by decreased spending associated with our double mutant recombinant protective antigen anthrax vaccine.

The decrease in spending on Biosciences product candidates, detailed in the table above, was primarily attributable to the timing of development efforts. The decrease in spending for our tuberculosis vaccine product candidate is related to the timing of costs incurred for the continued conduct of a Phase IIb clinical trial along with process development and manufacturing activities. As a result of clinical trial data published in February 2013, we expect that future spending will decrease significantly as we close out our tuberculosis product development efforts. The spending for our TRU-016 product candidate in 2012 and 2011 is primarily related to clinical manufacturing and clinical trial activities. The increase in spending for our T-Scorp product candidate was primarily due to characterization studies. The decrease in spending for our ES301 product candidate is primarily due to the timing of process and formulation development along with non-clinical study activities. The decrease in spending for our zanolimumab product candidate was primarily due to upfront and milestone payments incurred in 2011 related to our May 2011 acquisition

of certain assets of TenX BioPharma, Inc., partially offset by process and clinical development activities in 2012. We anticipate future spending for our ES301 and zanolimumab product candidates will be minimal unless we receive third party funding for these product candidates. The decrease in spending for our influenza vaccine product candidate is primarily due to the timing of process and manufacturing development. The decrease in spending for Typhella was primarily due to the completion of manufacturing and clinical studies coupled with the sale of it and the related spi-VEC technology in the second quarter of 2012. The decrease in spending for our other Biosciences activities was primarily due to a reduction of the contingent value right obligations associated with our agreement with Pfizer, decreased spending associated with our X1 product candidate and decreased spending associated with our preclinical product candidates, partially offset by increased spending associated with development of platform technologies. The spending for other research and development activities was primarily due to central research and development activities not attributable to product candidates.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $1.7 million, or 2%, to $76.0 million for 2012 from $74.3 million for 2011. This increase is primarily due to increased spending related to professional services and personnel costs. The majority of the expense is attributable to the Biodefense segment, in which selling, general and administrative expenses increased by $3.7 million, or 7%, to $56.0 million during 2012 from $52.4 million during 2011. Selling, general and administrative expenses related to our Biosciences segment decreased by $1.9 million, or 9%, to $20.0 million during 2012 from $21.9 million during 2011.

Impairment of in-process research and development

Impairment of in-process research and development was $9.6 million for the year ended December 31, 2012. The impairment charge for the year ended December 31, 2012 resulted from the full impairment of our SBI-087 in-process research and development asset during the year ended December 31, 2012. There was no impairment for the year ended December 31, 2011.

Total Other Income (Expense)

Total other income increased by $2.3 million to net other income of $2.1 million for the year ended December 31, 2012 from net other expense of $156,000 for the year ended December 31, 2011. The increase was primarily due to a business interruption insurance recovery related to a power outage at our Lansing, Michigan facility.

Income Taxes

Provision for income taxes decreased by $1.9 million, or 12%, to $13.9 million for 2012 from $15.8 million for 2011. The provision for income taxes for 2012 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of $37.4 million and an effective annual tax rate of approximately 37%. The provision for income taxes for 2011 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of $38.9 million and an effective annual tax rate of approximately 41%. The decrease in the effective annual tax rate is primarily related to orphan drug tax credits received on qualified expenditures from our TRU-016 product candidate. The provision for income taxes for 2012 reflects an orphan drug tax credit of $2.9 million. The provision for income taxes for 2011 reflects research and development tax credits of $1.4 million. The provision for income taxes for 2012 does not reflect research and development tax credits, as the legislation extending the credit was not signed into law until January 2013.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest decreased by $1.5 million, or 22%, to $5.4 million for 2012 from $6.9 million for 2011. The decrease resulted primarily from the timing of clinical and development activities and related expenses incurred by our joint ventures. These amounts represent the portion of the losses incurred by the joint ventures for the years ended December 31, 2012 and 2011, respectively that is attributable to our joint venture

partners.

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

Revenues

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

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

Cost of Product Sales

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

Research and Development Expenses

Research and development expenses increased by $35.5 million, or 40%, to $124.8 million for 2011 from $89.3 million for 2010. This increase primarily reflects higher contract service and personnel-related costs, and includes increased expenses of $28.7 million for product candidates and technology platform development activities that are categorized in the Biosciences segment, increased expenses of $5.6 million for product candidates that are categorized in the Biodefense segment, and increased expenses of $1.2 million in other research and development, which are in support of central research and development activities. Net of development contract and grant reimbursements along with the net loss attributable to noncontrolling interests, we incurred research and development expenses of $47.0 million and $50.0 million, respectively, during 2011 and 2010.

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

	Year ended December 31,	
(in thousands)	2011	2010
Biodefense:		
Large-scale manufacturing for BioThrax	$13,138	$9,099
BioThrax related programs	6,961	7,201
PreviThrax	14,404	3,767

NuThrax	11,632	9,876
Thravixa	3,460	8,148
Anthrivig	2,608	5,937
Other Biodefense	5,630	8,163
Total Biodefense	57,833	52,191
Biosciences:		
Tuberculosis vaccine	19,032	13,690
TRU-016	13,503	2,205
ES-301 (formerly DRACO)	7,165	693
Zanolimumab	4,821	-
Influenza vaccine	2,520	4,088
Typhella	1,271	3,398
Other Biosciences	13,254	8,821
Total Biosciences	61,566	32,895
Other	5,433	4,209
Total	$124,832	$89,295

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

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

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

Selling, General and Administrative Expenses

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

Total Other Income (Expense)

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

Income Taxes

Provision for income taxes decreased by $10.4 million, or 40%, to $15.8 million for 2011 from $26.2 million for 2010. The provision for income taxes for 2011 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of $38.9 million and an effective annual tax rate of approximately 41%. The provision for income taxes for 2010 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of $77.9 million and an effective annual tax rate of approximately 34%. The increase in the effective annual tax rate is primarily related to the timing of deductions related to our large scale manufacturing facility and the utilization of state net operating losses. The provision for income taxes also reflects research and development tax credits of $1.4 million for 2011 and $1.8 million for 2010.

Net Loss Attributable to Noncontrolling Interest

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

Liquidity and Capital Resources

Sources of Liquidity

We have funded our cash requirements from inception through 2012 principally with a combination of revenues from BioThrax product sales, debt financings and facilities leases, development funding from government entities and non-government and philanthropic organizations and collaborative partners, and the net proceeds from our initial public offering and the sale of our common stock upon exercise of stock options. We have operated profitably for each of the five years ended December 31, 2012.

As of December 31, 2012, we had cash and cash equivalents of $141.7 million. Additionally, at December 31, 2012, our accounts receivable balance was $96.0 million.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2012, 2011 and 2010.

	Year ended December 31,		
(in thousands)	2012	2011	2010
Net cash provided by (used in):			
Operating activities(1)	$39,644	$12,186	$98,000
Investing activities	(40,114)	(53,963)	(23,456)
Financing activities	(1,765)	16,659	(8,449)
Total net cash provided by (used in)	$(2,235)	$(25,118)	$66,095

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

Net cash provided by operating activities of $39.6 million in 2012 was principally due to our net income attributable to Emergent BioSolutions Inc. of $23.5 million, a net increase in income taxes of $11.4 million related to timing differences, non-cash charges of $11.1 million for stock-based compensation, $11.2 million for depreciation and amortization, and $9.6 million for the impairment of in-process research and development, partially offset by an increase in accounts receivable of $21.9 million due to the timing of collection of amounts billed primarily to CDC.

Net cash provided by operating activities of $12.2 million in 2011 was principally due to our net income attributable to Emergent BioSolutions Inc. of $23.0 million, a net increase in income taxes of $21.6 million related to timing differences, non-cash charges of $10.7 million for stock-based compensation, $9.4 million for depreciation and amortization, and $5.3 million for development expenses primarily from our joint ventures partially offset by a decrease in accounts receivable of $34.8 million due to the timing of collection of amounts billed primarily to HHS and a decrease in deferred revenue of $10.9 million primarily from our Abbott collaboration.

Net cash provided by operating activities of $98.0 million in 2010 was due principally to net income attributable to Emergent BioSolutions Inc. of $51.7 million, a decrease in accounts receivable of $19.1 million due to the timing of collection of amounts billed primarily to HHS, a net increase in income taxes related to timing differences of $4.8 million, a $6.2 million increase in accrued compensation and non-cash charges of $7.1 million for stock-based compensation, $6.0 million for depreciation and amortization, and $6.0 million for development expenses from our joint ventures.

Net cash used in investing activities of $40.1 million in 2012 was primarily due to capital expenditures of $53.8 million, and includes construction and related costs for our facility in Baltimore, Maryland, construction and renovation of facilities at our Lansing, Michigan campus, and costs of other infrastructure and equipment investments, partially offset by net proceeds of $11.8 million from the sale of our two Frederick, Maryland buildings and the maturity of U.S. Treasury securities of $2.0 million.

