Emergent BioSolutions Inc.
Form 10-K
March 10, 2014
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

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

For the fiscal year ended December 31, 2013

OR

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

Commission file number: 001-33137

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant Rule 405 of Regulation S-T during the

preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2013 was approximately $366 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, 2014, the registrant had 36,771,588 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2014 annual meeting of stockholders scheduled to be held on May 23, 2014, 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, 2013, 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 2014 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, 2013

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K and the documents we incorporate by reference include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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. We generally identify forward-looking statements by using words like "believes," "expects," "anticipates," "intends," "plans," "forecasts," "estimates" and similar expressions in conjunction with, among other things, discussions of financial performance or financial condition, growth strategy, product sales, manufacturing capabilities, product development, regulatory approvals or expenditures. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. You should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. You are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements, including, among others:

appropriations for the procurement of BioThrax® (Anthrax Vaccine Adsorbed), our FDA-approved anthrax vaccine;
our ability to successfully integrate Cangene Corporation, which we recently acquired, and realize the potential benefits of this acquisition;
our ability to successfully integrate the Healthcare Protective Products Division that we recently acquired from Bracco Diagnostics Inc. and realize the benefits of this acquisition;
our ability to perform under our contracts with the U.S. government related to BioThrax, including the timing of deliveries;
our ability to obtain new BioThrax sales contracts or modifications to existing contracts;
the availability of funding for our U.S. government grants and contracts;
our ability to successfully execute our growth strategy and achieve our financial and operational goals;
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 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 ability to identify and acquire companies or in-license products or late-stage product candidates that satisfy our selection criteria;
whether anticipated synergies and benefits from an acquisition or in-license are realized within expected time periods or at all;
our ability to selectively enter into collaboration arrangements;
our ability to obtain and maintain intellectual property protection for our products and product candidates;
our ability and plans to expand our manufacturing facilities and capabilities;
our ability to meet operating and financial restrictions placed on us and our subsidiaries under our senior secured credit facility;
the rate and degree of market acceptance and clinical utility of our products;
the success of our ongoing and planned development programs, preclinical studies and clinical trials of our product candidates;
the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;

our commercialization, marketing and manufacturing capabilities and strategy; and
our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. New factors emerge from time to time and it is not possible for management to predict all such factors, nor can it assess the impact of any such factor on the business or the extent to which any factor, or combination of factors, may cause results to differ materially from those contained in any forward-looking statement. You should consider this cautionary statement, the risk factors identified in the section entitled "Risk Factors" in this annual report on Form 10-K and the risk factors identified in our periodic reports filed with the SEC when evaluating our forward-looking statements.

PART I
ITEM 1. BUSINESS

OVERVIEW

Emergent BioSolutions Inc. is a specialty pharmaceutical company seeking to protect and enhance life by offering specialized products to healthcare providers and governments for use in addressing medical needs and emerging health threats.

We were incorporated in the State of Michigan in May 1998 and subsequently reorganized as a Delaware corporation in June 2004. Our common stock is traded on the New York Stock Exchange under the ticker symbol "EBS." Our principal executive offices are located at 2273 Research Boulevard, Suite 400, Rockville, Maryland 20850. Our telephone number is (301) 795-1800, and our website address is www.emergentbiosolutions.com.

We have two operating divisions: Biodefense and Biosciences. For financial reporting purposes, we report two business segments that correspond to these two divisions.

Biodefense

Our Biodefense division is a specialty pharmaceutical business focused on countermeasures that address CBRN (Chemical, Biological, Radiological and Nuclear) threats. The United States government is the primary purchaser of our Biodefense products and often provides us with substantial funding for the development of our Biodefense product candidates. Our Biodefense portfolio consists of five revenue generating products, including BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine approved by the U.S. Food and Drug Administration, or the FDA, for the prevention of anthrax disease, as well as RSDL® (decontamination lotion), three products we acquired in our acquisition of Cangene Corporation, which we completed in February 2014, and various investigational stage product candidates.

Our Biodefense division revenue generating products are:

BioThrax® (Anthrax Vaccine Adsorbed)
BAT™ (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-Equine)*
AIGIV (Anthrax Immune Globulin Intravenous (Human))*
RSDL® (decontamination lotion)
VIGIV (Vaccinia Immune Globulin Intravenous (Human))*

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* Denotes products acquired through our acquisition of Cangene Corporation.

Our Biodefense division investigational stage product candidates include: NuThrax™ (Anthrax Vaccine Adsorbed containing CPG 7909 Adjuvant), PreviThrax™ (Recombinant Protective Antigen Anthrax Vaccine, Purified), and other Biodefense product candidates. Operations that support this division include manufacturing, regulatory affairs, quality assurance, quality control, international sales and marketing, and domestic government affairs in support of our marketed products, as well as product development and manufacturing infrastructure in support of our investigational stage product candidates.

Biosciences

Our Biosciences division is a specialty pharmaceutical business focused on therapeutics and vaccines in hematology/oncology, transplantation and infectious disease. Our Biosciences portfolio consists of four revenue

generating products, all four of which we acquired in our recent acquisition of Cangene Corporation, as well as various investigational stage product candidates and a contract manufacturing services business.

Our Biosciences division revenue generating products are:

WinRho® SDF (Rh_o(D) Immune Globulin Intravenous (Human)) *
HepaGam B® (Hepatitis B Immune Globulin Intravenous (Human))*
VARIZIG® (Varicella Zoster Immune Globulin (Human))*
episil®*

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* Denotes products acquired through our acquisition of Cangene Corporation.

Our Biosciences division investigational stage product candidates include: otlertuzumab (Humanized Anti-CD37 therapeutic) (formerly known as TRU-016), IXINITY™ (trenonacog alfa), and other Biosciences product candidates. In addition, our Biosciences division includes several platform technologies, including our ADAPTIR™ (modular protein technology) platform, our MVAtor (viral vaccine vector) platform, and our hyperimmune specialty plasma product manufacturing platform. Operations that support this division include manufacturing, quality, regulatory medical affairs, and sales and marketing in support of our marketed products, as well as additional product development capabilities in support of our investigational stage product candidates.

For information regarding revenue, profit and loss, total assets and other information concerning our results of operations for both reporting segments for each of the last three fiscal years, please refer to our consolidated financial statements and the accompanying notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of this Annual Report on Form 10-K.

STRATEGY

In November 2012, we announced a growth plan that presented our strategic, operational and financial goals to be achieved by the end of 2015. This growth plan is built on a strategy that focuses on expanding our reach in the biodefense market and diversifying into additional specialty markets. In executing on the growth plan, we are leveraging our core competencies. Specifically, we are building upon our position in biodefense, extending our track record of acquisitions, expanding and diversifying our biologics manufacturing expertise and continuing to partner with governments and non-governmental organizations. Successful achievement of our growth goals will further require that we marshal our core competencies across the following key objectives: driving organic growth, acquiring revenue generating assets and focusing on controlling R&D costs by securing external funding for our development programs.

RECENT ACQUISITIONS

Acquisition of Healthcare Protective Products Division from Bracco Diagnostics Inc.

On August 1, 2013, we acquired the Healthcare Protective Products Division of Bracco Diagnostics Inc. for approximately $26 million in cash along with contingent purchase consideration obligations. The assets acquired in this transaction included RSDL, a medical countermeasure for the treatment of exposure to chemical warfare agents, a multi-year manufacturing agreement and a lease for a manufacturing facility in Hattiesburg, Mississippi. With this acquisition, we secured a second source of product sales for our Biodefense division and diversified into another pillar within the CBRN threat countermeasure market by acquiring a medical countermeasure focused on chemical warfare agents. Further, the acquisition broadened our technical expertise beyond vaccines and therapeutics into the medical devices area and, at the same time, expanded our capabilities with respect to ex-U.S. biodefense sales and marketing.

Acquisition of Cangene Corporation

On February 21, 2014, we acquired all of the outstanding common shares of Cangene Corporation for a total all-cash purchase price of $222 million. In this acquisition we acquired seven revenue generating products, three of which have been added to our Biodefense division and four of which have been added to our Biosciences division. Specifically, the Biodefense products include: BAT for treatment of botulism; AIGIV for treatment of anthrax; and VIGIV for treatment of adverse reactions to vaccinia virus, which is often used to vaccinate against smallpox. The Biosciences products include: WinRho SDF for treatment of autoimmune platelet disorder, also called immune thrombocytopenic purpura or ITP, and, separately, for the treatment of hemolytic disease of the newborn, or HDN; HepaGam B for post-exposure prophylactic treatment of hepatitis B; VARIZIG for post-exposure prophylactic treatment of varicella zoster virus, which causes chickenpox and shingles; and episil for relief of pain and soothing oral lesions of various etiologies, including oral mucositis/stomatitis caused by chemotherapy or radio therapy. We also acquired Cangene's fill/finish contract manufacturing services business, including agreements with customers to fill/finish a number of commercial and clinical-stage products worldwide, as well as facilities in Winnipeg, Manitoba, Canada, which house plasma collection and hyperimmune specialty plasma manufacturing operations.

PRODUCT PORTFOLIO

BIODEFENSE

Product	Indication	Regulatory Approvals
BioThrax® (Anthrax Vaccine Adsorbed)	Pre-exposure prophylaxis of anthrax disease	United States Germany Singapore
BAT™ (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-Equine)	Treatment of suspected or documented exposure to botulinum neurotoxin A, B, C, D, E, F or G	United States
AIGIV (Anthrax Immune Globulin Intravenous (Human))	Treatment of toxemia associated with inhalational anthrax	AIGIV is an investigational product, but is procured by U.S. Health & Human Services, or HHS, into the Strategic National Stockpile, or SNS, for use in an emergency under an Emergency Use Authorization, or EUA.
RSDL® (decontamination lotion)	Removal and/or neutralization of chemical warfare agents and T-2 toxin from the skin	United States 510(k) United Kingdom Australia Canada
VIGIV (Vaccinia Immune Globulin Intravenous (Human))	Post-exposure prophylaxis of vaccinia (a common virus used to vaccinate against small pox)	United States Canada

BIOSCIENCES

Product	Indication	Regulatory Approvals
WinRho® SDF (Rh_o(D) Immune Globulin Intravenous (Human))	HDN – hemolytic disease of the newborn ITP – immune thrombocytopenic purpura Preventing Rh_o(D) immunization in Rh_o(D)(-) women [1] Treating Rh_o(D)(-) patients after transfusions with incompatible Rh_o(D)(+) blood or erythrocyte products [2]	Canada – ITP, HDN United States – ITP, HDN Portugal – [1] and [2]
HepaGam B® (Hepatitis B Immune Globulin Intravenous (Human))	Post-exposure prophylaxis for hepatitis B Prevention of hepatitis B recurrence following liver transplantation in patients who are positive for hepatitis B surface antigen	United States Canada Israel Kuwait Turkey
VARIZIG® (Varicella Zoster Immune Globulin (Human))	Post-exposure prophylaxis for varicella (chickenpox) in high-risk patient groups, including immunocompromised children, newborns and pregnant women [1] Prevention and reduction of severity in maternal infections within four days of exposure to Varicella zoster virus [2]	United States – [1] Canada – [2]
episil®	Relief of pain, soothing oral lesions of various etiologies, including oral mucositis/stomatitis caused by chemotherapy and radio therapy	United States

BIODEFENSE DIVISION

Our Biodefense division is a specialty pharmaceutical business focused on countermeasures that address CBRN threats. Our Biodefense portfolio consists of marketed products and investigational stage product candidates.

Marketed Products

BioThrax® (Anthrax Vaccine Adsorbed). BioThrax is the only vaccine approved by the FDA for the prevention of anthrax disease. Anthrax is a potentially fatal disease caused by the spore forming bacterium, Bacillus anthracis. Inhalational anthrax is the most lethal form of anthrax. Death due to inhalational anthrax infection often occurs within 24-36 hours of the onset of advanced respiratory complications. BioThrax is administered by intramuscular injection in a three dose primary series over an initial six-month period. The vaccine is protective after this dosing. After the primary series, two additional doses are given at 12 and 18 months, with booster doses annually thereafter. Our current contract with the Centers for Disease Control and Prevention, or CDC, an agency within the HHS, 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 ending in September 2016. The maximum amount that could be paid to us under this current 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. As of December 31, 2013, $704 million in funding has been committed, of which approximately $479 million has been delivered, which represents approximately 17.9 million doses. To date, the principal customer for BioThrax has been the U.S. government, specifically HHS (including CDC) and the U.S. Department of Defense, or DoD.

We are continuing to identify and pursue opportunities to expand the market for BioThrax to foreign governments, non-governmental organizations and multinational companies (including transportation, critical infrastructure services and security companies), as well as health care providers (including hospitals and clinics). We are also working to expand the indications for BioThrax by adding a post-exposure prophylaxis, or PEP, indication to the BioThrax label. We plan to seek approval of BioThrax for the PEP indication administered in combination with antimicrobial therapy. With funding from a multi-year development contract with the Biological Advanced Research and Development Authority, or BARDA, an agency within HHS, we have completed enrollment and dosing in a pivotal, antibiotic non-interference study, and are currently compiling and reviewing data. We plan to use the data from this study, coupled with data from previously completed studies also funded by BARDA, to support the filing of a Supplemental Biologics License Application, or sBLA, with the FDA for marketing approval of BioThrax for the PEP indication.

BAT™ (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-Equine). BAT is a mixture of purified polyclonal equine immune globulins (antibodies) directed to the seven toxins (A through G) produced by Clostridium botulinum. BAT was approved in the United States in March 2013 for the treatment of suspected or documented exposure to botulinum neurotoxin A, B, C, D, E, F or G. Simultaneous with FDA approval, BAT also received orphan drug designation, giving it seven years of market exclusivity in the United States until March 2020. BAT is the only botulism antitoxin available in the United States for treating naturally occurring non-infant botulism. It can be administered to patients to treat naturally occurring non-infant botulism, as well as under emergency conditions. Botulinum toxin is a nerve toxin produced by the bacterium Clostridium botulinum that causes botulism, a serious paralytic illness. Naturally occurring cases are mainly seen in infants or in adults who have consumed improperly processed foods. Botulinum toxin can also be used as a bioterrorist weapon and has been identified in the United States as one of the highest priority bioterrorism threats. To date, the principal customer for BAT has been the U.S. government, specifically HHS (including BARDA). In our acquisition of Cangene, we acquired a five-year, $362 million contract with BARDA to deliver 200,000 doses of BAT into the SNS. BARDA has exercised options to extend that contract until 2018, adding $62 million in additional revenue for a total contract value of up to $427 million. The additional work covered by the exercised options primarily involves plasma collection until December 2014, as well as stability studies and activities to support licensure maintenance. In addition to domestic government sales, BAT has been sold to several foreign governments.

AIGIV (Anthrax Immune Globulin Intravenous (Human)). AIGIV is an investigational product candidate that is a mixture of purified polyclonal human immune globulins (antibodies) directed to the toxin produced by Bacillus anthracis. It is being developed to treat toxemia associated with inhalational anthrax. AIGIV is procured by HHS into the SNS for use in an emergency under an EUA. To date, the principal customer for AIGIV has been the U.S. government, specifically HHS (including BARDA). Our current contract with BARDA is a multiple award, indefinite delivery/indefinite quantity contract, which also includes a development component. It provides for the collection of AIGIV specialty plasma, as well as the manufacture of such plasma into bulk drug substance, the further manufacture of bulk drug substance into finished product and delivery of finished product into the SNS over a five-year period. The maximum amount that could be paid to us under this contract is approximately $264 million, subject to availability of funding to BARDA. The period of performance under the BARDA contract is from September 19, 2013 through September 13, 2017. Cangene received the first task/delivery order for the collection and storage of human anti-anthrax plasma that would be sufficient to manufacture 10,000 doses of bulk drug substance or final drug product at the time the contract was signed in September 2013. This task order is expected to generate aggregate revenue of approximately $63 million from 2014 to 2016 (this $63 million is included in the $264 million maximum potential amount under the contract).

RSDL® (decontamination lotion). RSDL is a medical device used to remove and/or neutralize chemical warfare agents from the skin, including nerve agents, mustard gas and T-2 toxins (a myco toxin capable of being weaponized). RSDL has been cleared by the FDA, Health Canada, the United Kingdom's Medicines and Healthcare Products Regulatory Agency and Australia's Therapeutics Goods Administration. To date, the principal customers for RSDL have been agencies of the U.S. government, including the DoD, the Department of State and the National Guard. Our current contract with the DoD is a five-year contract, including option years, that expires in June 2017. Our DoD contract is an indefinite delivery/indefinite quantity contract. In addition to domestic government sales, we have also made sales into 19 foreign countries in 2013. While we seek to identify and pursue opportunities to expand the market for RSDL by finding new customers, we are also seeking to expand the uses and indications for RSDL. For example, we are currently taking regulatory steps to allow RSDL to be recommended for removing organophosphate pesticides from the skin. We are also evaluating the potential use of RSDL to treat toxic industrial chemicals and to remove radioactive metals from the skin.

VIGIV (Vaccinia Immune Globulin Intravenous (Human)). VIGIV is a mixture of purified polyclonal human immune globulins (antibodies) directed to vaccinia virus, the virus that is used in the smallpox vaccine. Vaccinia is not the virus that causes smallpox, but it is similar enough to elicit a protective immune response when used as a smallpox vaccine. Individuals who are susceptible to vaccinia may develop an infection from the smallpox vaccination. These patients benefit from treatment with VIGIV. VIGIV is approved in the U.S. and in Canada for counteracting certain complications that can be associated with the smallpox vaccine. To date, the principal customer for VIGIV has been the U.S. government, specifically HHS (including CDC) and DoD. Our primary contract for this product is with the CDC. In September 2013, Cangene entered into a contract extension with the CDC, which includes the performance of additional services to support licensure maintenance activities, as well as options for additional manufacturing and plasma collections. In addition to domestic government sales, Cangene also made sales of VIGIV to several foreign governments in 2013.

Product Candidates

NuThrax™ (Anthrax Vaccine Adsorbed containing CPG 7909 Adjuvant). We are developing NuThrax, an anthrax vaccine product candidate based on BioThrax combined with CPG 7909, an adjuvant that we license from Pfizer Inc. in part with funding from the National Institute of Allergy and Infectious Disease, or NIAID. NuThrax may elicit a rapid onset of immune response and may require fewer doses to provide protective immunity in patients than BioThrax. We continue to support the efforts of the U.S. government to pursue a more cost-effective countermeasure solution on a per patient basis. If approved, NuThrax may be capable of providing protective immunity with fewer doses, reducing the cost of immunizing patients on a per patient basis. In September 2010, we obtained additional funding for this product through a four-year development contract with NIAID of up to $28.7 million to support further development, including: manufacturing and stability studies of Phase II clinical trial lots, process characterization, assay validation and clinical trial preparation. We enrolled and dosed the first subject in the Phase II clinical trial in January 2013. Enrollment is now complete and we are in the process of gathering and analyzing the data. We continue to seek additional government funding for this investigational product candidate to advance it further toward approval.

PreviThrax™ (Recombinant Protective Antigen Anthrax Vaccine, Purified). We are developing PreviThrax, a recombinant protective antigen anthrax vaccine product candidate, in part with funding from BARDA. 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 candidate, and are currently evaluating this vaccine formulated with the new adjuvant.

Research and Development

In our Biodefense division we are engaged in research and development and have incurred substantial expenses for these activities. These expenses generally include the cost of acquiring or inventing new technologies and products, as well as development work on new product candidates. Gross research and development expenses for the Biodefense division for the years ended December 31, 2013, 2012 and 2011 totaled approximately $62.7 million, $68.6 million and $57.8 million, respectively. Net research and development expenses (net of contracts and grants revenue) for the Biodefense division for the years ended December 31, 2013, 2012 and 2011 totaled approximately $9.0 million, $8.6 million and $9.2 million, respectively. See Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations – Research and Development Expense" for additional information regarding expenditures related to major research and development projects.

Marketing & Sales

We market and sell our Biodefense products to the U.S. government and domestic non-government organizations with a small, specialized marketing and sales group. Many of the personnel within this specialized marketing and sales group are retired military service or Department of Justice personnel, with extensive experience in the public and private sector dealing with counterterrorism and CBRN threat agent preparedness. We intend to use a similar approach to the marketing and sales of our other Biodefense product candidates that we successfully develop or acquire.

We have established a marketing and sales capability targeting sales of Biodefense products to foreign governments as well as non-governmental organizations. We have augmented our international efforts by engaging third-party marketing distributors and representatives to identify potential opportunities to sell our products in key international markets including Europe, the Middle East, Asia and the Pacific Rim. We anticipate engaging additional representatives as interest in CBRN threat countermeasures increases.

Competition

Our products and product candidates intended for the treatment or prevention of CBRN threat agents face significant competition for government funding for both development and procurement. Our products and any product or product candidate that we acquire or 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 our products and 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 us and to our competitors for the development of alternative anthrax vaccines. In addition, the United Kingdom Health Protection Agency manufactures an anthrax vaccine for use by the government of the United Kingdom. Other countries may also have anthrax vaccines in development for their own internal use.

RSDL. In the U.S., RSDL is the only FDA cleared chemical warfare agent decontamination device for use on the skin. Internationally, various Ministries of Defense have used Fullers Earth, Dutch Powder and French Powder to absorb liquid chemical weapons.

BAT. Our BAT is the only heptavalent botulinum immune globulin product licensed in the U.S. Other companies may be in stages of developing therapies aimed at treating or preventing botulism infections, however, direct competition is currently limited.

AIGIV. GlaxoSmithKline plc has obtained FDA licensure for ABthrax™ (raxibacumab), an anthrax monoclonal antibody therapeutic. Elusys Therapeutics, Inc. is developing Anthim™, an anthrax monoclonal antibody therapeutic.

VIGIV. Our VIGIV is the only vaccinia immune globulin product licensed in the U.S. and Canada. Other companies may be in stages of developing therapies aimed at treating or preventing vaccinia infections; however, direct competition is currently limited. SIGA Technologies, Inc. is developing Arestvyr™, an oral therapy that could potentially be used as a treatment for smallpox or vaccinia infections. SIGA is continuing clinical trials for Arestvyr.

PreviThrax and NuThrax. PharmAthene, Inc., PaxVax Inc., Vaxin Inc. and Pfenex Inc. are each currently developing anthrax vaccine product candidates with funding provided by NIAID and BARDA.

Customer Reliance

In the past, we have derived substantially all of our product revenues within our Biodefense division from sales to the U.S. government, specifically the HHS (including BARDA and CDC) and the DoD. We expect that this will be the case for the foreseeable future. Product revenues were $257.9 million in 2013, which consisted of $254.0 million from sales to the U.S. government and $3.9 million from international and other domestic customers. Product revenues were $215.9 million in 2012, which consisted of $215.3 million from sales to the U.S. government and $546,000 from international and other domestic customers. Product revenues were $202.4 million in 2011, which consisted of $200.9 million from sales to the U.S. government and $1.5 million from international and other customers. We are focused on increasing sales of our Biodefense products to the U.S. government, expanding the market for our Biodefense products, particularly BioThrax, through growth in sales to international and other domestic customers and pursuing ongoing product enhancements, including initiatives to secure a second label indication for use of BioThrax as a post-exposure prophylaxis.

A second significant source of revenue within our Biodefense division is our contracts and grants revenue, which represents development funding primarily from the U.S. government, specifically HHS (including BARDA and NIAID) for our Biodefense investigational product candidates. We expect that this will be the case for the foreseeable future. Contracts and grants revenue was $54.8 million in 2013, $66.0 million in 2012 and $71.0 million in 2011. These revenues substantially offset our costs in developing Biodefense investigational product candidates. We are focused on continuing to secure additional development funding for our Biodefense investigational product candidates.

BIOSCIENCES DIVISION

Our Biosciences division is a specialty pharmaceutical business focused on therapeutics and vaccines in hematology/oncology, transplantation and infectious disease. Our Biosciences portfolio consists of marketed products, investigational stage product candidates and contract manufacturing services.

Marketed Products

WinRho® SDF (Rho(D) Immune Globulin Intravenous (Human)). WinRho SDF is a mixture of purified polyclonal human immune globulins (antibodies) directed to Rh_o(D)(+) red blood cells. As antibodies that are directed to the Rh_o(D) antigen on these red blood cells, WinRho SDF can generally be referred to as an anti-D product. WinRho SDF is approved in the U.S. and Canada to treat an autoimmune platelet disorder called immune thrombocytopenic purpura, or ITP, a disease in which platelets are destroyed by a patient's own immune system. Because platelets are required for blood clotting, this disorder can result in uncontrolled bleeding, either spontaneously or as a result of even minor trauma. According to a study published in 2010 in the American Journal of Hematology, U.S. incidence rates of ITP are about 3.3 cases per 100,000 people per year in adults and up to 6.4 cases per 100,000 people per year in children. WinRho SDF is also approved in the U.S. and Canada to prevent hemolytic disease of the newborn, or HDN. HDN results from an Rho(D)(-) female giving birth to an Rho(D)(+) child.

HepaGam B® (Hepatitis B Immune Globulin Intravenous (Human)). HepaGam B is a mixture of purified polyclonal human immune globulins (antibodies) that are directed to the hepatitis B surface antigen. In the U.S., HepaGam B has

been approved for two indications: for the prevention of Hepatitis B reinfection after liver transplantation and for use as a post-exposure prophylaxis (i.e., treatment following exposure to the hepatitis B virus). Hepatitis B is a chronic infection and a major global health concern. HepaGam B is the first hepatitis B immune globulin product to be licensed in the U.S. for the liver transplant-related indication. It has orphan drug exclusivity in the U.S. through April 2014. HepaGam B is licensed to us from Apotex Corporation. We have ongoing royalty payment obligations to Apotex based on net sales of HepaGam B until June 2016. HepaGam B is also approved for both the post-exposure prophylaxis of hepatitis B and the post-liver transplantation indication in Canada, Israel, Kuwait and Turkey.

VARIZIG® (Varicella Zoster Immune Globulin (Human)). VARIZIG is a mixture of purified polyclonal human immune globulins (antibodies) directed to the Varicella zoster virus, the disease agent that causes chickenpox and shingles. While most North American adults have developed immunity to chickenpox, certain at-risk patient populations may be susceptible to infection. VARIZIG is approved in the U.S. for post-exposure prophylaxis of varicella (chickenpox) in high-risk patient groups, including immunocompromised children, newborns and pregnant women. VARIZIG has orphan drug exclusivity in the U.S. through December 2020. In Canada, VARIZIG is approved for the prevention and reduction of severity in maternal infections within four days of exposure to Varicella zoster virus.

episil®. Episil has been cleared by the FDA in the U.S. as a medical device for local management of pain associated with oral mucositis, or OM. Episil is indicated for the relief of pain, soothing oral lesions of various etiologies, including OM/stomatitis caused by chemotherapy and radio therapy. OM is characterized by painful ulceration and opportunistic mouth infections. According to a 2003 Datamonitor report, OM affects approximately 500,000 patients in the U.S. per year. It is currently managed through oral care, nutritional support, pain control, decontamination, palliation of dry mouth, management of oral bleeding and therapeutic interventions that include cryotherapy, topical agents, systemic analgesics, growth factors, anti-inflammatory agents, anti-oxidants and low-level laser therapy. We hold the exclusive rights to commercialize episil in the U.S. under an agreement with Camurus AB. Episil was launched in the U.S. in October 2012.

Product Candidates

Our Biosciences portfolio also includes investigational product candidates, including:

Otlertuzumab (Humanized Anti-CD37 therapeutic). Otlertuzumab (formerly known as TRU-016) is a humanized anti-CD37 ADAPTIR mono-specific protein therapeutic intended for the treatment of Chronic Lymphocytic Leukemia, or CLL. CLL is a type of cancer that affects the blood and bone marrow and is caused by B-cells within the blood and bone marrow that abnormally proliferate and die. According to the American Cancer Society, there are approximately 15,000 new diagnosed cases of CLL and about 4,600 deaths due to CLL per year in the U.S. We believe that otlertuzumab's novel properties may provide patients with improved therapeutic options and enhanced efficacy when used in combination with chemotherapy or other targeted therapeutics. Otlertuzumab is currently being evaluated in multiple clinical studies. In December 2013, we announced positive interim results from a Phase 2 study evaluating the combination of otlertuzumab and bendamustine (a chemotherapy agent) versus bendamustine alone in people with relapsed CLL (Study 16201). The data showed that the combination of otlertuzumab with bendamustine produced a higher response rate than bendamustine alone according to the International Workshop on CLL and National Cancer Institute response criteria. In December 2013, we also announced preliminary results from a Phase 1b single-arm, open-label study evaluating the safety and efficacy of otlertuzumab in combination with rituximab (anti-CD-20 directed biologic) in people with previously untreated CLL (Study 16009). The preliminary data showed that the combination was active and well tolerated. We continue to assess data from these studies and to evaluate opportunities for additional clinical studies of this product candidate in CLL.

IXINITY™ (trenonacog alfa). IXINITY (formerly known as IN1001) is a late-stage intravenous recombinant human coagulation factor IX therapeutic that is being developed for the prevention of bleeding episodes in people with hemophilia B. Hemophilia B, also known as Christmas disease, is a rare, inherited bleeding disorder. According to the

World Federation of Hemophilia 2011 World Annual Survey, approximately 27,000 people worldwide, including more than 4,000 in the U.S. have been diagnosed with hemophilia B. The blood of hemophilia B patients has an impaired clotting ability, which results from its substantially reduced or missing factor IX activity. People with hemophilia B require factor IX injections to restore normal blood coagulation and to prevent frequent bleeding that could otherwise result in pain, irreversible joint damage or life-threatening hemorrhages. Prophylaxis or on-demand treatment in hemophilia B typically requires multiple injections of factor IX (current therapies are either plasma-derived or recombinant products) to maintain adequate levels of clotting factor in the blood.

Research and Development

In our Biosciences division, we are engaged in research and development and have incurred substantial expenses for these activities. These expenses generally include the cost of acquiring or inventing new technologies and products, as well as development work on new product candidates. Gross research and development expenses for the Biosciences division the for the years ended December 31, 2013, 2012 and 2011 totaled approximately $50.7 million, $44.6 million and $61.6 million, respectively. Net research and development expenses (net of contracts and grants revenue and net loss attributable to noncontrolling interests) for the Biosciences division for the years ended December 31, 2013, 2012 and 2011 totaled approximately $48.6 million, $33.2 million and $32.3 million, respectively. See Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations – Research and Development Expense" for additional information regarding expenditures related to major research and development projects.

Contract Manufacturing Services

Our Biosciences division also provides contract manufacturing services to third-party customers. The majority of these services are performed at our facility located in Baltimore, Maryland. At this facility we perform biopharmaceutical product development and filling services for injectable and other sterile products, as well as process design, technical transfer, manufacturing validations, laboratory support, aseptic filling, lyophilization and accelerated and ongoing stability studies. We have manufactured both vial and pre-filled syringe formats for a wide variety of drug products in all stages of development and commercialization, including 20 licensed products, which are currently sold in more than 40 countries. This facility produces finished units of commercial drugs for a variety of customers ranging from small biopharmaceutical companies to major multinationals. The facility is an approved manufacturing facility under the regulatory regimes in the U.S., Canada, Japan, Brazil, the Middle East and several countries in the European Union.