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

Net cash used in investing activities of $23.5 million in 2010 was primarily due to capital expenditures of approximately $22.1 million for validation and qualification activities for Building 55 and build-out activities for our Baltimore, Maryland facility and infrastructure investments and other equipment along with net cash paid to acquire Trubion 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 financing activities of $1.8 million in 2012 resulted primarily from $10.2 million in principal payments on indebtedness, including $7.7 million in repayment of debts related to our Frederick, MD buildings, $5.9 million for stock repurchases under our share repurchase program, a $1.7 million CVR payment to former Trubion

stockholders and option holders, partially offset by $13.5 million in advances under our construction and equipment loans with PNC Bank related to the renovation, improvement and equipment purchases at our Baltimore facility and $1.6 million related to excess tax benefits from the exercise of stock options.

Net cash provided by financing activities of $16.7 million in 2011 resulted primarily from $27.5 million in advances under our construction and equipment loans with PNC Bank related to the renovation, improvement and equipment purchase at our Baltimore facility, $10.0 million in proceeds from stock option exercises and $4.6 million related to excess tax benefits from the exercise of stock options, partially offset by $15.5 million in principal payments on indebtedness and a $10.0 million CVR payment to former Trubion stockholders and option holders.

Net cash used in financing activities of $8.5 million in 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 $2.6 million related to excess tax benefits from the exercise of stock options.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2012:

	Payments due by period					
(in thousands)	Total	2013	2014	2015	2016	After 2016
Contractual obligations:						
Long-term indebtedness including current portion	$62,774	$4,470	$23,075	$2,607	$2,607	$30,015
Operating lease obligations	10,652	3,447	3,497	2,331	1,377	-
Total contractual obligations	$73,426	$7,917	$26,572	$4,938	$3,984	$30,015

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 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 $198 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 on our success in developing and commercializing our product candidates. If we are unable to commercialize these product candidates, or experience significant delays or unanticipated costs in doing so, our business would be materially affected." 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, 2012, we had $62.8 million principal amount of debt outstanding, comprised primarily of the following:

- § $18.2 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;
- § $4.1 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;
- § $29.4 million outstanding under a construction loan from PNC Bank used to fund the ongoing renovation of our Baltimore, Maryland facility; and
- § $11.1 million outstanding under an equipment loan from PNC Bank used to fund equipment purchases at our Baltimore, Maryland facility.

Our debt instruments contain financial and operating covenants. In particular:

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

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

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

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

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

Under our construction loan from PNC Bank to finance a portion of the construction and renovation costs at our Baltimore, Maryland facility, we are required to make monthly principal payments of $125,000. A residual payment of approximately $22.6 million is due upon maturity in July 2017. Interest is payable monthly and accrues at an

annual rate equal to the one-month LIBOR plus 3.0%.

Under our equipment loan from PNC Bank to finance a portion of the equipment purchase for our Baltimore, Maryland facility, we are required to make monthly principal payments of $92,000. A residual payment of approximately $5.6 million is due upon maturity in December 2017. Interest is payable monthly and accrues at an annual rate equal to the one-month LIBOR plus 3.0%.

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, development contract and grant funding, and any lines of credit we may establish from time to time. There are numerous risks and uncertainties associated with BioThrax product sales and with the development and commercialization of our product candidates. We may seek additional external financing to provide additional financial flexibility. Our future capital requirements will depend on many factors, including:

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

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 or debt offerings, bank loans or collaboration and licensing arrangements. We have an effective shelf registration statement on file with the Securities and Exchange Commission that allows us to issue up to an aggregate of $180 million of equity, debt and certain other types of securities through one or more future offerings. Current economic conditions may make it difficult to obtain financing on attractive terms or at all. Lenders may be able to impose covenants on us that could be difficult to satisfy, which could put us at increased risk of defaulting on debt. If financing is unavailable or lost, we could be forced to delay, reduce the scope of or eliminate our research and development programs or reduce our planned commercialization efforts.

Our ability to borrow amounts under any line of credit we may establish will likely be subject to our satisfaction of specified conditions. Additional equity or debt financing, development contracts and grants or 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 acquiring or investing in

companies, businesses, products or technologies, 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.

Share Repurchase Program

On May 17, 2012, our board of directors authorized the repurchase, from time to time through December 31, 2013, of up to an aggregate of $35 million of our common stock under a share repurchase program. For the year ended December 31, 2012, we repurchased approximately 399,000 shares for $5.8 million.

Recent Accounting Pronouncements

In June 2011, the FASB issued ASU No. 2011-05, which amended ASC Topic 220 regarding presentation of comprehensive income. The amendments in ASU No. 2011-05 require that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In the two-statement approach, the first statement should present total net income and its components followed consecutively by a second statement that should present total other comprehensive income, the components of other comprehensive income, and the total of comprehensive income. This amendment is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. We elected to present comprehensive income in two separate but consecutive statements as part of the consolidated financial statements included in this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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

The Board of Directors and Stockholders of Emergent BioSolutions Inc.

We have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2012. 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. at December 31, 2012 and 2011, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2012, 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.'s internal control over financial reporting as of December 31, 2012, 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 8, 2013 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia
March 8, 2013

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

	December 31,	
	2012	2011
ASSETS		
Current assets:		
Cash and cash equivalents	$141,666	$143,901
Investments	-	1,966
Accounts receivable	96,043	74,153
Inventories	15,161	14,661
Deferred tax assets, net	1,264	1,735
Income tax receivable, net	-	9,506
Restricted cash	-	220
Prepaid expenses and other current assets	9,213	8,276
Total current assets	263,347	254,418
Property, plant and equipment, net	241,764	208,973
In-process research and development	41,800	51,400
Goodwill	5,502	5,502
Assets held for sale	-	11,765
Deferred tax assets, net	11,087	13,999
Other assets	730	807
Total assets	$564,230	$546,864
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$31,297	$40,530
Accrued expenses and other current liabilities	1,488	1,170
Accrued compensation	22,726	20,884
Contingent value rights, current portion	-	1,748
Income tax payable, net	115	-
Long-term indebtedness, current portion	4,470	5,360
Deferred revenue	1,811	1,362
Total current liabilities	61,907	71,054
Contingent value rights, net of current portion	-	3,005
Long-term indebtedness, net of current portion	58,304	54,094
Other liabilities	1,891	1,984
Total liabilities	122,102	130,137
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2012 and December 31, 2011, respectively	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 36,272,550 shares issued and 35,869,392 shares outstanding at December 31, 2012; 36,002,698 shares issued and	36	36

outstanding at December 31, 2011		
Treasury stock, at cost, 403,158 and 0 common shares at December 31, 2012 and 2011, respectively	(5,906)	-
Additional paid-in capital	230,964	220,654
Accumulated other comprehensive loss	(4,129)	(3,313)
Retained earnings	220,393	196,869
Total Emergent BioSolutions Inc. stockholders' equity	441,358	414,246
Noncontrolling interest in subsidiaries	770	2,481
Total stockholders' equity	442,128	416,727
Total liabilities and stockholders' equity	$564,230	$546,864

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,		
	2012	2011	2010
Revenues:			
Product sales	$215,879	$202,409	$251,381
Contracts and grants	66,009	70,975	34,790
Total revenues	281,888	273,384	286,171
Operating expense:			
Cost of product sales	46,077	42,171	47,114
Research and development	120,226	124,832	89,295
Selling, general and administrative	76,018	74,282	76,205
Impairment of in-process research and development	9,600	-	-
Income from operations	29,967	32,099	73,557
Other income (expense):			
Interest income	134	105	832
Interest expense	(6)	-	-
Other income (expense), net	1,970	(261)	(1,023)
Total other income (expense)	2,098	(156)	(191)
Income before provision for income taxes	32,065	31,943	73,366
Provision for income taxes	13,922	15,830	26,182
Net income	18,143	16,113	47,184
Net loss attributable to noncontrolling interest	5,381	6,906	4,514
Net income attributable to Emergent BioSolutions Inc.	$23,524	$23,019	$51,698
Earnings per share - basic	$0.65	$0.65	$1.63
Earnings per share - diluted	$0.65	$0.64	$1.59
Weighted-average number of shares - basic	36,080,495	35,658,907	31,782,286
Weighted-average number of shares - diluted	36,420,662	36,206,052	32,539,500

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

Emergent BioSolutions Inc. and Subsidiaries
Consolidated Statements of Comprehensive Income
(in thousands)

	December 31,		
	2012	2011	2010
Net income attributable to Emergent BioSolutions Inc.	$23,524	$23,019	$51,698
Foreign currency translations, net of tax	(816)	(1,203)	(634)
Comprehensive income	$22,708	$21,816	$51,064