Distribution

Other than VARIZIG, in the U.S. our products are sold by our commercial sales force and distributed to end-users through major U.S. distributors and wholesalers like Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation. In the U.S., VARIZIG is exclusively distributed by FFF Enterprises, Inc. In Canada, all of our commercial products are exclusively distributed by Canadian Blood Services and Héma-Québec. Outside of North America, our commercial products are distributed primarily through third-party distributors.

Marketing & Sales

With our acquisition of Cangene, we acquired specialty biopharmaceutical commercial operations and medical affairs teams with experience in sales, marketing, distribution, reimbursement and medical support.

The commercial operations team includes a U.S.-based field sales force that focuses its selling efforts on hematology clinics, medical oncology clinics, radiation oncology clinics, transplant centers and public and private hospitals. This team is also responsible for managing day-to-day relationships with third parties, including managed care organizations, pharmacy benefit managers, group purchasing organizations, wholesalers, specialty distributors and

specialty pharmacies. Outside of the U.S., sales are managed by an international sales team that maintains a network of regional independent distributors who sell commercial product directly to international customers. The commercial operations team also includes a marketing team with experience in building pharmaceutical, biological and device brands across all stages of the product life cycle. Reimbursement support, patient assistance/compassionate use and non-medical customer inquiries are handled by customer service personnel within our commercial operations team.

Our medical affairs team includes field-based medical science liaisons, who respond to customer requests for information, establish and maintain company relationships with researchers and clinicians, train our product specialists and sales personnel and interface with clinical trial investigators. Our medical affairs team also supports customers by providing medical information, drug safety and pharmacovigilence services.

Competition

Our Biosciences products and product candidates face significant competition. Any product or product candidate that we acquire or successfully develop and commercialize is likely to compete with currently marketed products, as well as other novel product candidates that are in development for the same indications. Specifically, the competition for our products and product candidates includes the following:

WinRho SDF. In the U.S., the use of WinRho SDF is primarily for the ITP indication. In the U.S. ITP market, WinRho SDF competes against Rhophlac® (CSL Behring, a subsidiary of CSL Limited), Nplate® (Amgen Inc.) and Promacta® (GlaxoSmithKline plc). In Canada, the use of WinRho SDF is primarily for the HDN indication. WinRho SDF is the only anti-D product available for the prevention of HDN and treatment of ITP in Canada.

HepaGam B. Two competitive products are marketed in North America: Nabi-HB® (Biotest Pharmaceuticals Corporation) and HyperHEP B® S/D (Grifols USA, LLC). Nabi-HB® and HyperHEP B® S/D are both licensed to treat acute exposure to blood containing hepatitis B surface antigen and administered via intramuscular injection. HepaGam B is currently the only intravenous hepatitis B immune globulin licensed for the liver transplantation indication in the U.S. and Canada.

VARIZIG. No other currently manufactured competitive product is licensed in the North American markets.

episil®. Episil competes primarily with oral hygiene protocols, mouthwashes and oral rinses, topical anesthetics and mucosal barriers and coating agents. The most widely prescribed therapy is a pharmacist-compounded mouthwash known as Magic or Miracle mouthwash.

Otlertuzumab. If approved for CLL, we anticipate that otlertuzumab would compete with, or be combined with, other B-cell depleting therapies, targeted therapies and chemotherapeutics, including: Rituxan® (Genentech, Inc., a member of the Roche Group), Treanda® (Cephalon, a subsidiary of Teva Pharmaceutical Industries Ltd.), Arzerra® (GlaxoSmithKline plc and Genmab A/S), Imbruvica™ (Pharmacyclics, Inc. and Johnson and Johnson) and Gayzva™ (obinutuzumab, Genentech USA, Inc., a member of the Roche Group). In addition, Boehringer Ingelheim GmbH and ImmunoGen, Inc. are in early stage development for monoclonal antibodies directed to CD37. Gilead Sciences, Inc. is developing a phosphoinositide 3-kinase inhibitor (idelalisib) and AbbVie Inc. is developing ABT-199, a B-cell lymphoma 2 inhibitor, for treatment of CLL in collaboration with Genentech, Inc.

IXINITY. If approved, we anticipate that IXINITY would compete with Benefix (Pfizer Inc.), Rixubis (Baxter International Inc.), AlphaNine (Grifols USA, LLC), MonoNine (CSL Behring, a subsidiary of CSL Limited) and, if it is approved, Alprolix (Biogen Idec Inc.). We expect that Novo Nordisk Inc. and CSL Behring will also launch additional long acting recombinant factor IX agents in the future.

Contract Manufacturing Services Business. We compete for contract service business with several biopharmaceutical product development organizations, contract manufacturers of biopharmaceutical products and university research

laboratories, including, among others: OSO BioPharmaceuticals Manufacturing, LLC, JHP Pharmaceuticals, LLC, Jubilant Hollister-Stier Laboratories LLC (a subsidiary of Jubilant Life Sciences Limited), Patheon Inc., Hospira Inc., Ajinomoto Althea, Inc. (a subsidiary of Ajinomoto Co., Inc.), Cook Pharmica LLC (a subsidiary of Cook Group Inc.), and Albany Molecular Research, Inc. Although many of these competitors do not offer the same range of services that we do, they can and do compete effectively against certain areas of our business, including our biopharmaceutical production capabilities. We also compete with in-house research, development and support service departments of other biopharmaceutical companies.

MANUFACTURING

Biodefense Division

We have a manufacturing facility focused on bacterial fermentation located at our 12.5 acre, multi-building campus in Lansing, Michigan. We currently manufacture BioThrax at the 100-liter scale at this facility, or Building 12. To augment our existing BioThrax manufacturing capabilities, we have constructed a large-scale, multi-product facility, or Building 55, capable of producing BioThrax at the 1320-liter scale. In July 2010, we entered into a contract with BARDA that provides funding to support the work needed to approve manufacturing of BioThrax at Building 55. We continue to pursue FDA approval for BioThrax at this larger production scale.

We also have a manufacturing facility focused on disposable manufacturing for viral and non-viral products located in Baltimore, Maryland. This facility has been designed to leverage single-use bioreactor technology and is capable of making several different products. The facility is designed to produce proteins derived from cell culture or microbial systems. In June 2012, we entered into a contract with BARDA, which established this facility as a Center for Innovation in Advanced Development and Manufacturing, or CIADM. The CIADM contract with BARDA provides us with funding for manufacturing and development activities relating to a clinical stage pandemic flu vaccine candidate that we in-licensed from a third party. We envision this facility supporting future CIADM development and manufacturing activities for chemical, biological, radiological and nuclear threat countermeasures, as well as our current and future non-CIADM product development and manufacturing needs.

In connection with our acquisition of the Healthcare Protective Products Division of Bracco Diagnostics Inc., we acquired rights to a manufacturing and packaging facility at The University of Southern Mississippi's Accelerator, an innovation and commercialization park. This facility is equipped to manufacture and package RSDL. A significant portion of the doses of RSDL that we sell to domestic customers are packaged at this facility. In connection with this acquisition, we also entered into a three-year CMO agreement with Bracco Diagnostics Inc., and its wholly-owned subsidiary, E-Z-EM Canada Inc. (dba Therapex), to manufacture finished RSDL units and bulk quantities of RSDL's active ingredient. RSDL's active ingredient and other raw materials are shipped to and subsequently finished and packaged at our Mississippi facility.

Biosciences Division

In connection with our acquisition of Cangene, we acquired facilities with manufacturing and other capabilities located in Winnipeg, Manitoba, Canada. These facilities include space for plasma-derived hyperimmune therapeutics manufacturing, chromatography-based plasma fractionation, bacterial fermentation, downstream processing capability, aseptic filling, packaging and warehousing, quality assurance and control, development laboratories and office space. At these facilities, we manufacture our hyperimmune specialty plasma products, including WinRho SDF, HepaGam B, VARIZIG, BAT, AIGIV and VIGIV. Our Biodefense division depends on the operations at these facilities to manufacture its hyperimmune specialty plasma products, including BAT, AIGIV and VIGIV. Our Biosciences division also depends on the operations at these facilities to manufacture its hyperimmune specialty plasma products, including WinRho SDF, HepaGam B and VARIZIG.

Also, in connection with our acquisition of Cangene, we acquired a manufacturing facility focused on contract manufacturing services located in Baltimore, Maryland. This site provides biopharmaceutical contract manufacturing services and is an approved manufacturing facility under the regulatory regimes in the U.S., Canada, Japan, Brazil, the Middle East and several countries in the European Union. The facility includes warehousing space used for cold-storage and freezer capacity to support our Biosciences product distribution activities within the U.S. This facility and its capabilities may be utilized in the future to fill and finish our development and commercial stage products, for which we currently rely on third-party fill/finish providers.

Supplies and Raw Materials

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 in the production of our products. We typically acquire these supplies and raw materials on a purchase order basis in quantities we believe adequate to meet our needs. We obtain Alhydrogel, the adjuvant used to manufacture BioThrax and NuThrax, 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 these products. We also utilize a single-source supplier for the following other raw materials for other of our products: the sponge applicator device and the active ingredient used to make RSDL and various types of hyperimmune specialty plasmas used to manufacture our hyperimmune specialty plasma products, such as BAT, AIGIV, VIGIV, WinRho SDF, HepaGam B and VARIZIG.

INTELLECTUAL PROPERTY

We actively seek to protect the intellectual property that arises from our activities. It is our policy to respect the intellectual property rights of others. In general and where possible, we pursue worldwide patent protection for new and innovative processes and products that we develop. The term of protection for various patents associated with and expected to be associated with our marketed products and product candidates extend for varying periods of time depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. The protection afforded by a patent varies on a product-by-product basis and country-to-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patents. In some cases, we may decide that the best way to protect the intellectual property is to retain proprietary information as trade secrets and confidential information rather than to apply for patents, which would involve disclosure of proprietary information to the public. In other cases, we may be required to rely on trade secret protection on the basis that the subject matter is either not patentable or unlikely to be granted broad or useful claims. We take a number of measures to protect our trade secrets and confidential information, including entering into confidentiality agreements with employees and third parties. In general and where possible, we also pursue registered trademarks for our product candidates and marketed products. 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 and to secure freedom to operate where necessary. These agreements impose various commercial diligence and financial payment obligations on us. We expect to continue to enter into these types of license agreements in the future.

REGULATION

Regulations in the U.S. and other countries have a significant impact on our product development, manufacturing and marketing activities.

Government Contracting

Our status as a U.S. government contractor means that we are subject to various statutes and regulations, including the Federal Acquisition Regulation, or FAR, which governs the procurement of goods and services by agencies of the

U.S. government. These 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 regulations, our government contracts can be subject to unilateral termination or modification by the government for convenience, detailed auditing and accounting systems requirements, statutorily controlled pricing, sourcing and subcontracting restrictions, and statutorily mandated processes for adjudicating contract disputes.

Project BioShield. The Project BioShield Act of 2004, or Project BioShield, provides expedited procedures for bioterrorism-related procurement and the awarding of research grants, making it easier for HHS to quickly commit funds to countermeasure projects. Project BioShield relaxes procedures under the 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, in limited specified circumstances, HHS can contract to purchase unapproved countermeasures for the SNS and authorize the emergency use of medical products that have not yet been approved by the FDA.

Product Development for Therapeutics

Pre-Clinical Testing. Before beginning testing of any compounds with potential therapeutic value in human subjects in the U.S., stringent government requirements for pre-clinical data must be satisfied. Pre-clinical testing includes both in vitro, or in an artificial environment outside of a living organism, and in vivo, or within a living organism, laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation. We perform preclinical testing on all of our product candidates before we may initiate any human trials.

Investigational New Drug Application. Before clinical testing may begin, the results of preclinical testing, together with manufacturing information, analytical data and any other available clinical data or literature, must be submitted to the FDA as part of an Investigational New Drug Application, or IND. The sponsor must also include an initial protocol detailing the first phase of the proposed clinical investigation. The pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial clinical studies in human volunteers. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA imposes a clinical hold within that 30-day time period.

Clinical Trials. Clinical trials involve the administration of the drug to healthy human volunteers or to patients under the supervision of a qualified physician (also called an investigator) pursuant to an FDA-reviewed protocol. Human clinical trials typically are conducted in three sequential phases, although the phases may overlap with one another. Clinical trials must be conducted under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria, if any, to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

Phase 1 clinical trials test for safety, dose tolerance, absorption, bio-distribution, metabolism, excretion and clinical pharmacology and, if possible, for early evidence regarding efficacy.

Phase 2 clinical trials involve a small sample of individuals with the target disease or disorder and seek to assess the efficacy of the drug for specific targeted indications to determine dose response and the optimal dose range and to gather additional information relating to safety and potential adverse effects.

Phase 3 clinical trials consist of expanded, large-scale studies of patients with the target disease or disorder to obtain definitive statistical evidence of the efficacy and safety of the proposed product and dosing regimen. The safety and efficacy data generated from phase 3 clinical trials typically form the basis for FDA approval of the product candidate.

Phase 4 clinical trials are sometimes conducted after a product has been approved. These trials can be conducted for a number of purposes, including to collect long-term safety information or to collect additional data about a specific population. As part of a product approval, the FDA may require that certain Phase 4 studies, which are called post-marketing commitment studies, be conducted post-approval.

Good Clinical Practice. All of the phases of clinical studies must be conducted in conformance with the FDA's bioresearch monitoring regulations and Good Clinical Practices, or GCP, which are ethical and scientific quality standards for conducting, recording and reporting clinical trials to assure that the data and reported results are credible and accurate and that the rights, safety and well-being of trial participants are protected.

Animal Rule. For product candidates that are intended to treat or prevent infection from rare life-threatening diseases, conducting controlled clinical trials to determine efficacy may be unethical or unfeasible. Under regulations issued by the FDA in 2002, often referred to as "the Animal Rule," under some circumstances, approval of such product candidates can be based on clinical data from trials in healthy subjects that demonstrate adequate safety, 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 benefit 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 – Biologics and Drugs

Biologics License Application/New Drug Application. All data obtained from a comprehensive development program, including research and product development, manufacturing, pre-clinical and clinical trials, labeling and related information are submitted in a Biologics License Application, or BLA, to the FDA and in similar regulatory filings with the corresponding agencies in other countries for review and approval. For small molecule drugs, this information is submitted in a filing called a New Drug Application, or NDA. The submission of an application is not a guarantee that the FDA will find the application complete and accept it for filing. The FDA may refuse to file the application and request additional information rather than accept the application for filing, in which case the application must be resubmitted with the supplemental information. Once an application is accepted for filing, the U.S. Food, Drug and Cosmetic Act, or FDCA, requires the FDA to review the application within 180 days of its filing, although in practice, longer review times often occur.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, BLAs, NDAs and certain supplements must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug or biologic for an indication for which orphan designation has been granted.

In reviewing a BLA or NDA, the FDA may grant approval, deny the application if it determines the application does not provide an adequate basis for approval or again request additional information. Even if such additional information and data are submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval. The receipt of regulatory approval often takes many years, involving the expenditure of substantial financial resources. The speed with which approval is granted often depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. The FDA may also impose conditions upon approval. For example, it may require a Risk Evaluation and Mitigation Strategy, or REMS, for a product, which can include various required elements, such as publication of a medication guide, patient package insert, a communication plan to educate health care providers of the drug's risks

and/or restrictions on distribution and use such as limitations on who may prescribe or dispense the drug. The FDA may also significantly limit the indications approved for a given product and/or require, as a condition of approval, enhanced labeling, special packaging or labeling, post-approval clinical trials, expedited reporting of certain adverse events, pre-approval of promotional materials or restrictions on direct-to-consumer advertising, any of which could negatively impact the commercial success of a drug.

Fast Track Designation. The FDA may designate a product as a fast track drug if it is intended for the treatment of a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for this disease or condition. Sponsors granted a fast track designation for a drug are granted more opportunities to interact with the FDA during the approval process and are eligible for FDA review of the application on a rolling basis, before the application has been completed. The FDA has designated our following investigational product candidates for fast track status: otlertuzumab, post-exposure prophylaxis indication for BioThrax and NuThrax.

Orphan Drugs. Under the Orphan Drug Act, an applicant can request the FDA to designate a product as an "orphan drug" in the U.S. if the drug is intended to treat an orphan, or rare, disease or condition. A disease or condition is considered orphan if it affects fewer than 200,000 people in the U.S. Orphan drug designation must be requested before submitting a BLA or NDA. Products designated as orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits for research, reduced filing fees for marketing applications and a special seven-year period of market exclusivity after marketing approval. Orphan drug exclusivity (afforded to the first applicant to receive approval for an orphan designated drug) prevents FDA approval of applications by others for the same drug for the designated orphan disease or condition. The FDA may approve a subsequent application from another applicant if the FDA determines that the application is for a different drug or different use, or if the FDA determines that the subsequent product is clinically superior, or that the holder of the initial orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need. A grant of an orphan designation is not a guarantee that a product will be approved.

The FDA has granted orphan drug designation for our following products:

AIGIV;
BAT with exclusivity through March 2020 for treatment of suspected or documented exposure to botulinum neurotoxin A, B, C, D, E, F or G;
VARIZIG with exclusivity through December 2019 for post-exposure prophylaxis of varicella (chickenpox) in high-risk patient groups, including immunocompromised children, newborns and pregnant women; and
HepaGam B with exclusivity through April 2014 for prevention of hepatitis B recurrence following liver transplantation in patients who are positive for hepatitis B surface antigen.

Post-Approval Requirements. Any drug, biological or medical device product for which we receive FDA approval will be subject to continuing regulation by the FDA, including, among other things, record keeping requirements, reporting of adverse experiences, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, current good manufacturing practices, or cGMP, and restrictions on advertising and promotion. Adverse events that are reported after marketing approval can result in additional limitations being placed on the product's distribution or use and, potentially, withdrawal or suspension of the product from the market. In addition, the FDA has post-approval authority to require post-approval clinical trials and/or safety labeling changes if warranted by the appearance of new safety information. In certain circumstances, the FDA may impose a REMS after a product has been approved. Facilities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA for compliance with cGMP and other laws. The FDA also closely monitors advertising and promotional materials we may disseminate for our products for compliance with restrictions on off-label promotion and other laws. We may not promote our products for conditions of use that are not included in the approved package inserts for our products. Certain additional restrictions on advertising and promotion exist for products that have so-called "black box warnings" in their approved package inserts, such as WinRho SDF.

Vaccine Lot Release and FDA Review. Because the manufacturing process for biological products is very complex, the FDA requires for many biological products, including most vaccines, that each product lot undergo thorough testing for purity, potency, identity and sterility. Before a lot of BioThrax can be used, for example, 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.

Marketing Approval – Medical Devices

Medical devices are also subject to FDA clearance or approval and extensive regulation under the U.S. Food, Drug and Cosmetic Act. Under the FDCA, medical devices are classified into one of three classes: Class I, Class II or Class III. The classification of a device generally depends on the degree of risk associated with the medical device and the extent of control needed to ensure safety and efficacy. RSDL is regulated as a Class II medical device and episil is regulated as an unclassified medical device.

Class I devices are those for which safety and efficacy can be assured by adherence to a set of general controls. These general controls include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, which sets forth requirements for manufacturing practices, record keeping, reporting of adverse medical events, labeling and promotion only for cleared or approved intended uses.

Class II devices are also subject to these general controls and to any other special controls as deemed necessary by the FDA to ensure the safety and efficacy of the device. Review and clearance by the FDA for these devices is typically accomplished through the so-called 510(k) pre-market notification procedure. When 510(k) clearance is sought, a sponsor must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a device approved by the FDA after May 28, 1976. This previously-approved device is called the predicate device. If the FDA agrees that the proposed device is substantially equivalent to the predicate device, then 510(k) clearance to market will be granted. After a device receives 510(k) clearance, any modification that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require pre-market approval. If a proposed device is substantially equivalent to a predicate device that was approved prior to May 28, 1976, the proposed device is approved based on a pre-amendment and is approved as an unclassified device.

A Class III device requires approval of a pre-market application, or PMA, which is an expensive, lengthy and uncertain process requiring many years to complete. Clinical trials are almost always required to support a PMA and are sometimes required for a 510(k) pre-market notification. These trials generally require submission of an application for an investigational device exemption, or IDE. An IDE must be supported by pre-clinical data, such as animal and laboratory testing results, which show that the device is safe to test in humans and that the study protocols are scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and is eligible for more abbreviated investigational device exemption requirements.

Both before and after a medical device is commercially distributed, manufacturers and marketers of the device have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, record keeping, reports of adverse events, labeling and other information to identify potential problems with marketed medical devices. Device manufacturers are subject to periodic and unannounced inspection by the FDA for compliance with cGMP requirements that govern the methods used in, and the facilities and controls used for, the

design, manufacture, packaging, servicing, labeling, storage, installation and distribution of all finished medical devices intended for human use. If the FDA finds that a manufacturer has failed to comply or that a medical device is ineffective or poses an unreasonable health risk, it can institute or seek a wide variety of enforcement actions and remedies, ranging from a public warning letter to more severe actions, including:

fines, injunctions, and civil penalties;
recall or seizure of products;
operating restrictions, partial suspension or total shutdown of production;
refusal of requests for 510(k) clearance or PMA approval of new products;
withdrawal of 510(k) clearance or PMA approvals already granted; and
criminal prosecution.

The FDA also has the authority to require repair, replacement or refund of the cost of any medical device. The FDA also administers certain controls over the export of medical devices from the U.S., as international sales of medical devices that have not received FDA approval are subject to FDA export requirements. Additionally, each foreign country subjects such medical devices to its own regulatory requirements. In the European Union, a single regulatory approval process has been created and approval is represented by the CE Mark.

Pricing and Reimbursement

In the U.S. and internationally, sales of our Biosciences products and our ability to generate revenues on such sales are dependent, in significant part, on the availability and level of reimbursement from third-party payors, such as state and federal governments and private insurance plans. Insurers have implemented cost-cutting measures and other initiatives to enforce more stringent reimbursement standards and likely will continue to do so in the future. These measures include the establishment of more restrictive formularies and increases in the out-of-pocket obligations of patients for such products. In addition, particularly in the U.S. and increasingly in other countries, we are required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities. Various provisions of the Patient Protection and Affordable Care Act (as amended by the Health Care and Education Reconciliation Act), collectively referred to as the Affordable Care Act, increased the levels of rebates and discounts that we have to provide in connection with sales of such products that are paid for, or reimbursed by, certain state and federal government agencies and programs. It is possible that future legislation in the U.S. and other jurisdictions could be enacted, which could potentially impact the reimbursement rates for our Biosciences products and also could further impact the levels of discounts and rebates we are required to pay to state and federal government entities. The most significant governmental reimbursement programs in the U.S. relevant to our products are described below:

Medicare Part B. Medicare Part B covers drug products provided in a physician's office or hospital outpatient setting under a payment methodology using "average sales price," or ASP, information. We are required to provide ASP information to the Centers for Medicare and Medicaid Services, or CMS, on a quarterly basis. Medicare payment rates are currently set at ASP plus six percent, although this rate could change in future years. If we fail to timely or accurately submit ASP, we could be subject to civil and criminal penalties. WinRho SDF, HepaGam B and VARIZIG are all eligible to be reimbursed under Medicare Part B.

Medicaid Rebate Program. For products to be covered by Medicaid, drug manufacturers must enter into a rebate agreement with the Secretary of HHS on behalf of the states and must regularly submit certain pricing information to CMS. The pricing information submitted, including information about the "average manufacturer price," or AMP, and "best price" for each of our covered drugs, determines the amount of the rebate we must pay. The total rebate also includes an "additional" rebate, which functions as an "inflation penalty." The Affordable Care Act increased the amount of the basic rebate and, for some "line extensions," increased the additional rebate. It also requires manufacturers to pay rebates on utilization by enrollees in managed care organizations. If we fail to timely or accurately submit required pricing information, we could be subject to civil and criminal penalties. In addition, the

Affordable Care Act made changes to the definition of AMP, which still need to be clarified by CMS and could affect the rebate liability for our products. Sales of WinRho SDF, HepaGam B and VARIZIG that are reimbursed through Medicaid are subject to the obligations related to this program.

340B/PHS Drug Pricing Program. The availability of federal funds to pay for WinRho SDF, HepaGam B and VARIZIG under the Medicaid and Medicare Part B programs requires that we extend discounts under the 340B/Public Health Service, or PHS, drug pricing program. The 340B/PHS drug pricing program requires participating manufacturers to charge no more than a statutorily-determined "ceiling" price to a variety of community health clinics and other entities that receive health services grants from the PHS, as well as the outpatient departments of hospitals that serve a disproportionate share of Medicaid and Medicare beneficiaries. A product's ceiling price for a quarter reflects its Medicaid AMP from two quarters earlier less its Medicaid rebate amount from two quarters earlier. Therefore, the above-mentioned revisions to the Medicaid rebate formula and AMP definition enacted by the Affordable Care Act could cause the discount produced by the ceiling price to increase. Under the Affordable Care Act, four additional classes of entities were made eligible for these discounts, increasing the volume of sales for which we must now offer the 340B/PHS discounts.

Federal Supply Schedule. We make WinRho SDF, HepaGam B, VARIZIG and episil available for purchase by authorized users of the Federal Supply Schedule, or FSS, administered by the Department of Veterans Affairs, or DVA, pursuant to our FSS contract with the DVA. Under the Veterans Health Care Act of 1992, we are required to offer deeply discounted FSS contract pricing to four federal agencies—the DVA, the DoD, the Coast Guard and the PHS (including the Indian Health Service)—for federal funding to be made available for reimbursement of any of our products under the Medicaid program, Medicare Part B and for our products to be eligible to be purchased by those four federal agencies and certain federal grantees. FSS pricing to those four federal agencies must be equal to or less than the "Federal Ceiling Price," which is, at a minimum, 24% less than the Non-Federal Average Manufacturer Price for the prior fiscal year.

Foreign Regulation

We may further expand our commercial presence to foreign countries and territories outside of the U.S. and Canada in the future, but at this time our commercial presence outside of North America is in select countries only. In the European Union, medicinal products are authorized following a process similarly demanding as the process required in the U.S. Medicinal products must be authorized in one of two ways, either through the decentralized procedure, which provides for the mutual recognition procedure of national approval decisions by the competent authorities of the EU Member States or through the centralized procedure by the European Commission, which provides for the grant of a single marketing authorization that is valid for all EU member states. The authorization process is essentially the same irrespective of which route is used. We are also subject to many of the same continuing post-approval requirements in the EU as we are in the U.S. (e.g., good manufacturing practices).

Anti-Corruption Laws

We are subject to various federal and state laws pertaining to health care "fraud and abuse," including state and federal anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a drug manufacturer to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. If we violate the kickback or false claims laws, we could be subject to civil and criminal penalties, including exclusion from participation in federal healthcare programs such as Medicare

and Medicaid. Similar restrictions are imposed on the promotion and marketing of medicinal products in the European Union and other countries. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct are often strictly enforced. Even in those countries where we are not directly responsible for the promotion and marketing of our products, inappropriate activity by our international distribution partners can have implications for us. In addition, as part of the Affordable Care Act, the federal government has enacted the Physician Payment Sunshine Act. Beginning in 2014, manufacturers of drugs will be required to publicly report payments and transfers of value made to physicians and teaching hospitals. This information will be posted on a public website. Failure to timely and accurately submit required information could subject us to civil penalties. Many of these requirements are new and uncertain and the extent to which the laws will be enforced is not always clear.

Our operations are also subject to compliance with the Foreign Corrupt Practices Act, or FCPA, which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. We also may be implicated under the FCPA by the activities of our partners, collaborators, contract research organizations, vendors or other agents. The FCPA also requires us, as a public company, to make and keep books and records that accurately and fairly reflect all of our transactions and to devise and maintain an adequate system of internal accounting controls. Our operations could also be subject to compliance with the U.K. Bribery Act, which applies to bribery activities both in the public and private sector, Canada's Corruption of Foreign Public Officials Act and similar laws in other countries.

Other Regulation

Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import, export, use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents used in connection with our research work, are or may be applicable to our activities.

EMPLOYEES

As of February 28, 2014, we had 1,353 employees. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

AVAILABLE INFORMATION

We maintain a website at www.emergentbiosolutions.com. We make available, free of charge on our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, 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. We have included our website address as an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of, or incorporated by reference into, this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

You should carefully consider, among other matters, the following risk factors in addition to the other information in this Annual Report on Form 10-K when evaluating our business because these risk factors may have a significant impact on our business, financial condition, operating results or cash flow. If any of the risks described below or in subsequent reports we file with the SEC actually occur, they may materially harm our business, financial condition, operating results or cash flow. Additional risks and uncertainties that we have not yet identified or that we presently consider to be immaterial may also materially harm our business, financial condition, operating results or cash flow.

GOVERNMENT CONTRACTING RISKS

We derive the majority of our revenue from sales of BioThrax to our principal customer, the U.S. government. If the U.S. government's demand for BioThrax is reduced, our business, financial condition, operating results and cash flow could be materially harmed.

We have derived and expect for the foreseeable future to derive the majority of our revenue from sales to the U.S. government of BioThrax, our FDA-approved anthrax vaccine. 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 Strategic National Stockpile, or SNS, over a five-year period ending in September 2016.

The procurement of doses of BioThrax by the CDC is subject to the availability of funding. Our existing contract with the CDC does not guarantee that funding for the procurement of doses will be made available. If the SNS priorities change, funding to procure doses of BioThrax may be limited or not available at all, 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 significantly dependent on funding for the procurement of BioThrax and the terms of our BioThrax sales to the U.S. government, including the 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 business, financial condition, operating results and cash flow to suffer materially.

Our principal customer for BioThrax, BAT, AIGIV, VIGIV and RSDL is the U.S. government. We anticipate that the U.S. government will also be a principal customer for other biodefense products that we successfully acquire or develop. Additionally, a significant portion of our revenue comes 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, generally 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 an approximately three-year base period of performance valued at approximately $51 million and three successive one-year option periods valued at a total of approximately $101 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, 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. Congress recently passed, and President Obama recently signed, legislation suspending the federal debt ceiling until March 16, 2015. We cannot predict the ultimate outcome of the budget process or federal debt ceiling negotiations or whether such efforts will result in significant funding delays, cancellation of orders or possible default on obligations by the U.S. government, any of which 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 and grants, which may be 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 or grant 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 our Biodefense products and 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 or 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.

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 result in significant civil and criminal penalties and materially damage our relationship with the U.S. government.