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,		
	2012	2011	2010
Cash flows from operating activities:			
Net income	$18,143	$16,113	$47,184
Adjustments to reconcile to net cash provided by operating activities:			
Stock-based compensation expense	11,115	10,739	7,063
Depreciation and amortization	11,197	9,355	5,990
Deferred income taxes	3,383	20,188	9,229
Non-cash development expenses from joint venture	3,670	5,290	5,995
Change in fair value of contingent value rights	(3,005)	221	-
Impairment of in-process research and development	9,600	-	-
Impairment of long-lived assets	-	976	1,218
Provision for impairment of accrued interest on note receivable	-	-	1,032
Excess tax benefits from stock-based compensation	(1,588)	(4,608)	(2,609)
Other	(40)	392	(38)
Changes in operating assets and liabilities:			
Accounts receivable	(21,890)	(34,873)	19,094
Inventories	(500)	(1,939)	799
Income taxes	8,055	1,422	(4,454)
Prepaid expenses and other assets	(1,038)	660	(764)
Accounts payable	274	2,510	3,392
Accrued expenses and other liabilities	169	(95)	(447)
Accrued compensation	1,649	(3,303)	6,175
Deferred revenue	449	(10,863)	(838)
Net cash provided by operating activities	39,643	12,185	98,021
Cash flows from investing activities:			
Purchases of property, plant and equipment	(53,845)	(54,026)	(22,101)
Proceeds from sale of assets	11,765	-	-
Proceeds from maturity of investments	1,966	4,250	6,518
Purchase of investments	-	(4,187)	-
Acquisition of Trubion Pharmaceuticals, Inc., net of cash acquired	-	-	(17,873)
Repayment of note receivable	-	-	10,000
Net cash used in investing activities	(40,114)	(53,963)	(23,456)
Cash flows from financing activities:			
Proceeds from borrowings on long-term indebtedness	13,547	27,522	15,000
Issuance of common stock subject to exercise of stock options	761	10,026	7,235
Excess tax benefits from stock-based compensation	1,588	4,608	2,609
Principal payments on long-term indebtedness and line of credit	(10,227)	(15,494)	(33,291)
Contingent value right payment	(1,748)	(10,000)	-
Purchase of treasury stock	(5,906)	-	-
Restricted cash deposit	220	(3)	(2)
Net cash provided by (used in) financing activities	(1,765)	16,659	(8,449)
Effect of exchange rate changes on cash and cash equivalents	1	1	(21)
Net increase (decrease) in cash and cash equivalents	(2,235)	(25,118)	66,095

Cash and cash equivalents at beginning of year	143,901	169,019	102,924
Cash and cash equivalents at end of year	$141,666	$143,901	$169,019
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$2,137	$1,740	$2,176
Cash paid during the year for income taxes	$6,537	$4,280	$22,440
Supplemental information on non-cash investing and financing activities:			
Issuance of common stock to acquire Trubion Pharmaceuticals, Inc.	$-	$-	$61,203
Purchases of property, plant and equipment unpaid at year end	$5,612	$15,509	$3,519

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		Additional Paid-In	Treasury Stock		Accumulated Other Comprehensive	Noncontrolling Interest in	Retained	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	Loss	Subsidiary	Earnings	Equity
Balance at December 31, 2009	30,831,360	$ 31	$ 120,492	-	$ -	$ (1,476)	$ 2,616	$ 122,152	$ 243,815
Issuance of stock for Trubion Pharmaceuticals, Inc. acquisition	3,351,817	3	61,200	-	-	-	-	-	61,203
Employee equity award plans activity	828,246	1	15,997	-	-	-	-	-	15,998
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, net of tax	-	-	-	-	-	(634)	-	-	(634)
Balance at December 31, 2010	35,011,423	$ 35	$ 197,689	-	$ -	$ (2,110)	$ 4,097	$ 173,850	$ 373,561
Employee equity award plans activity	991,275	1	22,965	-	-	-	-	-	22,966
Non-cash development expenses from joint venture	-	-	-	-	-	-	5,290	-	5,290
Net loss attributable to noncontrolling interest	-	-	-	-	-	-	(6,906)	-	(6,906)
Net income	-	-	-	-	-	-	-	23,019	23,019
	-	-	-	-	-	(1,203)	-	-	(1,203)

Foreign currency translation, net of tax									
Balance at December 31, 2011	36,002,698	$ 36	$ 220,654	-	$ -	$ (3,313)	$ 2,481	$ 196,869	$ 416,727
Employee equity award plans activity	269,852	-	10,310			-	-	-	10,310
Non-cash development expenses from joint venture	-	-	-	-	-	-	3,670	-	3,670
Net loss attributable to noncontrolling interest	-	-	-	-	-	-	(5,381)	-	(5,381)
Treasury stock	-	-	-	(403,158)	(5,906)	-	-		(5,906)
Net income	-	-	-	-	-	-	-	23,524	23,524
Foreign currency translation, net of tax	-	-	-	-	-	(816)	-	-	(816)
Balance at December 31, 2012	36,272,550	$ 36	$ 230,964	(403,158)	$ (5,906)	$ (4,129)	$ 770	$ 220,393	$ 442,128

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 specialty pharmaceutical company seeking to protect and enhance life by developing and offering specialized products to healthcare providers and governments for use in addressing medical needs and emerging health threats. The Company is developing products to be offered both to 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 subsequently renamed and converted this subsidiary 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 renamed Microscience as Emergent Product Development UK Limited. The assets acquired from Antex are held in an entity incorporated as Emergent Product Development Gaithersburg Inc., and the assets acquired from ViVacs are held in an entity 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 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 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 fair value of U.S. Treasury securities (Level 2) is obtained from an independent pricing service and is based on recent sales of similar securities and other observable market data.

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.

Restricted cash

Restricted cash at December 31, 2011 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, 2011 the Company had restricted cash of $220,000. The Company had no restricted cash as of December 31, 2012.

Significant customers and accounts receivable

For the years ended December 31, 2012, 2011 and 2010, the Company's primary customer was the U.S. Department of Health and Human Services ("HHS"). For the years ended December 31, 2012, 2011 and 2010, revenues from HHS and HHS agencies comprised 97.9%, 91.3% and 97.5%, respectively, of total revenues and are included in the Company's Biodefense segment. As of December 31, 2012 and 2011, the Company's receivable balances were comprised of 99.9% and 90.0%, respectively, from this customer. Unbilled accounts receivable, included in accounts

receivable, totaling $19.9 million and $19.0 million as of December 31, 2012 and 2011, 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 the U.S. government and collaborative partners 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, 2012 and 2011, 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. government for product sales and from government agencies under government grants and development contracts, management deems there to be minimal credit risk.

Inventories

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

Property, plant and equipment

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

Buildings	31-39 years
Building improvements	10-39 years
Furniture and equipment	3-15 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 2005 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 or title has passed to the Company's customer;
§ the fee is fixed or determinable; and
§ collectability 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 to the customer. 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 to the customer.

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. Effective September 30, 2011, the Company has a contract from the Centers for Disease Control and Prevention ("CDC"), an operating division of HHS, to supply up to 44.75 million doses of BioThrax over a five year period. Under the Company's contract from the CDC, the Company invoices the CDC and recognizes the related revenue upon acceptance by the government at delivery site, at which time title to the product passes the CDC.

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 both of the following criteria are met: (1) the delivered item(s) has value to the customer on a stand-alone basis; (2) 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 the relative selling price of each deliverable. 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. 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, 2012, the costs incurred under the contracts and grants approximated the revenue earned.

The Company previously generated revenues from its agreements with Pfizer, Inc. ("Pfizer") and Abbott Laboratories ("Abbott"). Certain internal and external research and development costs and patent costs were reimbursed in connection with the Company's agreements. Reimbursed costs under the Pfizer agreement, which was terminated in September 2012, were recognized as revenue in the period in which the costs were incurred. Under the Company's agreement with Abbott, which was terminated in March 2012, Abbott shared development and clinical costs equally with the Company. Under the collaboration agreement, each of the Company and Abbott were required to report to the other party the total costs incurred for development. The total spending by each party was then compared to the spending by to the other party. In the event that the Company's spending for a given quarter exceeded the spending of Abbott, the Company recorded a net receivable in its financial statements equal to the difference between the Company's spending and 50% of the total spending for the period, and recognized revenue in this amount. If Abbott's spending for the quarterly period exceeded the Company's spending, the Company recorded a net payable in its financial statements equal to the difference between the Company's spending and 50% of the total spending, and recorded additional research and development expenses in this amount.