We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts. Among the most significant government contracting regulations that affect the business of our Biodefense division are:

the Federal Acquisition Regulation, or FAR, and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
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, the Procurement Integrity Act, the False Claims Act and the Foreign Corrupt Practices Act;
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.

U.S. government agencies routinely audit and investigate government contractors for compliance with applicable laws and standards. If we are audited and such audit were to uncover improper or illegal activities, we could be subject to civil and criminal penalties, administrative sanctions, including suspension or debarment from government contracting and significant reputational harm.

The amount we are paid under our fixed price government contracts is based on estimates we have made 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, which could harm our operating results and materially reduce our net income.

Some of our current contracts with HHS and DoD for the procurement of our Biodefense products are fixed price contracts. We expect that our potential future contracts with the U.S. government for our 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. 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 such a contract or cause a loss, which could harm our operating results and materially reduce our net income.

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 our 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, in whole or in part, to exercise an option to purchase product under a contract or renew 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;
direct the course of a development program in a manner not chosen by the government contractor;
suspend or debar the contractor from doing business with the government or a specific government agency;
pursue civil or criminal remedies under acts such as the False Claims Act and False Statements Act; and
control or prohibit the export of products.

Generally, government contracts, including our 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. Our CDC contract for the procurement of BioThrax is, and our future U.S. government procurement and development contracts are likely to be,

terminable at the U.S. government's convenience with these potential consequences.

Our U.S. government contracts grant the U.S. government the right to use technologies developed by us under the government contract or the right to share data related to our technologies, for or on behalf of the U.S. government. Under our U.S. government contracts, we might not be able to prohibit third parties, including our competitors, from accessing such technology or data, including intellectual property, in providing products and services to the U.S. government.

COMMERCIALIZATION RISKS

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

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid technological advances. We may face future competition with respect to our products, any products that we acquire, our current product candidates and any products we may seek to develop or commercialize in the future from other biopharmaceutical companies and governments, universities and other non-profit research organizations, who are increasingly aware of the commercial value of their research. Our competitors may develop products that are safer, more effective, more convenient or less costly than any products that we may develop or market. Our competitors may 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, or more effectively negotiate third-party licensing and collaborative arrangements.

There are a number of companies with biodefense products or product candidates competing with us for both U.S. government procurement and development resources. For example, in terms of additional procurement of licensed countermeasures, HHS awarded a development and SNS procurement contract to GlaxoSmithKline plc for ABThrax (raxibacumab), an anthrax monoclonal antibody therapeutic.

We believe that our most significant competitors in the hematology/oncology, transplantation and infectious disease markets include: CSL Behring, a subsidiary of CSL Limited, Amgen Inc., GlaxoSmithKline plc, Grifols USA LLC and Baxter International Inc. Our most significant competitors in the vaccine markets include: Merck & Co., Inc., GlaxoSmithKline plc, Sanofi Pasteur SA, Novartis AG and Pfizer Inc.

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 could adversely affect our business and operating results.

We rely on third parties to distribute some of our products and those third parties may not perform.

A portion of our revenues from product sales is derived from sales through exclusive distributors in Canada and international markets. For example, in Canada, a sole distributor has rights to our WinRho SDF, HepaGam B and VARIZIG products. As a result, we rely on the sales and marketing strength of these distributors and the distribution channels through which they operate for a portion of our revenues. We may not be able to retain these distribution relationships indefinitely and these distributors may not adequately support the sales, marketing and distribution efforts of our products in these significant markets. If third parties do not successfully carry out their contractual duties in maximizing the commercial potential of our products, or if there is a delay or interruption in the distribution of our products, it could negatively impact our revenue from sales of such products.

The commercial success of our Biosciences products will depend upon the degree of market acceptance by the government, physicians, patients, healthcare payors and others in the medical community.

Our Biosciences products may not gain or maintain market acceptance by potential government customers, physicians, patients, third-party payors and others in the medical community. In particular, the success of our Biosciences products, including our hyperimmune specialty products, 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 of our products do not achieve and maintain an adequate level of acceptance, we may not generate material revenues from sales of these products. The degree of market acceptance of our products 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 products 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.

Reimbursement policies or changes in health care systems and payer policies could result in a decline in our potential sales and a reduction in our expected revenue from our products.

The revenues and profitability of biopharmaceutical companies like ours may be affected by the continuing efforts of government and third-party payers to contain or reduce the costs of health care through various means. For example, in certain foreign markets, pricing or profitability of therapeutic and other pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental control. Recent U.S. legislation, rules and regulations instituted significant changes to the U.S. healthcare system that could have a material adverse effect on our business, financial condition and profitability. We cannot predict what effects, if any, this legislation might have on our company and our products as this legislation is implemented over the next few years, nor can we predict whether additional legislative or regulatory proposals may be adopted.

In addition, in the U.S. and elsewhere, sales of therapeutic and other pharmaceutical products depend, in part, on the availability of reimbursement from third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. Third-party payers may limit access to biopharmaceutical products through the use of prior authorizations and step therapy. Any reimbursement granted may not be maintained, or limits on reimbursement available from third parties may reduce the demand for or negatively affect the price and profitability of those products. Payers may pursue aggressive cost cutting initiatives such as comparing the effectiveness, benefits and costs of similar treatments, which could result in lower reimbursement. Policies that decrease reimbursement would likely have a material adverse effect on our business, financial condition and results of operations. Our ability to successfully commercialize our products and product candidates and the demand for our products depend, in part, on the extent to which reimbursement and access is available from such third-party payers.

Our biologic products may face risks of competition from biosimilar manufacturers.

Competition for BioThrax, WinRho SDF, BAT, AIGIV, HepaGam B, VARIZIG and VIGIV, or our "Biologic Products," may be affected by follow-on biologics, which are also referred to as "biosimilars," in the U.S. and other

jurisdictions. Regulatory and legislative activity in the U.S. and other countries may make it easier for generic drug manufacturers to manufacture and sell biological drugs similar or identical to our Biologic Products, which might affect the profitability or commercial viability of our Biologic Products. Under the Biologics Price Competition and Innovation Act of 2010, the FDA cannot approve a biosimilar application until the 12-year exclusivity period for the innovator biologic has expired. Regulators in the European Union and in other foreign jurisdictions have already approved biosimilars, although the European Medicines Agency has expressly excluded blood or plasma-derived products and their recombinant alternatives from the biosimilar pathway for a period of time. Vaccine and allergen products are considered on a case-by-case basis. The specific regulatory framework for this new approval pathway, whether the FDA will permit biosimilars for blood products and vaccines, and the extent to which an approved biosimilar would be substituted for the innovator biologic are not yet clear and will depend on many factors that are currently unknown. If a biosimilar version of one of our Biologic Products were approved, it could have a material adverse effect on the sales and gross profits of the affected Biologic Product and adversely affect our business and operating results.

Political or social factors may delay or impair our ability to market our products 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 CBRN (Chemical, Biological, Radiological and Nuclear) threats are subject to changing political and social environments. The political responses and social awareness of the risks of biowarfare and bioterrorism attacks on military personnel or civilians may vary over time. Changes in the leadership of prominent terrorist networks could result in a public perception that the risk of bioterrorism is reduced. This perception, as well as political or social pressures, could delay or cause resistance to bringing our products to market or limit pricing or purchases of our products, any of which could negatively affect our revenues.

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 and could potentially damage the public's perception of us and our products. Any publicity campaigns or other negative publicity may adversely affect the degree of market acceptance of our Biodefense products and thereby limit the demand for our Biodefense products, which would adversely affect our revenues.

REGULATORY AND COMPLIANCE RISKS

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, including testing, manufacture, recordkeeping, storage and approval, 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 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.

In the United States, to obtain approval from the FDA to market any of our future biologic products, 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 efficacy 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.

However, NuThrax and PreviThrax are subject to a different regulatory approval pathway. Specifically, because humans are rarely exposed to anthrax toxins under natural conditions, and cannot be intentionally exposed,

statistically significant efficacy for these product candidates cannot be demonstrated in humans. Instead, efficacy must be demonstrated, in part, by utilizing animal models before they can be approved for marketing. This is known as the FDA's "Animal Rule. We cannot guarantee that the FDA will permit us to proceed with licensure of NuThrax, PreviThrax or any Biodefense 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 to support approval and require additional preclinical, clinical or other studies, refuse to approve our products, or place restrictions on our ability to commercialize those products. Furthermore, products approved under the Animal Rule are subject to certain additional post-marketing requirements. For example, to the extent feasible and ethical, manufacturers of products approved pursuant to the Animal Rule must conduct post-marketing studies, such as field studies, to verify and describe the drug's clinical benefit and to assess its safety when used as indicated. We cannot guarantee that we will be able to meet this regulatory requirement even if one or more of our product candidates are approved under the Animal Rule.

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 candidate involved. Changes in the regulatory approval process 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 to support 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, therapeutic product or medical device 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. Our approved products are 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, restrictions on advertising and promotion, import and export restrictions and recordkeeping requirements. In addition, various state laws require that companies that manufacture and/or distribute drug products within the state obtain and maintain a manufacturer or distributor license, as appropriate. Because of the breadth of these laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

The FDA enforces its cGMP and other requirements through periodic unannounced inspections of manufacturing facilities. The FDA is authorized to inspect domestic manufacturing facilities without prior notice at reasonable times and in a reasonable manner. The FDA conducts periodic inspections of our facilities. For example, our Lansing facility was inspected most recently in November 2013. Following each of these inspections, the FDA has issued inspectional observations, some of which were significant, but all of which are being addressed through corrective actions. 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, the FDA may undertake enforcement action against us, which may include:

warning letters and other communications;
product seizure or withdrawal of the product from the market;
restrictions on the marketing or manufacturing of a product;

suspension or withdrawal of regulatory approvals or refusal to approve pending applications or supplements to approved applications;
fines or disgorgement of profits or revenue; and
injunctions or the imposition of civil or criminal penalties.

Similar action may be taken against us upon our failure to comply with regulatory requirements, or later discovery of previously unknown problems with our products or manufacturing processes. 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. If we experience any of these post-approval events, our business, financial condition and operating results could be materially and adversely affected.

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

We currently sell and intend to sell our products 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. Approval by the FDA does not ensure approval by foreign regulatory authorities. The approval procedures in foreign jurisdictions can vary widely and can involve additional clinical trials and data review. We and our collaborators may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and therefore we may be unable to commercialize our products internationally.

Our international operations increase our risk of exposure to potential claims of bribery and corruption.

As we expand our commercialization activities outside of the United States, we will be subject to an increased risk of inadvertently conducting activities in a manner that violates the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act, Canada's Corruption of Foreign Public Officials Act, or other similar foreign laws which prohibit corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. In the course of establishing and expanding our commercial operations and seeking regulatory approvals outside of the United States, we will need to establish and expand business relationships with various third parties and will interact more frequently with foreign officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be foreign officials under the FCPA or similar foreign laws. If our business practices outside the United States are found to be in violation of the FCPA or similar foreign laws, we and our senior management may be subject to significant civil and criminal penalties, potential debarment from public procurement and reputational damage, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

MANUFACTURING RISKS

Our biologic products and product candidates are complex to manufacture and ship, which could cause us to experience delays in product manufacturing or development and resulting delays in revenues.

BioThrax, WinRho SDF, BAT, AIGIV, HepaGam B, VARIZIG and VIGIV 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. 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 obtaining materials, maintaining master seed or cell banks and preventing genetic drift, 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. Such deviations may require us to revise manufacturing processes or change manufacturers. Additionally, 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. Success rates can also 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, damage our reputation 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. For example, we must provide the FDA with the results of certain tests, including potency tests, before lots are released for sale. Potency testing of each lot of BioThrax is performed against a qualified control lot that we maintain. We have one mechanism for conducting this potency testing that is reliant on a unique animal strain for which we currently have no alternative. We continually monitor the status of our control lot and periodically produce and qualify a new control lot to replace the existing control lot. If we are not able to produce and qualify a new control lot or otherwise 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.

We are contractually required to ship our biologic products at a prescribed temperature range and variations from that temperature range could result in loss of product and could significantly impact our revenues. 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 potential clinical trials or result in litigation or regulatory action against us, any of which could be costly to us and otherwise harm our business.

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

We have constructed Building 55, a large-scale manufacturing facility on our Lansing, Michigan campus for which we received a development contract 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 a separate development contract from BARDA to establish a Center for Innovation in Advanced Development and Manufacturing. The process for qualifying and validating these facilities may result in unanticipated delays and may cost more than expected due to a number of factors, including regulatory requirements. The costs and time required to comply with cGMP regulations or similar foreign regulatory requirements for sales of our products may be significant. In addition, if we experience delays, we may be in breach of the obligations under our government-funded development contracts. We have experienced such delays in the past and may experience further delays in the future. If our facility licensure activities are delayed, we may not be able to utilize Building 55 to increase our production of BioThrax or manufacture product candidates in our Baltimore facility, which could significantly impact our revenues.

Currently, only Building 12, our manufacturing facility in Lansing, Michigan has regulatory approval to manufacture BioThrax. A significant interruption of the ability of this facility to manufacture BioThrax would reduce our revenues and materially harm our business, financial condition, operating results and cash flow.

We currently rely on our manufacturing facility at a single location in Lansing, Michigan, Building 12, 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; or
product tampering.

Providers of bioterrorism countermeasures could be subject to an increased risk of terrorist activities. The U.S. government has designated both our Lansing, Michigan and our Biodefense Baltimore facility as facilities requiring additional security. Although, we continually evaluate and update security measures, there can be no assurance that any additional security measures would protect our facilities from terrorist efforts determined to disrupt our manufacturing activities.

The factors listed above could also cause disruptions at our other facilities, including our manufacturing facility in Winnipeg, Manitoba, Canada. Any such disruption, damage, or destruction of these facilities could impede our ability to manufacture our Biologic Products and our product candidates, 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.

If we are unable to obtain supplies for the manufacture of BioThrax or our other products and product candidates in sufficient quantities and at an acceptable cost, our ability to manufacture BioThrax or to develop and commercialize our other products and 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 other products and product candidates. For example, we rely on a single-source supplier to provide us with Alhydrogel in sufficient quantities to meet our needs to manufacture BioThrax and NuThrax. We also rely on single-source suppliers for the sponge applicator device and the active ingredient used to make RSDL and the specialty plasma in our hyperimmune specialty plasma products. A disruption in the availability of such materials or services from these suppliers could require us to qualify and validate alternative suppliers. If we are unable to locate or establish alternative suppliers, our ability to manufacture our products and 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.

We are currently dependent on third-party manufacturers for the manufacture of RSDL and episil. Certain of our third-party manufacturers currently constitute the sole source supplier for these products, and we have and will continue to have limited control over the manufacturing process and costs of these products.

Third-party manufacturers currently supply a significant amount of RSDL and episil, pursuant to contractual arrangements. Certain manufacturers currently constitute the sole source for RSDL and episil. For example, E-Z-EM Canada Inc. (dba Therapex) is our sole source manufacturer for RSDL. Because of contractual restraints and the lead-time necessary to obtain FDA approval of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may cause interruptions in our supply of these products to our customers.

We have a limited ability to control the manufacturing process or costs related to the third-party manufacture of our products. Increases in the prices we pay our manufacturers, interruptions in the supply of our products or lapses in quality could adversely impact our margins, profitability and cash flows. We are reliant on our third-party manufacturers to maintain the facilities at which they manufacture our products in compliance with all FDA and other applicable regulatory requirements. If these manufacturers fail to maintain compliance with FDA or other applicable regulatory requirements, they could be ordered to cease manufacturing, which could have a materially adverse impact on our revenues and operating results.

We may be forced to consider entering into additional manufacturing arrangements with other third-party manufacturers. In each case, we will incur significant costs and time in obtaining the regulatory approvals for these third-party facilities and in taking the necessary steps to prepare these third parties for the manufacture of our products.

Our operations, including our use of hazardous materials, chemicals, bacteria and viruses, require us to comply with regulatory requirements and expose us to significant potential liabilities.

Our operations involve the use of hazardous materials, including chemicals, bacteria, viruses and radioactive materials, and may produce dangerous waste products. Accordingly, we, along with the third parties that conduct clinical trials on and manufacture our products and product candidates on our behalf are subject to federal, state, local and foreign laws and regulations that govern the use, manufacture, distribution, storage, handling, exposure, disposal and recordkeeping with respect to these materials. Under the Federal Select Agent Program, as per the Public Health Security and Bioterrorism Preparedness and Response Act, we are required to register and be inspected by the CDC and the Animal and Plant Health Inspection Service if we have in our possession, or if we use or transfer 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 and occupational health and safety laws. Compliance with current or future laws and regulations can require significant costs and we could be subject to substantial fines and penalties in the event of noncompliance. In addition, the risk of contamination or injury from these materials cannot be completely eliminated. In such event, we could be held liable for substantial civil damages or costs associated with the cleanup of hazardous materials. From time to time, we have been involved in remediation activities and may be so involved in the future. Any related cost or liability might not be fully covered by insurance, could exceed our resources and could have a material adverse effect on our business. 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 Department of Defense, or DoD, as well as regulatory authorities in Canada.

PRODUCT DEVELOPMENT RISKS

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 our product sales, our ability to generate revenue is dependent on the success of our development programs, on the U.S. government's interest in providing development funding for or procuring certain of our Biodefense Division product candidates, on the interest of non-governmental organizations and other commercial entities in providing grant funding for development of certain of our Biosciences Division product candidates and on the commercial viability of our acquired or developed 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 completion of clinical or non-clinical development, including toxicology studies and studies in approved animal models;
receipt of marketing approvals from the FDA and equivalent foreign regulatory authorities;
establishment of commercial manufacturing processes and product supply of our own or arrangements with contract manufacturers;
establishment and training of a commercial sales force for the product, whether alone or in collaboration with others;
successful registration and maintenance of patent and/or other proprietary protection for our commercial products; and
acceptance of the product by potential government customers, physicians, patients, healthcare payors and others in the medical community.

If we are delayed or prevented from developing or commercializing a product candidate in an economically acceptable manner, or if doing so requires us to incur significant unanticipated costs, 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 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. For a product approved under the Animal Rule, certain additional post-marketing requirements apply. For example, to the extent feasible and ethical, applicants must conduct post-marketing studies, such as field studies, to verify and describe the drug's clinical benefit and to assess its safety when used as indicated. 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. Under the Project BioShield Act of 2004, the Secretary of HHS can contract to purchase countermeasures for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield also allows the FDA commissioner to authorize the emergency use of medical products that have not yet been approved by the FDA under an Emergency Use Authorization, or EUA. If our Biodefense product candidates are not selected under this Project BioShield authority, they generally will have to be approved by the FDA through traditional regulatory mechanisms.

We may experience unforeseen events or issues during, or as a result of, preclinical testing, clinical trials or animal efficacy studies. These issues and events could delay or prevent our ability to receive regulatory approval for a product candidate and include, among others:

our inability to manufacture sufficient quantities of materials for use in trials;
the unavailability or variability in the number and types of subjects for each study;
safety issues or inconclusive or incomplete testing, trial or study results;
lack of efficacy of product candidates during the trials;
government or regulatory restrictions or delays; and
greater than anticipated costs of trials.

For example, in February 2013, we announced results of a Phase IIb clinical trial evaluating the safety and efficacy of MVA85A in preventing tuberculosis in infants, which indicated that a single dose of MVA85A was not sufficient to confer statistically significant protection against tuberculosis in infants. As a consequence of these results, we ceased further development work on MVA85A.

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. Our reliance on these service providers does not relieve us of our regulatory responsibilities, including ensuring that our trials are conducted in accordance with good clinical practice regulations and the plan and protocols contained in the relevant regulatory application. In addition, these organizations may not complete these activities on our anticipated or desired timeframe. We also 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, which may prove difficult, costly and result in a delay of our trials. Any delay in or inability to complete our trials could delay or prevent the development, approval and commercialization of our product candidates.

In certain cases, government entities and non-government organizations conduct studies of our product candidates, and we may seek to rely on these studies in applying for marketing approval for certain of our product candidates. 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.

If we are unable to obtain any necessary third-party services on acceptable terms or if these service providers do not successfully carry out their contractual duties or meet expected deadlines, our efforts to obtain regulatory approvals for our product candidates may be delayed or prevented.

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 ceased further development work on MVA85A, our 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 our personnel. 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. 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.

INTELLECTUAL PROPERTY RISKS

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. Obtaining and maintaining this protection is very costly. The patentability of technology in the field of vaccines, therapeutics and medical devices 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 inadvertently lapse or 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. We have in the past, and may in the future, abandon the prosecution and/or maintenance of a family of patent applications in the ordinary course of business. If these patent rights are later determined to be valuable or necessary to our business, our competitive position may be adversely affected. 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 defensive measures.

The cost of litigation to uphold the validity of patents to prevent infringement or to otherwise protect or enforce our proprietary rights could be substantial, and from time to time our patents are subject to opposition proceedings. 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 management's time and attention and other resources, even if the outcome were successful. In addition, there is a risk that a court would decide that our patents are not valid and that we do not have the right to stop the other party from using the inventions covered by or incorporating them. 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.

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 sufficient 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 to defend against these claims 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, if at all, or if an injunction is granted against us, which could harm our business significantly.

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 and/or sue us for breach, in which event we might not be able to market any product that is covered by the licensed patents and may be subject to damages.

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 any of our current products, our only intellectual property protection for these products, other than trademarks, is confidentiality regarding our manufacturing capability and specialty know-how, such as techniques, processes and unique 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 as well as confidentiality policies and audits, although these may not be successful in protecting our trade secrets and confidential information.

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 cyber 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.

RISKS RELATED TO STRATEGIC ACQUISITIONS AND COLLABORATIONS

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 and commercializing additional products on favorable terms, or at all. 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 the vaccine and therapeutic field. These companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote significant 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 or, even if an acquired product is commercialized, competing products or technologies could render a product noncompetitive, uneconomical or obsolete. 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. For example, in part to fund our acquisition of Cangene Corporation, we issued $250 million of senior convertible notes in January 2014. 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, including our recent acquisitions of Cangene Corporation and the Healthcare Protective Products Division from Bracco Diagnostics Inc., could adversely affect our business.

We may not be able to integrate any acquired business successfully, including our recent acquisitions of Cangene Corporation and the Healthcare Protective Products Division from Bracco Diagnostics Inc., or operate any acquired business profitably. In addition, cost synergies, if achieved at all, may be less than we expect, or may take greater time to achieve than we anticipate.

Issues that could delay or prevent successful integration or cost synergies of an acquired business include, among others:

retaining existing customers and attracting new customers;
retaining key employees;
diversion of management attention and resources;
conforming internal controls, policies and procedures, business cultures and compensation programs;
consolidating corporate and administrative infrastructures;
consolidating sales and marketing operations;
identifying and eliminating redundant and underperforming operations and assets;
assumption of known and unknown liabilities;
coordinating geographically dispersed organizations; and
managing tax costs or inefficiencies associated with integrating operations.

If we are unable to successfully integrate the Cangene acquisition, the Healthcare Protective Products Division from Bracco Diagnostics Inc. or future acquisitions with our existing businesses, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect our business and our ability to develop and introduce new products.

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, including otlertuzumab (Humanized Anti-CD37 therapeutic) (formerly known as TRU-016), we plan to evaluate the merits of entering into collaboration arrangements with leading biopharmaceutical companies or non-governmental organizations. We expect to selectively pursue collaboration arrangements with collaborators that have particular technology, expertise or resources for the development or commercialization of our product candidates or for accessing particular markets. We face, and will continue to face, significant competition in seeking appropriate partners for our product candidates. If we are unable to identify partners whose capabilities complement and integrate well with ours and reach collaboration arrangements with such partners on acceptable terms, or if the arrangements we establish turn out to be unproductive for us, we may fail to meet our business objectives for the particular product candidate.

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 any of our collaborations include the following, among others:

- our collaborators may not commit adequate resources to the development, marketing and distribution of any collaboration products, limiting our potential revenues from these products;
- our collaborators may experience financial difficulties and may therefore be unable to meet their commitments to us;
- our collaborators may pursue a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- our collaborators may terminate our relationship.

For example, our previous collaborative partner Pfizer Inc. terminated its collaboration with us for the development of SBI-087 following a portfolio reprioritization process in 2012. As a result, we experienced a charge of $9.6 million in 2012 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 otlertuzumab (formerly TRU-016) following a similar portfolio reprioritization process.

Failure of any of our future collaborative partners to perform as expected could place us at a competitive disadvantage and adversely affect us financially, including delay and increased costs of development, loss of market opportunities, lower than expected revenues and impairment of the value of the related product candidate.

FINANCIAL RISKS

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our operations to pay our substantial debt.

As of February 28, 2014, our total consolidated indebtedness was $250 million, consisting of our obligations under our senior convertible notes. Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the senior convertible notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Our current indebtedness and any additional debt financing may restrict the operation of our business and limit the cash available for investment in our business operations.

In addition to our current debt, we also have a senior secured revolving credit facility with available capacity of up to $100 million effective until December 11, 2018 (or such earlier date to the extent required by the terms of this facility). We may seek additional debt financing to support our ongoing activities or to provide additional financial flexibility. Debt financing could have significant adverse consequences for our business, including:

- requiring us to dedicate a substantial portion of any cash flow from operations to payment on our debt, which would reduce the amounts available to fund other corporate purposes;

increasing the amount of interest that we have to pay on debt with variable interest rates, if market rates of interest increase;
subjecting us, as under our senior secured revolving credit facility, to restrictive covenants that may reduce our ability to take certain corporate actions, acquire companies, products or technology, or obtain further debt financing;
requiring us to pledge our assets as collateral, which could limit our ability to obtain additional debt financing;
limiting our flexibility in planning for, or reacting to, general adverse economic and industry conditions; 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 be able to obtain additional financing to pay the amounts due under our indebtedness. In addition, failure to comply with the covenants under our debt instruments could result in an event of default under those instruments. An event of default could result in the acceleration of amounts due under a particular debt instrument and a cross default and acceleration under other debt instruments, and we may not have sufficient funds or be able to obtain additional financing to make any accelerated payments. Under these circumstances, our lenders could seek to enforce security interests, if any, in our assets securing our indebtedness.

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 or products, 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, 2013, we had $240.2 million of cash, cash equivalents and accounts receivable. Our future capital requirements will depend on many factors, including, among others:

the level, timing and cost of product sales;
the extent to which we acquire or invest in companies, businesses, products or technologies;
the acquisition of new facilities and capital improvements to new or existing facilities;
the payment obligations under our indebtedness;
the scope, progress, results and costs of our development activities;
our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
the costs of commercialization activities, including product marketing, sales and distribution; and
the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs.

If 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. If we raise funds by issuing equity securities, our stockholders may experience dilution. Public or bank debt financing, if available, may involve agreements that include covenants, like those contained in our senior secured revolving credit facility, limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities or declaring dividends. If we raise 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. We are not restricted under the terms of the indenture governing our senior convertible notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that could have the effect of

diminishing our ability to make payments on our indebtedness.

Current economic conditions may make it difficult to obtain financing on attractive terms, or at all. If financing is unavailable or lost, our business, results of operations and financial condition would be adversely affected and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

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 both 2013 and 2012. Our profitability has been 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.

OTHER BUSINESS RISKS

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 our products, any other products that we successfully acquire or develop and the testing of our product candidates in clinical trials.

One measure of protection against such lawsuits is coverage under the Public Readiness and Emergency Preparedness Act, or PREP Act, which was signed into law in December 2005. The PREP Act 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 federal or state 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, BAT, AIGIV and VIGIV as covered countermeasures. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct. We cannot predict whether the Secretary of HHS will renew the declarations when they expire, whether Congress will fund the relevant PREP Act compensation programs, or whether the necessary prerequisites for immunity would be triggered with respect to our products or product candidates

Additionally, BioThrax and RSDL are certified anti-terrorism products covered under the protections of the Support Anti-Terrorism by Fostering Effective Technology Act of 2002, or SAFETY Act. The SAFETY Act creates product liability limitations for qualifying anti-terrorism technologies for claims arising from or related to an act of terrorism. Although we are entitled to the benefits of the SAFETY Act for BioThrax and RSDL, the SAFETY Act may not provide adequate protection from claims made against us.

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

decreased demand or withdrawal of a product;
injury to our reputation;
withdrawal of clinical trial participants;
costs to defend the related litigation;

substantial monetary awards to trial participants or patients;
loss of revenue; and
an inability to commercialize products that we may develop.

We currently have product liability insurance with coverage up to a $30 million annual aggregate limit with a deductible of $75,000 per claim up to $375,000 in the aggregate. The amount of insurance that we currently hold may not be adequate to cover all liabilities that may occur. Further 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 all potential liabilities. For example, we may not have sufficient insurance against potential liabilities associated with a possible large scale deployment of BioThrax as a countermeasure to a bioterrorism threat. We rely on PREP Act protection for BioThrax, BAT, AIGIV and VIGIV and SAFETY Act protection for BioThrax and RSDL in addition to our insurance coverage to help mitigate our product liability exposure for these products. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

We may incur losses associated with foreign currency fluctuations.

With our acquisition of Cangene Corporation, we expect to incur a significant Canadian-dollar denominated expense in our Canadian operations. Our net income may be materially affected directly by exchange-rate fluctuations as net income from Canadian operations is translated into U.S. dollars for reporting purposes.

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.

Our success is dependent on our continued ability to attract, motivate and retain key personnel. If we fail to attract or retain key personnel, we may be unable to maintain or expand our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly qualified managerial and key scientific and technical personnel. If we lose the services of one or more of the principal members of senior management or other key employees, our ability to implement our business strategy could be materially harmed. We face intense competition for qualified employees from biopharmaceutical companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. We believe part of being able to attract, motivate and retain personnel is our ability to offer a competitive compensation package, including

equity incentive awards. If we cannot offer a competitive compensation package or otherwise attract and retain the qualified personnel necessary for the continued development of our business, we may not be able to maintain our operations or grow our business.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

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

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 common stock. As of February 28, 2014, Mr. El-Hibri was the beneficial owner of approximately 16% of our outstanding common stock. Because of Mr. El-Hibri's significant beneficial ownership of our common stock, Mr. El-Hibri also has 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. In addition, Mr. El-Hibri's significant beneficial ownership of our shares could present the potential for a conflict of interest.

Provisions in our certificate of incorporation and by-laws and under Delaware law may discourage acquisition proposals, delay a change in control or prevent transactions that stockholders may consider favorable.

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 to the Board of Directors and other proposals;
the inability of stockholders to act by written consent;
the inability of stockholders to call special meetings; and
the ability of our Board of Directors to designate the terms of and issue a 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 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. The market price of our common stock could fluctuate significantly for many reasons, including in response to the risks described in this "Risk Factors" section, or for reasons unrelated to our operations, such as reports by industry analysts, investor perceptions or negative announcements by our customers, competitors or suppliers regarding their own performance, as well as industry conditions and general financial, economic and political instability. From November 15, 2006, when our common stock first began trading on the New York Stock Exchange, through February 28, 2014, 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 biopharmaceutical 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:

decisions and procurement policies by the U.S. government affecting BioThrax;
the success of competitive products or technologies;
results of clinical and non-clinical trials of our product candidates;
announcements of acquisitions, collaborations, financings or other transactions by us;
public concern as to the safety of our products;
termination or delay of a development program;
disputes concerning patents or other proprietary rights;
the recruitment or departure of key personnel;
variations in our product revenue and profitability; and
the other factors described in this "Risk Factors" section.