Contingent value rights

The Company records contingent value right ("CVR") obligations at fair value. Obligations generally become due and payable only upon achievement of certain developmental, regulatory or commercial milestones. 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 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 the Company acquires 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 cost projections used to value acquired IPR&D are, 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 are commensurate with the stage of development of the projects and uncertainties in the economic estimates used in the projections described above. The Company determines 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 the likelihood and timing of 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. 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 are assessed for impairment on an annual basis or more frequently if indicators of impairment are present. The Company has selected October 1st as its annual impairment test date.

Goodwill

The Company assesses the carrying value of goodwill on an annual basis, 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 unit to the carrying value of the reporting unit. If the carrying value of the reporting unit exceeds the fair value of the reporting unit, then the second step of the impairment test is performed in order to determine the implied fair value of the reporting unit's goodwill. If the carrying value of the reporting unit's goodwill exceeds its implied fair value, an impairment loss equal to the difference is recorded and charged to general and administrative expense. The Company calculates the fair value of the reporting unit utilizing the income approach. The income approach utilizes a discounted cash flow model, using a discount rate based on the Company's estimated weighted average cost of capital.

The determination of the fair value of a reporting unit 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. The Company selected October 1st

as its annual impairment test date.

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.

Research and development

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

Comprehensive income

Comprehensive income is comprised of net income and other changes in equity that are excluded from net income. The Company includes 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, 2012, 2011 and 2010, the Company incurred interest of $2.2 million, $1.7 million and $1.8 million, respectively. Of these amounts, the Company capitalized $2.2 million, $1.7 million and $1.8 million, respectively.

Certain risks and uncertainties

The Company has derived substantially all of its revenue from sales of BioThrax under contracts with the U.S. government. The Company's CDC 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.

Accounting for stock-based compensation

The Company has two stock-based employee compensation plans, the Second 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 Emergent Plans have both incentive and non-qualified stock option features. The Company no longer grants equity awards under the 2004 Plan.

On May 17, 2012, the Company's shareholders approved amendments to the 2006 Plan, which increased the number of shares of common stock available for issuance under plan awards by 2,500,000. As of December 31, 2012, an aggregate of 11,178,826 shares of common stock were authorized for issuance under the 2006 Plan, of which a total of 3,752,260 shares of common stock remain available for future awards to be made to plan participants. As part of the May 2012 amendment, awards of restricted stock units after May 17, 2012 are counted against the maximum aggregate number of shares of common stock available for issuance under the 2006 Plan as 1.86 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 compensation committee of the Company's board of directors, which administers the Emergent Plans. Each equity award granted under the Emergent Plans vests as specified in the relevant agreement with the award recipient and no option can be exercised after ten years from the date of grant.

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,		
	2012	2011	2010
Expected dividend yield	0 %	0 %	0 %
Expected volatility	41-52 %	60 %	55 %
Risk-free interest rate	0.36-0.54%	0.35-1.04%	0.49-1.46%
Expected average life of options	3.4 years	3.4 years	3.4 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 (implied volatility) during a period. The Company analyzed its own historical volatility to estimate expected volatility over the same period as the expected average life of the options.
- 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.

Recent accounting pronouncements

In June 2011, the FASB issued ASU No. 2011-05, which amended ASC Topic 220 regarding presentation of comprehensive income. The amendments in ASU No. 2011-05 require that all nonowner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In the two-statement approach, the first statement should present total net income and its components followed consecutively by a second statement that should present total other comprehensive income, the components of other comprehensive income, and the total of comprehensive income. This amendment is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The Company elected to present comprehensive income in two separate but consecutive statements as part of the consolidated financial statements included in this Annual Report on Form 10-K.

3. Fair value measurements

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

	At December 31, 2012			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Investment in money market funds (1)	$42,720	$-	$-	$42,720
Total assets	$42,720	$-	$-	$42,720

	At December 31, 2011			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Investment in money market funds (1)	$73,005	$-	$-	$73,005
U.S. Treasury securities (2)	-	1,966	-	1,966
Total assets	$73,005	$1,966	$-	$74,971
Liabilities:				
Contingent value rights	$-	$-	$4,753	$4,753
Total liabilities	$-	$-	$4,753	$4,753

(1) Included in cash and cash equivalents in accompanying consolidated balance sheets.
(2) Included in investments in accompanying consolidated balance sheets.
As of December 31, 2012 and 2011, the Company did not have any transfers between Level 1 and Level 2 assets or liabilities.
The fair value of the CVR obligations is based on management's assessment of certain development and collaboration milestones, which are inputs that have no observable market (Level 3). The obligation is measured using a discounted cash flow model. For the year ended December 31, 2012, the Company recorded a decrease in the CVR obligations of $3.0 million due to Pfizer ceasing development of programs related to the CVR milestones and made a $1.7 million CVR payment under the Company's agreement with Abbott. For the year ended December 31, 2011, the Company recorded an increase of $221,000 in the value for the CVRs, due to an adjustment to the discount rates along with an update to the probability and estimated timing of achievement for certain development milestones, and made a $10.0 million CVR payment under the Abbott agreement. The adjustments to fair value are classified in the Company's

statement of operations as research and development expense within the Company's Biosciences segment.

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) during the year ended December 31, 2012 and 2011.

(in thousands)	
Balance at January 1, 2011	$14,532
Expense (income) included in earnings	221
Settlements	(10,000)
Purchases, sales and issuances	-
Transfers in/(out) of Level 3	-
Balance at December 31, 2011	4,753
Expense (income) included in earnings	(3,005)
Settlements	(1,748)
Purchases, sales and issuances	-
Transfers in/(out) of Level 3	-
Balance at December 31, 2012	$-

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. During the year ended December 31, 2012, the Company's SBI-087 IPR&D asset was measured at fair value on a nonrecurring basis (see Note 8), which is categorized as a level 3 fair value measurement. As of December 31, 2012 and 2011, the Company had no other assets or liabilities that were measured at fair value on a nonrecurring basis.

Both the carrying value and fair value of long-term indebtedness at December 31, 2012 and 2011 were $62.8 million and $59.5 million, respectively.

4. Investments

The Company has no available-for-sale securities at December 31, 2012. In 2011, the Company invested in U.S. Treasury Securities that were short in duration. The following is a summary of the Company's available-for-sale securities at December 31, 2011:

	At December 31, 2011			
(in thousands)	Amortized Costs	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Market Value
U.S. Treasury securities	$1,966	$ -	$ -	$ 1,966

The estimated fair value and amortized cost of investments available-for-sale by contractual maturity are due in one year or less. Unrealized gains and losses on cash equivalents and available-for-sale securities are included in accumulated other comprehensive income in the accompanying consolidated balance sheets. As of December 31, 2012 and 2011, the unrealized losses on investments were immaterial.

5. Accounts receivable

Accounts receivable consist of the following:

	December 31,	
(in thousands)	2012	2011
Billed	$76,155	$55,188
Unbilled	19,888	18,965
Total	$96,043	$74,153

6. Inventories

Inventories consist of the following:

	December 31,	
(in thousands)	2012	2011
Raw materials and supplies	$2,733	$2,313
Work-in-process	9,813	10,149
Finished goods	2,615	2,199
Total inventories	$15,161	$14,661

7. Property, plant and equipment

Property, plant and equipment consist of the following:

	December 31,	
(in thousands)	2012	2011
Land and improvements	$4,839	$4,115
Buildings, building improvements and leasehold improvements	66,953	26,122
Furniture and equipment	91,772	42,135
Software	15,691	11,854
Construction-in-progress	105,452	157,206
	284,707	241,432
Less: Accumulated depreciation and amortization	(42,943)	(32,459)
Total Property, plant and equipment, net	$241,764	$208,973

For the year ended December 31, 2012, 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. For the year ended December 31, 2011, construction-in-progress included costs related to Building 55, along with costs related to the purchase and renovation of the Company's manufacturing facility in Baltimore, Maryland.

Depreciation and amortization expense was $11.2 million, $9.4 million and $6.0 million for the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012, 2011 and 2010 there was no unamortized internal use software-cost.

8. In-process research and development and goodwill

During the year ended December 31, 2012, Pfizer terminated its development programs with respect to the Company's SBI-087 product candidate. The Company considered this termination a potential indicator of impairment of the related SBI-087 IPR&D asset, and assessed the fair value of this asset. As part of the assessment, the Company considered the impact of Pfizer's decision, along with the Company's decision to no longer pursue further development of this asset due to reduced overall probability of success and increased development costs for the product candidate. As a result, the Company recorded an impairment charge of $9.6 million during the year ended December 31, 2012, which represented the entire carrying value of the SBI-087 IPR&D asset. This charge is classified in the Company's statement of operations as impairment of in-process research and development, within the Company's Biosciences segment.

As a result of the impairment of the SBI-087 IPR&D asset, the Company also performed an analysis of the Biosciences therapeutic reporting unit, which contains all goodwill reported on the Company's consolidated balance sheets as of December 31, 2012. Based on the analysis, the Company concluded that goodwill was not more likely than not impaired and therefore an interim impairment analysis was deemed unnecessary.