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.

We currently do not anticipate paying dividends on our common stock in the foreseeable future. Our senior secured credit facility 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 million shares of our common stock outstanding as of February 28, 2014, have the right to require us to register these shares of common stock under specified circumstances. In 2012, the SEC declared effective our shelf registration statement that included registration of up to 3 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
Gaithersburg, Maryland	Office space/rental real estate	Biodefense/Biosciences	134,000	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
Hattiesburg, Mississippi	Manufacturing facilities	Biodefense	4,000	Lease expires 2020
Winnipeg, Manitoba, Canada	Manufacturing operations facilities, office space and laboratory space	Biosciences	315,000	Owned
Baltimore, Maryland	Manufacturing facilities and office and laboratory space	Biosciences	70,000	Owned

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.

Hattiesburg, Mississippi. In connection with our acquisition of the Healthcare Protective Products Division of Bracco Diagnostics Inc., we acquired rights to a manufacturing and packaging facility at The University of Southern Mississippi's Accelerator, an innovation and commercialization park. This facility is equipped to manufacture and package RSDL.

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 2013, we acquired a 134,000 square foot building in Gaithersburg, Maryland, a portion of which we intend to utilize as our corporate headquarters, while continuing to rent the remainder of the space.

With our acquisition of Cangene Corporation, or Cangene, on February 21, 2014, we acquired facilities in Winnipeg, Manitoba, Canada: a manufacturing facility focused primarily on plasma-derived hyperimmune therapeutics; a manufacturing facility focused primarily on bacterial fermentation; and a leased facility focused primarily on plasma collection and development activities. Additionally, as part of the Cangene acquisition, we acquired a manufacturing facility focused on contract manufacturing services located in Baltimore, Maryland. This facility provides contract manufacturing services to the biopharmaceutical industry, and is an approved manufacturing facility under the regulatory regimes in the United States, Canada, Japan, Brazil, the Middle East and several countries in the European Union. In addition, we acquired leased office space in Berwyn, Pennsylvania.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are involved in various routine legal proceedings incident to the ordinary course of our business. We believe that the outcome of all pending legal proceedings in the aggregate is unlikely to have a material adverse effect on our business, financial condition or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information and Holders

Our common stock trades on the New York Stock Exchange under the symbol "EBS". The following table sets forth the high and low sales prices per share of our common stock during each quarter of the years ended December 31, 2013 and 2012:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year Ended December 31, 2013				
High	$ 16.99	$ 15.89	$ 19.53	$ 24.04
Low	$ 13.75	$ 13.02	$ 14.49	$ 17.31

Year Ended December 31, 2012				
High	$ 18.34	$ 16.32	$ 15.87	$ 16.15
Low	$ 14.22	$ 13.30	$ 13.49	$ 12.50

As of February 28, 2013, the closing price per share of our common stock on the New York Stock Exchange was $24.74 and we had 32 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.

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 three months ended December 31, 2013.

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
October 1 to December 31, 2013 (1)	9,795	21.78	-	$ -
Total	9,795	$ 21.78	-	$ -

(1) In December 2013, 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 transactions with certain employees in which we acquired 9,795 shares of common stock as payment for the exercise price of 21,057 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, 2013, 2012 and 2011 and the consolidated balance sheet data as of December 31, 2013 and 2012 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, 2010 and 2009 and the consolidated balance sheet data as of December 31, 2011, 2010 and 2009 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)	2013	2012	2011	2010	2009
Statements of operations data:					
Revenues:					
Product sales	$257,922	$215,879	$202,409	$251,381	$217,172
Contracts and grants	54,823	66,009	70,975	34,790	17,614
Total revenues	312,745	281,888	273,384	286,171	234,786
Operating expenses:					
Cost of product sales	62,127	46,077	42,171	47,114	46,262
Research and development	119,933	120,226	124,832	89,295	74,588
Selling, general & administrative	87,883	76,018	74,282	76,205	73,786
Impairment of in-process research and development	-	9,600	-	-	-
Total operating expenses	269,943	251,921	241,285	212,614	194,636
Income from operations	42,802	29,967	32,099	73,557	40,150
Other income (expense):					
Interest income	139	134	105	832	1,418
Interest expense	-	(6)	-	-	(7)
Other income (expense), net	426	1,970	(261)	(1,023)	(50)
Total other income (expense)	565	2,098	(156)	(191)	1,361
Income before provision for income taxes	43,367	32,065	31,943	73,366	41,511
Provision for income taxes	13,108	13,922	15,830	26,182	14,966
Net income	$30,259	$18,143	$16,113	$47,184	$26,545
Net loss attributable to noncontrolling interest	876	5,381	6,906	4,514	4,599
Net income attributable to Emergent BioSolutions Inc.	$31,135	$23,524	$23,019	$51,698	$31,144
Earnings per share — basic	$0.86	$0.65	$0.65	$1.63	$1.02
Earnings per share — diluted	$0.85	$0.65	$0.64	$1.59	$0.99
Weighted average number of shares — basic	36,201,283	36,080,495	35,658,907	31,782,286	30,444,485
Weighted average number of shares — diluted	36,747,556	36,420,662	36,206,052	32,539,500	31,375,305

(in thousands)	As of December 31, 2013	2012	2011	2010	2009
Balance Sheet Data:					
Cash and cash equivalents	$179,338	$141,666	$143,901	$169,019	$102,924
Working capital	216,464	201,440	183,364	167,774	139,113
Total assets	626,630	564,230	546,864	500,319	344,689
Total long-term liabilities	80,814	60,195	59,083	51,039	46,173
Total stockholders' equity	489,165	442,128	416,727	373,561	243,815

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 Inc. is a specialty pharmaceutical company seeking to protect and enhance life by 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 divisions.

Our Biodefense division is a specialty pharmaceutical business focused on countermeasures that address CBRN (Chemical, Biological, Radiological and Nuclear) threats. The United States government is the primary purchaser of our Biodefense products, and often provides us with substantial funding for the development of our Biodefense product candidates. Our Biodefense portfolio consists of five revenue-generating products, including BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine approved by the U.S. Food and Drug Administration, or the FDA, for the prevention of anthrax disease, as well as RSDL® (decontamination lotion) and three products we acquired in our recent acquisition of Cangene Corporation, and various investigational stage product candidates. Operations that support this division include manufacturing, regulatory affairs, quality assurance, quality control, international sales and marketing, and domestic government affairs in support of our marketed products, as well as product development and manufacturing infrastructure in support of our investigational stage product candidates.

Our Biosciences division is a specialty pharmaceutical business focused on therapeutics and vaccines in hematology/oncology, transplantation and infectious disease. Our Biosciences portfolio consists of four revenue generating products, all four of which we acquired in our recent acquisition of Cangene Corporation, or Cangene, as well as various investigational stage product candidates and a contract manufacturing services business.

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.

On February 21, 2014, we acquired Cangene Corporation for $222 million. As part of the acquisition, we received the following revenue-generating products: BAT™ (Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G)-Equine) , AIGIV (Anthrax Immune Globulin Intravenous (Human)) and VIGIV (Vaccinia Immune Globulin Intravenous (Human)) in the Biodefense division; and WinRho® SDF (Rh_o(D) Immune Globulin Intravenous (Human)), HepaGam B® (Hepatitis B Immune Globulin Intravenous (Human)), VARIZIG® (Varicella Zoster Immune Globulin (Human)) and episil® in the Biosciences division.

Product Sales

We have derived substantially all of our historical 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 that we will continue to derive substantial product sales revenues from our sales of BioThrax to the U.S. government. Our total revenues from BioThrax sales were $246.7 million, $215.9 million and $202.4 million for the years ended December 31, 2013, 2012 and 2011, respectively. In addition, we had RSDL product sales of $11.2 million during the year ended December 31, 2013. We are focused on increasing sales of BioThrax and RSDL to U.S. government customers, expanding the market for BioThrax and RSDL to other customers domestically and internationally and pursuing label expansions and improvements.

Contracts and Grants

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

BioThrax as a post-exposure prophylaxis, or PEP;
NuThrax;
Large-scale manufacturing for BioThrax; and
PreviThrax.

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 have a manufacturing facility focused on bacterial fermentation located at our 12.5 acre, multi-building campus in Lansing, Michigan. We currently manufacture BioThrax at the 100 liter scale at this facility. To augment our existing BioThrax manufacturing capabilities, we have constructed a large-scale, multi-product facility capable of producing BioThrax at the 1320 liter scale. In July 2010, we entered into a contract with the Biomedical Advanced Research and Development Authority, or BARDA, which provides funding to support the work needed to approve manufacturing of BioThrax at the larger scale. We continue to pursue FDA approval for BioThrax at this larger production scale.

We also have a manufacturing facility focused on disposable manufacturing for viral and non-viral products located at our Biodefense manufacturing facility in Baltimore, Maryland. This facility has been designed to leverage single-use bioreactor technology and is capable of making several different products. The facility is designed to produce proteins derived from cell culture or microbial systems. In June 2012, we entered into a contract with BARDA, which established our Baltimore facility as a Center for Innovation in Advanced Development and Manufacturing, or CIADM. The CIADM contract with BARDA provides us with funding for manufacturing and development activities relating to a clinical stage pandemic flu vaccine candidate that we in-licensed from a third party. We envision our Biodefense Baltimore facility supporting future CIADM development and manufacturing activities for chemical, biological, radiological and nuclear threat countermeasures, as well as our current and future non-CIADM product development and manufacturing needs.

In connection with our acquisition of the Healthcare Protective Products Division of Bracco Diagnostics Inc., we acquired rights to a manufacturing and packaging facility at The University of Southern Mississippi's Accelerator, an innovation and commercialization park. This facility is equipped to manufacture and package RSDL. A significant

portion of the doses of RSDL that we sell to domestic customers are packaged at this facility. In connection with this acquisition in August 2013, we also entered into a three year manufacturing agreement with Bracco Diagnostics Inc., and its wholly-owned subsidiary, E-Z-EM Canada Inc. (dba Therapex), to manufacture finished RSDL units and bulk quantities of RSDL's active ingredient.

In connection with the Cangene acquisition, we acquired facilities with manufacturing and other capabilities located in Winnipeg, Manitoba, Canada. These facilities include space for plasma-derived hyperimmune therapeutics manufacturing, chromatography-based plasma fractionation, bacterial fermentation, downstream processing capability, aseptic filling, packaging and warehousing, quality assurance and control, development laboratories and office space. This facility has the potential capacity to provide additional contract research and manufacturing activities if needed.

Additionally, as part of the Cangene acquisition we acquired a manufacturing facility focused on contract manufacturing services located in Baltimore, Maryland. This facility provides biopharmaceutical contract manufacturing services and is an approved manufacturing facility under the regulatory regimes in the United States, Canada, Japan, Brazil, the Middle East and several countries in the European Union. The facility includes warehousing space used for cold-storage and freezer capacity to support our Biosciences product distribution activities within the U.S. This facility and its capabilities may be utilized in the future to fill and finish our development and commercial stage products, which currently rely upon third party fill/finish providers.

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. Our analysis of financial conditions and results of operations along with our critical accounting policies and estimates excludes the impact of Cangene.

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. In addition, we have generated sales under our indefinite delivery/indefinite quantity contract with the U.S. government and recognize revenue upon

delivery.

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.

We analyze our multiple element revenue-generating arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. An item can generally be considered a separate unit of accounting if both of the following criteria are met: the delivered item(s) has value to the customer on a stand-alone basis and if the arrangement includes a general right of return and delivery or performance of the undelivered item(s) is considered probable and substantially in the control of ours. 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 unit's selling price and is recognized in full when the criteria are met. We deem services to be rendered if no continuing obligation exists on the part of us.

Our contract with BARDA to establish a CIADM is a service arrangement that includes multiple elements. The CIADM contract requires us to provide a flexible infrastructure to supply medical countermeasures to the U.S. government over the contract period and includes such items as construction and facility design, workforce development and licensure of a pandemic flu vaccine. Since none of the individual elements by themselves satisfy the purpose of the contract, we have concluded that the CIADM contract elements cannot be separated as they do not have stand-alone value to the U.S. government. Therefore, we have concluded that there is a single unit of accounting associated with the CIADM contract. We recognize revenue under the CIADM contract on a straight-line basis, based upon its estimate of the total payments to be received under the contract. We analyze the estimated payments to be received on a quarterly basis to determine if an adjustment to revenue is required. Changes in estimates attributed to modifications in the estimate of total payments to be received are recorded prospectively.

Contingent purchase consideration obligations

In accordance with the terms of the Company's August 2013 acquisition of the Health Protective Products Division, or HPPD, from Bracco Daignostics Inc., or Bracco, we are committed to make potential payments to Bracco based on achievement of certain net sales thresholds of RSDL through 2028. We record this obligation at fair value. Contingent purchase consideration is based on a percentage of future net RSDL sales. The fair value model used to calculate this obligation is based on the income approach (a discounted cash flow model) that has been risk adjusted based on the probability of achievement of net sales.

The inputs we use for determining the fair value of the contingent purchase consideration are Level 3 fair value measurements. We re-evaluate the fair value on a quarterly basis. Changes in the fair value can result from adjustments to the discount rates and updates in the assumed timing of or achievement of net sales. Any future increase in the fair value of the contingent purchase consideration obligation is based on an increased likelihood that

the underlying net sales will be achieved. The associated payment or payments which will therefore become due and payable, will result in a charge to cost of product sales in the period in which the increase is determined. Similarly, any future decrease in the fair value of the contingent purchase consideration obligation will result in a reduction in cost of product sales.

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.

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.

Intangible assets and Acquired in-process research and development

Intangible assets represent the fair value assigned to products and medical devices that we acquire. The value assigned to intangible assets is determined by estimating the revenues and costs from these products and medical devices, and discounting the net cash flows to present value. The revenue and cost projections used to value intangibles assets are, as applicable, reduced based on the probability of achieving sales and cost forecasts.

Acquired in-process research and development, or IPR&D, represents the fair value assigned to research and development assets that the Company acquire that have not been completed at the date of acquisition. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flows to present value. The revenue and cost projections used to value acquired IPR&D are, as applicable, reduced based on the probability of developing a new drug

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. 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.

We believe the fair values assigned to intangible and IPR&D assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition date. If these assets are not successful or successfully developed, our sales and profitability will be adversely affected in future periods, and as a result, the value of the assets may become impaired.

Intangible assets are tested for impairment whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. Our annual assessment of IPR&D assets includes a comparison of the fair value to the 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 assets are reasonable and are based upon our best estimate of likely outcomes of our sales and clinical development. The underlying assumptions and estimates used to value these 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

Goodwill is assigned to reporting units, which are components of our business segments. 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 have the option to evaluate goodwill using the qualitative assessment method which

permits companies to qualitatively assess whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount. We consider developments in our operations, the industry in which we operate and overall macroeconomic factors that could have affected the fair value of the reporting unit since the date of the most recent calculation of a reporting unit's fair value when evaluating whether to perform a quantitative evaluation.

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 $704 million for the procurement of BioThrax doses under this contract. Through December 31, 2013, we have delivered and, upon CDC acceptance, recognized revenue on approximately 17.9 million doses, representing approximately $479 million under this contract.