The Company completed its annual impairment assessment for its IPR&D assets and goodwill as of October 1, 2012 and 2011, respectively, and determined that the fair value of the IPR&D assets and goodwill was in excess of carrying

value. On December 21, 2011, Abbott notified the Company that it was terminating the collaboration agreement effective March 20, 2012. The Company determined the Abbott termination of the collaboration agreement was an indication of a potential impairment of the Company's TRU-016 IPR&D asset and goodwill. The Company performed an assessment and determined that there was no interim impairment of these assets as of December 31, 2011. The Company has determined that all of its IPR&D assets and goodwill are included in the Biosciences therapeutics reporting unit, a component of the Biosciences business segment.

9. Assets held for sale

During the year ended December 31, 2012, the Company completed the sale of two buildings, which were classified as assets held for sale, for $12.2 million. The Company realized proceeds equal to the carrying value, less cost to sell, of these buildings and there was no gain or loss on the 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. There was no impairment charge for the year ended December 31, 2012. The Company recorded impairment charges of $1.0 million and $1.2 million for the years ended December 31, 2011 and 2010, respectively, which are classified in the Company's statement of operations as selling, general and administrative expense within the Company's Biosciences segment.

10. Long-term debt

The components of long-term indebtedness are as follows:

	December 31,	
(in thousands)	2012	2011
Construction loan dated July 2011; one month LIBOR plus 3%, due July 2017	$29,375	$26,095
Equipment loan dated August 2011; one month LIBOR plus 3%, due December 2017	11,068	1,426
Term loan dated December 2009; three month LIBOR plus 3.25%, due December 2014	18,200	19,717
Term loan dated November 2009; three month LIBOR plus 3.25%, due November 2014	4,131	4,478
Loan dated October 2004; 3.0%, repaid in March 2012	-	2,500
Term loan dated October 2004; 3.48%, repaid in March 2012	-	5,238
Total long-term indebtedness	62,774	59,454
Less current portion of long-term indebtedness	(4,470)	(5,360)
Noncurrent portion of long-term indebtedness	$58,304	$54,094

In August 2011, the Company entered into a loan agreement with PNC Bank ("PNC") to provide the Company with an equipment loan of up to $12.0 million to fund equipment purchases at the Company's Baltimore, Maryland product development and manufacturing facility. Under the equipment loan agreement, PNC agreed to make advances to the Company of up to $12.0 million through December 2012 based on periodic requests from the Company. The Company was required to make monthly interest only payments through December 2012. Beginning in December 2012, the Company is required to make monthly payments of principal of $92,000 plus interest with a balloon payment for the remaining unpaid principal and interest. The loan is collateralized by the equipment purchased. The annual interest rate is based on the one month LIBOR plus 3.0% and equaled 3.21% as of December 31, 2012.

In July 2011, the Company entered into a loan agreement and related agreements with PNC, under which PNC agreed to provide the Company with a construction loan of up to $30.0 million, primarily to fund the renovation and improvement of the Baltimore facility. A portion of the loan was also used to repay the Company's loan with HSBC Bank, which the Company used to finance a portion of the purchase price of the facility. Under the Company's loan agreement with PNC, PNC agreed to make advances to the Company of up to $30.0 million through July 2012. The Company was required to make monthly interest only payments through July 2012. Beginning in July 2012, the Company is required to make monthly payments of $125,000 plus interest with a balloon payment for the remaining unpaid principal and interest due in July 2017. Payment of the loan is secured by the Baltimore building along with Emergent BioDefense Operations Lansing LLC's accounts receivable under the Company's BioThrax supply

contracts. The annual interest rate is based on the one month LIBOR plus 3.0% and equaled 3.21% as of December 31, 2012.

Under the terms of the construction and equipment loans with PNC, the Company is required to maintain certain financial covenants including minimum cash and liquid investments balance of $50.0 million, a leverage ratio of less than 2.0 and a debt coverage ratio of not less than 1.25 to 1.00. The leverage ratio is calculated by dividing the funded debt by net income before interests, taxes, depreciation, amortization, equity award compensation, non-cash development expenses from joint ventures, write-ff off intangibles and changes in fair value of contingent value rights for the most recent four quarters. The debt coverage ratio is calculated by dividing net income before interests, taxes, depreciation, amortization, equity award compensation, non-cash development expenses from joint ventures, write-ff off intangibles and changes in fair value of contingent value rights for the most recent four quarters less cash taxes by the sum of current obligation and interest expenses for borrowed money, in each case due and payable following four quarters. The Company was in compliance with these covenants as of December 31, 2012 and 2011.

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 the U.S. government. The annual interest rate is based on the three month LIBOR plus 3.25% and equaled −−−3.56% as of December 31, 2012 and 2011.

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 was repaid in July 2011.

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% and equaled 3.56% as of December 31, 2012.

In April 2006, the Company acquired 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. The loan was repaid in April 2011.

Under the terms of the 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 was in compliance with these covenants as of December 31, 2012 and 2011.

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 was secured by a $1.3 million letter of credit and a security interest in the building. The loan was repaid in March 2012.

In connection with the 2004 purchase of the building in Frederick, Maryland, the Company entered into a loan agreement for $7.0 million with PNC to finance the remaining portion of the purchase price. The loan was repaid in March 2012.

Scheduled principal repayments and maturities on long-term debt as of December 31, 2012 are as follows:

(in thousands)	
2013	$4,470
2014	23,075
2015	2,607
2016	2,607
2017	30,015
	$62,774

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 rights, voting rights, conversion privileges, redemption characteristics, and sinking fund requirements as approved by the Company's board of directors.

Common stock

The Company currently has one class of common stock, $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 Common Stock. Holders of Common Stock are entitled to one vote for each share of Common Stock held on all matters, except as may be provided by law.

Treasury stock

On May 17, 2012, the Company's Board of Directors authorized the repurchase of up to $35.0 million of its common stock through a share repurchase program. The repurchase program terminates on December 31, 2013. Under the program, the Company is authorized to repurchase shares through Rule 10b5−1 plans, open market purchases, block purchases or otherwise in accordance with applicable federal securities laws, including Rule 10b−18 of the Securities Exchange Act of 1934. This share repurchase program does not obligate the Company to acquire any specific number of shares and may be suspended or discontinued at any time. The timing and amount of the shares to be repurchased will be based on market conditions and other factors, including price, corporate and regulatory requirements, and alternative investment opportunities. The Company repurchased 398,481 shares for $5.8 million during the year ended December 31, 2012. In addition, in December 2012, in a form of stock transaction provided for under the terms of our stock incentive plan and stock option agreement, the Company engaged in a transaction with its chief executive officer in which the Company acquired 4,677 shares of common stock, valued at $74,000 as payment of the exercise price for 7,300 options.

Employee Stock Purchase Plan

On May 17, 2012, the Company's shareholders approved the 2012 Employee Stock Purchase Plan ("ESPP"), as defined in Section 423 of the Internal Revenue Code of 1986. All employees of the Company are eligible to participate in the ESPP, except those owning 5% or more of the Company's stock. One million shares of common stock have been approved for the ESPP. The ESPP has two plan periods: December 1st to May 31st and June 1st to November 30th. Employees are permitted to contribute between 1% and 10% of compensation during a plan period. The ESPP allows for employees to purchase shares of the Company's stock at a 15% discount at the end of each plan period based on the share price at that time. The maximum number of shares an employee may purchase during any plan period is 800 shares. The Company utilizes the Black-Scholes valuation model for estimating the fair value of all shares under its ESPP. The fair value of each option is estimated on the date of grant. During the year ended December 31, 2012, the Company recorded stock-based compensation expense of $11,000 related to the ESPP.

Stock options and restricted stock units

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, 2011	3,090,909	$ 17.35	53,156	$ 8.86	$6,238,427
Exercisable at December 31, 2011	1,459,049	$ 14.19	53,156	$ 8.86	$5,650,832
Granted	785,941	15.65	-	-	
Exercised	(89,125)	8.53	-	-	
Forfeited	(221,328)	19.24	-	-	
Outstanding at December 31, 2012	3,566,397	$ 17.08	53,156	$ 8.86	$4,802,547
Exercisable at December 31, 2012	2,151,700	$ 16.26	53,156	$ 8.86	$4,477,056
Options expected to vest at December 31, 2012	1,056,036	$ 18.15	-	$ -	$245,395

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

	Number of Shares	Weighted-Average Grant Price	Aggregate Intrinsic Value
Outstanding at December 31, 2011	635,500	$ 20.89	$10,714,450
Granted	413,022	15.61	
Vested	(260,738)	15.22	
Forfeited	(67,716)	19.36	
Outstanding at December 31, 2012	720,068	$ 20.89	$11,549,891

The weighted average remaining contractual term of options outstanding as of December 31, 2012 and 2011 was 4.2 and 4.9 years, respectively. The weighted average remaining contractual term of options exercisable as of December 31, 2012 and 2011 was 3.5 and 4.1 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2012, 2010 and 2009 was $5.16, $10.09 and $6.48 respectively. The total intrinsic value of options exercised during the years ended December 31, 2012, 2011 and 2010 was $589,000, $10.2 million and $7.5 million, respectively. The total fair value of awards vested during 2012, 2011 and 2010 was $10.3 million, $7.9 million and $5.8 million, respectively.

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

	December 31,		
(in thousands)	2012	2011	2010
Cost of product sales	$513	$466	$324
Research and development	3,451	3,203	1,635
Selling, general and administrative	7,151	7,070	5,104
Total stock-based compensation expense	$11,115	$10,739	$7,063

12. Income taxes

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

	Year ended December 31,		
(in thousands)	2012	2011	2010
Current			
Federal	$11,481	$(3,795)	$16,664

State	(1,045)	(1,110)	187
International	103	74	102
Total current	10,539	(4,831)	16,953
Deferred			
Federal	3,758	19,055	10,003
State	(375)	1,606	(774)
Total deferred	3,383	20,661	9,229
Total provision for income taxes	$13,922	$15,830	$26,182

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

	December 31,	
(in thousands)	2012	2011
Net operating loss carryforward	$26,102	$28,621
Research and development carryforward	3,556	3,556
Stock compensation	5,289	3,666
Foreign deferrals	64,009	61,255
Deferred revenue	-	485
Other	9,005	9,596
Deferred tax asset	107,961	107,179
Fixed assets	(22,040)	(21,760)
Other	(6,158)	(6,902)
Deferred tax liability	(28,198)	(28,662)
Valuation allowance	(67,412)	(62,783)
Net deferred tax asset	$12,351	$15,734

The Company currently has approximately $43.9 million in net operating loss carryforwards along with $3.6 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 $200.5 million in state net operating loss carryforwards, primarily in Maryland, that will begin to expire in 2018. The Company has approximately $223.3 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:

	Year ended December 31,		
(in thousands)	2012	2011	2010
US	$52,391	$66,756	$111,775
International	(14,945)	(27,907)	(33,895)
Earnings before taxes on income	37,446	38,849	77,880
Federal tax at statutory rates	$13,106	$13,597	$27,258
State taxes, net of federal benefit	(2,079)	46	666
Impact of foreign operations	(3,604)	(2,371)	(7,713)
Change in valuation allowance	4,629	3,193	6,394
Effect of foreign rates	(22)	(12)	(30)
Tax credits	(2,904)	(1,405)	(1,754)

Other differences	139	556	398
Permanent differences	4,657	2,226	963
Provision for income taxes	$13,922	$15,830	$26,182

The effective annual tax rate for the years ended December 31, 2012, 2011 and 2010 was 37%, 41% and 34%, respectively. The decrease in the effective annual tax rate in 2012 from 2011 is primarily related to orphan drug tax credits related to our TRU-016 product candidate. The increase in the effective annual tax rate in 2011 from 2010 is due primarily to the benefit of certain costs capitalized for book purposes that are deductible for tax purposes in 2011 that did not occur in 2010. In January 2013, Congress passed the American Taxpayer Relief Act of 2012, which among other things extended the research and development tax credit through December 31, 2013. The Company expects this legislation to have a favorable impact on its 2013 effective tax rate.
During the year ended December 31, 2012, the Company corrected certain immaterial prior period errors for the years ending December 31, 2011 and 2010 of approximately $2.4 million and $909,000, respectively. These immaterial errors related to the cash flow presentation of the excess tax benefit attributed to the exercise of non-qualified stock options and restricted stock units. The immaterial errors had no impact on the Company's consolidated cash flows, consolidated statements of income and comprehensive income or the consolidated balance sheets. The correction of the errors is reflected as a reduction of operating cash flow from operating activities and an increase in cash flow from financing activities.

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 $25,000 and $26,000, for the payment of interest and penalties as of December 31, 2012 and 2011, respectively. Of the total unrecognized tax benefits recorded at December 31, 2012 and 2011, $153,000 and $104,000, respectively is classified as a current liability and $863,000 and $952,000, respectively, is classified as a non-current liability on the balance sheet. As of December 31, 2012 and 2011, the Company estimated that approximately, $75,000 and $50,000, respectively, of unrecognized tax benefits will reverse within the next twelve months.

The table below presents the gross unrecognized tax benefits activity for 2012, 2011 and 2010:

(in thousands)	
Gross unrecognized tax benefits at January 1, 2010	$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 statute of limitations	-
Gross unrecognized tax benefits at December 31, 2010	950
Increases for tax positions for prior years	167
Decreases for tax positions for prior years	(61)
Increases for tax positions for current year	-
Settlements	-
Lapse of statute of limitations	-
Gross unrecognized tax benefits at December 31, 2011	1,056
Increases for tax positions for prior years	25
Decreases for tax positions for prior years	(65)
Increases for tax positions for current year	-
Settlements	-
Lapse of statute of limitations	-
Gross unrecognized tax benefits at December 31, 2012	$1,016

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 2011 remain open to examination. The Company's tax returns in the United Kingdom remain open to examination for the tax years 2011 to 2004, and tax returns in Germany remain open indefinitely.

As of December 31, 2012, the Company's 2008, 2009 and 2010 federal income tax returns are under audit by the Internal Revenue service. The Company believes appropriate provisions have been made for any outstanding issues.

13. Variable interest entities

In July 2008, the Company entered into a collaboration with the University of Oxford ("Oxford") and certain Oxford researchers to advance 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 had certain funding and service obligations related to its investment. As a result of clinical trial data for the Company's tuberculosis vaccine product candidate published in February 2012, the Company expects future funding of OETC to be minimal.

The Company evaluates its variable interests in OETC on a quarterly basis and has determined that it is the primary beneficiary as it has the power to direct the activities of OETC that most significantly impact OETC's economic performance and will absorb the majority of expected losses. Accordingly, the Company consolidates OETC. As of December 31, 2012 and 2011, respectively, assets of $2.0 million and $461,000 and liabilities of $2.0 million and $947,000 related to OETC were included within the Company's consolidated balance sheets. During the year ended December 31, 2012, OETC incurred net losses of $10.7 million of which $5.4 million is included in the Company's consolidated statement of operations. During the year ended December 31, 2011, OETC incurred net losses of $13.2 million, of which $6.7 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 certain Oxford researchers whereby the Company may be required to acquire all of the OETC shares held by Oxford and the Oxford researchers at the 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 tuberculosis vaccine product candidate. 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 had no value as of December 31, 2012.

14. Collaboration Agreements

Abbott Laboratories

In August 2009, Trubion, which the Company acquired in October 2010, 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. The collaboration agreement covered TRU-016 in all indications and all other CD37-directed protein therapeutics. The collaboration agreement was terminated on March 20, 2012 and all rights to TRU-016 and other CD37-directed protein therapeutics under the collaboration agreement reverted back to the Company.

During the year ended December 31, 2012, 2011 and 2010, the Company recorded revenue of $2.7 million, $17.7 million and $1.2 million, respectively, for research and development services pursuant to the Abbott agreement, which are included in the Company's financial statements of operations as contracts and grants revenue within the Company's Biosciences segment. For the year ended December 31, 2012, the Company recorded $1.4 million related to deferred revenue recognition and $1.4 million for collaborative research funding. For the year ended December 31, 2011, the revenue is comprised of $10.5 million related to the recognition of deferred revenue, $6.0 million related to the achievement of a development milestone and $1.2 million for collaborative research funding. For the year ended December 31, 2010, the revenue is comprised of $831,000 related to the recognition of deferred revenue and $398,000 for collaborative research funding. As of December 31, 2012, there were no receivables or payables under the

agreement. As of December 31, 2011, the Company had a net receivable of $6.8 million.

Pfizer Inc.

In December 2005, Trubion entered into an agreement (the "Pfizer Agreement") with Wyeth Pharmaceuticals, now a wholly-owned subsidiary of Pfizer, for the development and worldwide commercialization of CD20-directed therapeutics. In September 2012, the Pfizer Agreement was terminated. The Company's right to receive royalty payments under the Biosimilar Amendment survives termination of the Pfizer Agreement.

During the year ended December 31, 2012, 2011 and 2010, the Company recorded revenue of $1.2 million, $1.9 million and $992,000, respectively, for research and development services pursuant to the Pfizer agreement, which are included in the Company's financial statements of operations as contracts and grants revenue within the Company's Biosciences segment. For the year ended December 31, 2012, the Company recorded $68,000 related to deferred revenue recognition and $1.1 million for collaborative research funding. For the year ended December 31, 2011, the revenue is comprised of $52,000 related to the recognition of deferred revenue and $1.8 million for collaborative research funding. For the year ended December 31, 2010, the revenue is comprised of $9,000 related to the recognition of deferred revenue and $983,000 for collaborative research funding. As of December 31, 2012 and 2011, the Company has a receivable of $52,000 and $302,000, respectively.

15. Restructuring

In November 2010, the Company adopted a plan to restructure and reprioritize the operations of Emergent Product Development UK Limited ("EPDU"). The restructuring was completed by the year ended December 31, 2011. For the years ended December 31, 2011 and 2010, the Company incurred restructuring expenses of $3.1 million and $2.5 million, respectively, which is included in selling, general and administrative expense in the Company's statement of operations, and is included within the Biosciences segment.

The Company has completed this restructuring. The costs of the restructuring are detailed below:

(in thousands)	Incurred in 2011	Inception to Date Costs Incurred	Total Incurred
Termination benefits	$ 475	$ 2,893	$ 2,893
Contract termination costs	1,923	2,295	2,295
Other costs	90	350	350
Total	$ 2,488	$ 5,538	$ 5,538

The following is a summary of the activity for the liabilities related to the EPDU restructuring:

(in thousands)	Termination Benefits	Lease Termination Costs	Total
Balance at December 31, 2010	$ 2,418	$ 650	$3,068
Expenses incurred	475	1,923	2,398
Amount paid	(2,893)	(2,295)	(5,188)
Other adjustments	-	(278)	(278)
Balance at December 31, 2011	$ -	$ -	$-

16. 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, 2012, 2011 and 2010, the Company made matching contributions of approximately $1.9 million, $1.8 million and $1.3 million, respectively.

17. Leases

The Company leases laboratory and office facilities, office equipment and vehicles under various operating lease agreements. The Company leases office space and laboratory space in Munich, Germany under a non-cancelable operating lease that expires in June 2015. The Company leases primarily office space in Wokingham, England under an operating lease that expires in November 2016. The Company leases office space in Rockville, Maryland under an operating lease that contain a 3% annual escalation clause, which expires 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 an operating lease agreement in Seattle, Washington, which expires in April 2015. For the years ended December 31, 2012, 2011 and 2010, total lease expense was $3.6 million, $3.8 million and $2.6 million, respectively.

Future minimum lease payments under operating lease obligations as of December 31, 2012 were as follows:

(in thousands)	
2013	$3,447
2014	3,497
2015	2,331
2016	1,377
2017	-
Total minimum lease payments	$10,652

18. Business interruption insurance recovery

During the year ended December 31, 2012, the Company recorded $1.7 million in insurance recovery related to a power outage at its Lansing, Michigan facility. The insurance recovery is classified in the Company's statement of operations as other income (expense), net.

19. Related party transactions

The Company entered into an agreement in February 2009 with an entity controlled by family members of the Company's Executive Chairman 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 expenses were incurred under this agreement during 2012 and 2011.

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 Executive Chairman. The agreement, which terminated in August 2011, provided for consulting services in connection with special projects as assigned by the Company's President. During 2011 and 2010, the Company incurred approximately $35,000 and $25,000, respectively, for services rendered under this agreement, of which no balance remained in unpaid accounts payable at December 31, 2011.

The Company was previously a party to a consulting agreement with a member of the Company's Board of Directors. In October 2011, this director resigned from the Company's Board of Directors, and the consulting agreement was terminated in November 2011. During the years ended 2011 and 2010, the Company incurred approximately $225,000 and $180,000 under this agreement for strategic consultation and project support for the Company's marketing and communications group, of which no balance remained unpaid in accounts payable at December 31, 2011.

20. Earnings per share

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

	Year Ended December 31,		
(in thousands, except share and per share data)	2012	2011	2010
Numerator:			
Net income	$23,524	$23,019	$51,698
Denominator:			
Weighted-average number of shares—basic	36,080,495	35,658,907	31,782,286
Dilutive securities—equity awards	340,167	547,145	757,214
Weighted-average number of shares—diluted	36,420,662	36,206,052	32,539,500
Earnings per share-basic	$0.65	$0.65	$1.63
Earnings per share-diluted	$0.65	$0.64	$1.59

For the years ending December 31, 2012, 2011 and 2010, outstanding stock options to purchase approximately 2.9 million, 746,000 and 1.4 million shares of common stock, respectively, 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.

21. Segment information

For financial reporting purposes, the Company reports financial information for two business segments: Biodefense and Biosciences. The Company's two business segments, or divisions, engage in business activities for which discrete financial information is reviewed by the chief operating decision maker. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies. The Company's reportable segments are business units that offer different products and product candidates and are managed separately because they manufacture and develop distinct products with different development processes.

The Biodefense division is directed to government-sponsored development and supply of countermeasures against potential agents of bioterror or biowarfare and targets the infectious disease anthrax. Revenues in this segment are primarily from sales of the Company's FDA-licensed product, BioThrax® (Anthrax Vaccine Adsorbed), to the U.S. government. The Biosciences division is directed to commercial opportunities and primarily targets oncology indications, and consists of two business units, therapeutics and vaccines. 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 activities that are not classified as Biodefense or Biosciences. The assets in this segment consist primarily of cash.

The Company's segment presentation for the years ended December 31, 2011 and 2010 have been reclassified to conform to the 2012 presentation. In the third quarter of 2012, as a result of the Company receiving a contract from the U.S. government to establish a Center for Innovation in Advanced Development and Manufacturing, the Company reevaluated its segments. The Company reclassified certain components of its segments to reflect the current presentation to, and review of, financial information by the chief operating decision maker. Total assets by reportable segments are not disclosed as these assets are not reviewed separately by the Company's chief operating decision maker.

	Reportable Segments			
(in thousands)	Biodefense	Biosciences	All Other	Total
Year Ended December 31, 2012				
External revenue	$276,469	$ 5,419	$-	$281,888
Intersegment revenue (expense)	-	-	-	-
Research and development	68,579	44,588	7,059	120,226
Interest revenue	-	-	134	134
Interest expense	-	-	(6)	(6)

Depreciation and amortization	8,951	2,147	99	11,197
Net income (loss)	94,865	(63,928)	(7,413)	23,524
In-process research and development assets	-	41,800	-	41,800
Goodwill	-	5,502	-	5,502
Total assets	354,010	56,148	154,072	564,230
Expenditures for long-lived assets	52,957	810	78	53,845
Year Ended December 31, 2011				
External revenue	$251,037	$ 22,347	$ -	$273,384
Intersegment revenue (expense)	-	-	-	-
Research and development	57,833	61,566	5,433	124,832
Interest revenue	-	-	105	105
Interest expense	-	-	-	-
Depreciation and amortization	6,213	3,070	72	9,355
Net income (loss)	86,836	(56,438)	(7,379)	23,019
In-process research and development assets	-	51,400	-	51,400
Goodwill	-	5,502	-	5,502
Total assets	290,302	92,321	164,241	546,864
Expenditures for long-lived assets	52,326	1,608	92	54,026
Year Ended December 31, 2010				
External revenue	$282,727	$ 3,444	$-	$286,171
Intersegment revenue (expense)	-	-	-	-
Research and development	52,191	32,895	4,209	89,295
Interest revenue	-	-	832	832
Interest expense	-	-	-	-
Depreciation and amortization	4,584	1,333	73	5,990
Net income (loss)	113,249	(53,676)	(7,875)	51,698
In-process research and development assets	-	51,400	-	51,400
Goodwill	-	5,502	-	5,502
Total assets	216,529	99,754	184,036	500,319
Expenditures for long-lived assets	21,728	373	-	22,101

22. Quarterly financial data (unaudited)

Quarterly financial information for the years ended December 31, 2012 and 2011 is presented in the following tables:

	Three months ended			
(in thousands)	March 31,	June 30,	September 30,	December 31,
Fiscal year 2012				
Revenue	$50,311	$70,379	$ 66,592	$94,606
Income (loss) from operations	(12,538)	8,653	9,817	24,035
Net income (loss)	(6,829)	7,632	6,617	16,104
Net income (loss) per share, basic	(0.19)	0.21	0.18	0.45
Net income (loss) per share, diluted	(0.19)	0.21	0.18	0.44
Fiscal year 2011				
Revenue	$18,533	$88,141	$ 58,762	$107,948
Income (loss) from operations	(35,506)	20,207	1,408	45,990
Net income (loss)	(21,397)	14,210	1,549	28,657
Net income (loss) per share, basic	(0.61)	0.40	0.04	0.80
Net income (loss) per share, diluted	(0.61)	0.39	0.04	0.78

23. Subsequent events

In January 2013, the Company entered into an agreement to purchase an office building for $27.5 million. The Company plans to utilize a portion of the new building for its headquarters operations and continue to lease the remaining space under existing lease agreements with third parties. The Company anticipates the purchase will be completed during the first quarter of 2013.

In February 2013, the Company initiated plans to close its operations in the United Kingdom and South Africa. The restructuring entails a headcount reduction of employees in the United Kingdom and South Africa, the termination of the UK facility lease, and the impairment of fixed assets. The Company expects to complete this restructuring during 2013, and estimates that the total cost of the restructuring will be approximately $3 million.

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, 2012. 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, 2012, 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, 2012. 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, 2012, our internal control over financial reporting is effective based on those criteria.

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, 2012, 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, 2012 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 Controls Over Financial Reporting

The Board of Directors and Shareholders of Emergent BioSolutions Inc.

We have audited Emergent BioSolutions Inc.'s internal control over financial reporting as of December 31, 2012, 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.'s 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.

In our opinion, Emergent BioSolutions Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2012 consolidated financial statements of Emergent BioSolutions Inc., and our report dated March 8, 2013, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia
March 8, 2013

ITEM 9B. OTHER INFORMATION

On March 5, 2013, the compensation committee of our board of directors took a number of actions with respect to the compensation of our named executive officers. The compensation committee awarded cash bonuses to our named executive officers for their performance in fiscal 2012 as follows: Fuad El-Hibri, $159,515; Daniel Abdun-Nabi, $321,591; Robert Kramer, $52,793; Adam Havey, $130,774; and Stephen Chatfield, £86,302.

The compensation committee also approved grants of equity awards to be made on March 12, 2013 to the following named executive officers in the following amounts: Fuad El-Hibri, based on a value of $625,000; Daniel J. Abdun-Nabi, based on a value of $1,221,000; Robert Kramer, based on a value of $117,810; Adam Havey, based on a value of $357,000 and Steven Chatfield, based on a value of $357,000. Half of the value to be granted to each executive will be in the form of restricted stock units, and the other half will be in the form of stock options.

The compensation committee also approved base salaries and target bonuses for fiscal year 2013 for our named executive officers. Annualized base salaries and target bonus percentages for our named executive officers for fiscal year 2013 are as follows: Fuad El-Hibri, $728,020; Daniel Abdun-Nabi, $572,020 and 65%; Adam Havey, $332,592 and 45%; and Steven Chatfield, £219,485 and 45%.

Effective April 1, 2012, when Mr. El-Hibri assumed the Executive Chairman position, he became no longer eligible for cash bonuses. As previously disclosed, on Janury 16, 2013 the compensation committee approved a base salary and target bonus for fiscal year 2013 for Robert Kramer of $430,000 and 50%. Additonally, Mr. Kramer's 2012 bonus and 2013 equity grant, as disclosed above, were prorated based on his September 2012 hire date.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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.

The remaining information required by Item 10 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2013 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2013 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

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

The information required by Item 12 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2013 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

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

The information required by Item 13 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2013 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2013 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

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, 2012 and 2011
Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010
Consolidated Statements of Comprehensive Income for the years ended December 31, 2012, 2011 and 2010
Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010
Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2012, 2011 and 2010
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/ Daniel J. Abdun-Nabi
Daniel J. Abdun-Nabi
President and Chief Executive Officer
Date: March 8, 2013

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/Daniel J. Abdun-Nabi Daniel J. Abdun-Nabi	President and Chief Executive Officer (Principal Executive Officer)	March 8, 2013
/s/Robert G. Kramer Robert G. Kramer	Executive Vice President Corporate Services Division, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 8, 2013
/s/Fuad El-Hibri Fuad El-Hibri	Executive Chairman of the Board of Directors	March 8, 2013
_____ Zsolt Harsanyi, Ph.D.	Director	
/s/Dr. John Niederhuber Dr. John Niederhuber	Director	March 8, 2013
/s/Ronald B. Richard Ronald B. Richard	Director	March 8, 2013
/s/Louis W. Sullivan, M.D. Louis W. Sullivan, M.D.	Director	March 8, 2013
/s/Marvin White Marvin White	Director	March 8, 2013

_____ Dr. Sue Bailey	Director

Exhibit Index

All documents referenced below were filed pursuant to the Securities Exchange Act of 1934 by the Company, (File No. 001-33137), unless otherwise indicated.

Exhibit Number		Description
3.1		Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 filed on December 8, 2006) (File No. 333-139190).
3.2		Amended and Restated By-laws of the Company (incorporated by reference to Exhibit 3 to the Company's Current Report on Form 8-K filed on August 16, 2012).
4.1		Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 3 to the Company's Registration Statement on Form S-1 filed on October 20, 2006) (File No. 333-136622).
4.2		Rights Agreement, dated as of November 14, 2006, between the Company and American Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-8 filed on December 8, 2006) (File No. 333-139190).
4.3		Registration Rights Agreement, dated as of September 22, 2006, among the Company and the stockholders listed on Schedule 1 thereto (incorporated by reference to Exhibit 4.3 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on September 25, 2006) (File No. 333-136622).
9.1		Voting and Right of First Refusal Agreement, dated as of 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 Company's Registration Statement on Form S-1 filed on August 14, 2006) (File No. 333-136622).
10.1	*	Emergent BioSolutions Inc. Employee Stock Option Plan, as amended and restated on January 26, 2005 (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed on August 14, 2006) (File No. 333-136622).
10.2	*	Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 5 to the Company's Registration Statement on Form S-1 filed on October 30, 2006) (File No. 001-33137).
10.3	*	Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 7, 2009).
10.4	*	Second Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Appendix A to the Company's definitive proxy statement on Schedule 14A filed on April 6, 2012).
10.5	#*	Form of Director Nonstatutory Stock Option Agreement.
10.6	#*	Form of Director Restricted Stock Unit Agreement.
10.7	#*	Form of Non-Qualified Stock Option Agreement.
10.8	#*	Form of Restricted Stock Unit Agreement.
10.9	*	Form of Indemnity Agreement for directors and senior officers (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on January 18, 2013).
10.10	#*	Director Compensation Program.
10.11	*	Employment Agreement, effective January 1, 2012, between Emergent Product Development UK Ltd and Dr. Steven Chatfield (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed on March 9, 2012).
10.12	*	Annual Bonus Plan for Executive Officers (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on March 5, 2010).
10.13	*	Amended and Restated Senior Management Severance Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 22, 2011).
10.14		Amended and Restated Marketing Agreement, dated as of November 5, 2008, between Emergent Biodefense Operations Lansing LLC (formerly known as Emergent Biodefense Operations Lansing Inc.) and Intergen N.V. (incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed on March 6, 2009).

10.15	†	Solicitation, Offer and Award (the "CDC BioThrax Procurement Contract"), effective September 30, 2011, from the Centers for Disease Control and Prevention to Emergent BioDefense Operations Lansing LLC (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on May 4, 2012).
10.16	†	Modification No. 1 to the CDC BioThrax Procurement Contract, effective March 21, 2012, between Emergent BioDefense Operations Lansing LLC and the Centers for Disease Control and Prevention (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 1, 2012).
10.17	†	Modification No. 2 to the CDC BioThrax Procurement Contract, effective September 1, 2012, between Emergent BioDefense Operations Lansing LLC and the Centers for Disease Control and Prevention (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on November 1, 2012).
10.18		Lease Agreement, dated June 27, 2006, between Brandywine Research LLC and the Company (the "Rockville Lease") (incorporated by reference to Exhibit 10.24 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 filed on September 25, 2006) (File No. 333-136622).
10.19		First Amendment to the Rockville Lease, dated November 13, 2007, between Brandywine Research LLC and the Company (incorporated by reference to Exhibit 10.45 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011 filed on March 9, 2012).
10.20		Second Amendment to the Rockville Lease, dated December 13, 2010, between Brandywine Research LLC and the Company (incorporated by reference to Exhibit 10.46 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011 filed on March 9, 2012).
10.21		Third Amendment to the Rockville Lease, dated effective February 27, 2012, between Brandywine Research LLC and the Company (incorporated by reference to Exhibit 10.47 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2011 filed on March 9, 2012).
12	#	Ratio of Earnings to Fixed Charges.
21	#	Subsidiaries of the Company.
23	#	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.

Attached as Exhibit 101 to this Annual Report on Form 10-K are the following formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011, (ii) Consolidated Statements of Operations for the Years Ended December 31, 2012, 2011 and 2010, (iii) Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2012, 2011 and 2010 (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2012, 2011 and 2010, (v) Consolidated Statements of Changes in Stockholders' Equity for the Years ended December 31, 2012, 2011 and 2010, and (vi) Notes to Consolidated Financial Statements.

In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Annual Report on Form 10-K is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, is deemed not filed for purposes of section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.