As part of the August 2013 acquisition of the assets of HPPD, we assumed responsibility for an indefinite delivery/indefinite quantity contract with the U.S. Department of Defense, or DOD, to provide RSDL to active military personnel. The contract term runs through 2017. Through December 31, 2013, we recognized revenue of approximately $9.9 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
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
CIADM	BARDA	6/2012	6/2012 — 6/2037

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, consisting of fixed and variable costs. Variable manufacturing costs for BioThrax consist primarily of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff and contract filling operations. Fixed manufacturing costs include facilities and utilities. 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.

The primary expense that we incur to deliver RSDL to our customers is the cost per unit of production from our third-party contract manufacturer. Other associated expenses include sales-based royalties, amoritization of intangible assets, shipping, logistics and the cost of support functions.

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 obtaining 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 seek to utilize collaborations or non-dilutive funding. We plan to seek funding for earlier stage development activities from external sources and third parties, such as governments and non-governmental organizations. 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 spending, the number of product candidates under development, the size, structure and duration of any follow-on clinical programs that we may initiate, the 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 and RSDL directly to the U.S. and foreign governments with a small, targeted marketing and sales group. As we seek to broaden the market for BioThrax, RSDL and we acquire additional product candidates or 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.

Results of Operations

Year Ended December 31, 2013 Compared to Year Ended December 31, 2012

Revenues

Product sales revenues increased by $42.0 million, or 19%, to $257.9 million for 2013 from $215.9 million for 2012. This increase in product sales revenues was due to a 12% increase in the number of doses of BioThrax delivered, attributable to the timing of deliveries to the SNS, along with $11.2 million in sales from RSDL, which we acquired in August 2013. Product sales revenues in 2013 consisted of BioThrax sales to the CDC of $244.1 million and aggregate international and other sales of $2.5 million. RSDL sales in 2013 consisted of sales to the U.S. government of $9.9 million and aggregate international and other sales of $1.3 million. 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.

Contracts and grants revenues decreased by $11.2 million, or 17%, to $54.8 million in 2013 from $66.0 million in 2012. The decrease in contracts and grants revenues was primarily due to decreased revenue associated with:

- milestone payments received for our PEP indication for BioThrax related to the 2012 achievement of development milestones;
- our PreviThrax product candidate related to the timing of development activities;
- the sale of our spi-VEC technology during 2012; and
- our agreements with Abbott and Pfizer that terminated during 2012.

These decreases in revenue from 2012 were partially offset by increased revenues in 2013 from BARDA related to the establishment of our CIADM.

Contracts and grants revenues in 2013 primarily consisted of $54.6 million in development contract and grant revenue from NIAID and BARDA. 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.

Cost of Product Sales

Cost of product sales increased by $16.1 million, or 35%, to $62.1 million for 2013 from $46.1 million for 2012. This increase was attributable to the 12% increase in the number of BioThrax doses delivered coupled with an increase in the costs per dose associated with lower production yields in the period in which the doses were produced, and a lower cost per dose in 2012 associated with an adjustment to certain BioThrax testing specifications that allowed us to sell doses that were previously expensed. Cost of product sales also includes $7.2 million in costs attributable to RSDL.

Research and Development Expense

Research and development expenses decreased by $293,000 to $119.9 million for 2013 from $120.2 million for 2012. This decrease primarily reflects lower contract service costs, and includes decreased expenses of $5.9 million for product candidates and manufacturing development categorized in the Biodefense segment and decreased expenses of $441,000 in other research and development, which are in support of central research and development activities. These decreases were largely offset by increased expenses of $6.1 million for product candidates and technology platform development activities categorized in the Biosciences segment. Net of development contract and grant reimbursements along with the net loss attributable to noncontrolling interests, we incurred research and development expenses of $64.2 million and $48.8 million, respectively, during 2013 and 2012.

Our principal research and development expenses for 2013 and 2012 are shown in the following table:

	Year ended December 31,	
(in thousands)	2013	2012
Biodefense:		
Large-scale manufacturing for BioThrax	$17,876	$18,908
BioThrax related programs	10,613	10,934
PreviThrax	14,953	19,805
NuThrax	9,236	8,591
Pandemic influenza (1)	2,545	2,500
Thravixa	-	1,362
Other Biodefense	7,440	6,479
Total biodefense	62,663	68,579
Biosciences:		
Tuberculosis vaccine	4,882	15,736
Otlertuzumab (formerlyTRU-016)	27,035	13,585
ES414 (formerly T-Scorp)	7,719	4,673
ES301 (formerly DRACO)	-	2,047
Other biosciences	11,016	8,547
Total biosciences	50,652	44,588
Other	6,618	7,059
Total	$119,933	$120,226

The decrease in spending for our large-scale manufacturing for BioThrax was primarily due to the timing of non-clinical studies and manufacturing development activities. The decrease in spending for BioThrax related programs was related to the timing of clinical and non-clinical studies to support applications for label expansion for BioThrax. The decrease in spending for PreviThrax was primarily due to the timing of model optimization and non-clinical studies. The increase in spending for NuThrax was primarily due to the timing of clinical trial activities. The spending for pandemic influenza was primarily related to payments for an exclusive license to the rights to

manufacture and sell pandemic influenza products. The spending for Thravixa in 2012 was for clinical trial activities. The increase in spending for our other Biodefense activities was primarily due to increased spending related to manufacturing development, which includes increased depreciation expense related to our Baltimore facility.

The decrease in spending for our tuberculosis vaccine product candidate is related to the substantial completion of the Phase IIb clinical trial activities during 2012 partially offset by manufacturing development activities during 2013. As a result of clinical trial data published in February 2013, we ceased spending on our tuberculosis product development efforts. The increase in spending for our otlertuzumab (formerly TRU-016) product candidate is primarily related to the timing of Phase Ib/II relapsed refractory and Phase I front-line clinical trials for CLL along with manufacturing activities. The increase in spending for our ES414 (formerly T-Scorp) product candidate was primarily due to process development and non-clinical studies. The spending for our ES301 product candidate in 2012 was primarily for process development and non-clinical activities. The increase in spending for our other Biosciences activities was primarily due to increased costs associated with the development of platform technologies, as well as a reduction in 2012 of the contingent value right, or CVR, obligations associated with our agreement with Pfizer, which was terminated in 2012.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $11.9 million, or 16%, to $87.9 million for 2013 from $76.0 million for 2012. This increase was primarily due to $2.8 million in costs related to the restructuring of our U.K. operations, increased spending for transaction costs of $3.8 million associated with the acquisition of Cangene Corporation in February 2014 and HPPD from Bracco along with additional selling costs associated with our RSDL sales. The majority of the expense is attributable to the Biodefense segment, in which selling, general and administrative expenses increased by $4.9 million, or 9%, to $60.9 million during 2013 from $56.0 million during 2012. Selling, general and administrative expenses related to our Biosciences segment increased by $7.0 million, or 35%, to $27.0 million for the year ended December 31, 2013 from $20.0 million for the year ended December 31, 2012, due to our U.K. restructuring and increased professional services to support due diligence and other acquisition-related activities associated with our growth plan, including costs associated with our acquisition of Cangene.

Impairment of in-process research and development

Impairment of IPR&D 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. There was no impairment for the year ended December 31, 2013.

Total Other Income (Expense)

Total net other income decreased by $1.5 million, or 69%, to $565,000 for 2013 from $2.1 million for 2012. The decrease was primarily due to a business interruption insurance recovery related to a power outage at our Lansing, Michigan facility in 2012. For 2013, net other income includes $446,000 in rental income.

Income Taxes

Provision for income taxes decreased by $814,000, or 6%, to $13.1 million for 2013 from $13.9 million for 2012. The provision for income taxes for 2013 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of $44.2 million and an effective annual tax rate of approximately 30%. 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 2013 and 2012, respectively, reflects tax credits associated with research and developments activities of $5.9 million and $2.9 million, respectively. The decrease in the effective annual tax rate

was primarily attributable to the utilization of these tax credits.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest decreased by $4.5 million, or 84%, to $876,000 for 2013 from $5.4 million for 2012. The decrease resulted primarily from the termination of clinical and development activities and related expenses related to our tuberculosis vaccine candidate. These amounts represent the portion of the loss incurred by the joint ventures for the year ended December 30, 2013 and 2012, respectively, that was attributable to our joint venture partners.

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	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
Otlertuzumab (formerly TRU-016)	13,585	13,503
ES414 (formerly 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

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. Spending for our Anthrivig and Thravixa product candidates has ceased 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 decreased spending on our tuberculosis product development efforts. The spending for our otlertuzumab (formerly TRU-016) product candidate in 2012 and 2011 was primarily related to clinical manufacturing and clinical trial activities. The increase in

spending for our ES414 (formerly T-Scorp) product candidate was primarily due to characterization studies. The decrease in spending for our ES301 product candidate was 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. The decrease in spending for our influenza vaccine product candidate was 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 was primarily due to increased spending related to professional services and personnel costs. The majority of the expense was 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 IPR&D 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 was primarily related to orphan drug tax credits received on qualified expenditures from our otlertuzumab (formerly 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 represented the portion of the losses incurred by the joint ventures for the years ended December 31, 2012 and 2011, respectively that was attributable to our joint venture partners.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our cash requirements from inception through 2013 principally with a combination of revenues from BioThrax product sales, debt financings, 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, 2013.

As of December 31, 2013, we had cash and cash equivalents of $179.3 million. Additionally, at December 31, 2013, our accounts receivable balance was $60.6 million.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2013, 2012 and 2011.

	Year ended December 31,		
(in thousands)	2013	2012	2011
Net cash provided by (used in):			
Operating activities(1)	$96,954	$39,644	$12,186
Investing activities	(67,894)	(40,114)	(53,963)
Financing activities	8,612	(1,765)	16,659
Total net cash provided by (used in)	$37,672	$(2,235)	$(25,118)

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

Net cash provided by operating activities of $97.0 million in 2013 was primarily due to our net income of $31.1 million, a decrease in accounts receivable of $35.5 million related to the timing of collection of amounts billed primarily to the CDC, along with the effect of non-cash charges of $11.2 million for stock-based compensation and $19.0 million for depreciation and amortization.

Net cash provided by operating activities of $39.6 million in 2012 was principally due to our net income 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 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 used in investing activities of $67.9 million in 2013 was primarily due to the acquisition of HPPD from Bracco for $25.9 million and capital expenditures of $42.0 million, which includes the purchase of a new headquarters facility, construction and renovation of facilities at our Lansing, Michigan campus, and costs of other infrastructure and equipment investments.

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 provided by financing activities of $8.6 million in 2013 was primarily due to proceeds of $62.0 million from our revolving credit facility with Bank of America N.A., $6.8 million in proceeds from employee equity plans and $3.1 million in excess tax benefits from the exercise of stock options, partially offset by principal payments on indebtedness of $62.8 million (which includes the repayment of $40.4 million for our loans with PNC Bank and $22.3 million for our loans with HSBC Realty Credit).

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.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2013:

	Payments due by period					
(in thousands)	Total	2014	2015	2017	2018	After 2018
Contractual obligations:						
Long-term indebtedness including current portion	$62,000	$-	$-	$-	$62,000	$ -
Operating lease obligations	6,349	3,151	1,981	1,217	-	-
Total contractual obligations	$68,349	$3,151	$1,981	$1,217	$62,000	$ -

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 $97 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. Deferred income taxes and liabilities for unrecognized income tax benefits are excluded from the above table since they are not contractually fixed as to timing and amount.

Debt Financing

On December 11, 2013, we entered into a senior secured credit agreement, or the Credit Agreement, with the three lending financial institutions, or the Lenders, led by Bank of America, N.A., as administrative agent. The Credit Agreement provides for a revolving credit facility of up to $100.0 million through December 11, 2018, or such earlier date required by the terms of the Credit Agreement, and a term loan facility of up to $125.0 million to be drawn in full, if at all, on or prior to March 31, 2014. In connection with the entry into the Credit Agreement, we borrowed $62.0 million under the revolving credit facility primarily to repay obligations under existing loan agreements. As of December 31, 2013, we have drawn $62.0 million under the revolving credit facility in order to refinance the PNC Banks and HSBC Reality Credit Corporation. As of December 31, 2013, we had $62.0 million principal amount of debt outstanding.

Our payment obligations under the Credit Agreement are secured by a lien on substantially all of our assets, including the stock of all of the our subsidiaries, and the assets of the subsidiary guarantors, including mortgages over certain of their real properties, including our large-scale vaccine manufacturing facility in Lansing, Michigan and our biodefense facility in Baltimore, Maryland.

Under the Credit Agreement, we are required to make quarterly interest payments calculated using a combination of conventional base-rate measures plus a margin over those rates. The base rates consist of LIBOR rates and prime rates. The actual rates will depend on the level of these underlying rates plus a margin based on our leverage, on a consolidated basis, from quarter to quarter.

The Credit Agreement, as amended, contains affirmative and negative covenants customary for financings of this type. Negative covenants in the Credit Agreement, among other things, limit our ability to incur indebtedness and liens; dispose of assets; make investments including loans, advances or guarantees; and enter into certain mergers or similar transactions. The Credit Agreement also contains financial covenants, tested quarterly and in connection with any triggering events under the Credit Agreement: (1) a minimum consolidated debt service coverage ratio of 2.50 to 1.00, (2) a maximum consolidated leverage ratio of 3.50 to 1.00, (3) a maximum consolidated senior leverage ratio of 2.00 to 1.00 (when no term loan is outstanding) and (4) a minimum liquidity requirement of $50.0 million. Upon the occurrence and continuance of an event of default under the Credit Agreement, the commitments of the lenders to

make loans under the Credit Agreement may be terminated (other than commitments to make the term loan, which may only be terminated upon the occurrence and continuance of certain specified defaults) and our payment obligations under the Credit Agreement may be accelerated. The events of default under the Credit Agreement include, among others, subject in some cases to specified cure periods, payment defaults; inaccuracy of representations and warranties in any material respect; defaults in the observance or performance of covenants; bankruptcy and insolvency related defaults; the entry of a final judgment in excess of a threshold amount; change of control; and the invalidity of loan documents relating to the Credit Agreement.

On January 29, 2014, we issued $250.0 million aggregate principal amount of 2.875% Convertible Senior Notes due 2021, or the Notes. The Notes will bear interest at a rate of 2.875% per year, payable semi-annually in arrears on January 15 and July 15 of each year, commencing July 15, 2014. The Notes will mature on January 15, 2021, unless earlier purchased by us, redeemed or converted. The conversion rate will initially equal 30.8821 shares of common stock per $1,000 principal amount of notes, which is equivalent to an initial conversion price of approximately $32.38 per share of common stock. The conversion rate will be subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest.

On January 29, 2014, in connection with our issuance of the Notes, the unused $125 million term loan portion of our Credit Agreement terminated automatically in accordance with the terms of the senior secured credit agreement, dated December 11, 2013, with the Lenders. In addition, following the issuance of the Notes, we repaid the $62.0 million outstanding indebtedness under the revolving credit portion of the credit facility, which restored the full $100.0 million revolving credit capacity under this facility.

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 product sales, development contract and grant funding, and our revolving line of credit and any other lines of credit we may establish from time to time. There are numerous risks and uncertainties associated with 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, timing and cost of product sales;
the extent to which we acquire or invest in and integrate companies, business, products or technologies;
the acquisition of new facilities and capital improvements to new or existing facilities,;
the payment obligations under our indebtedness;
the scope, progress, results and costs of our development activities;
our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
the costs of commercialization activities, including product marketing, sales and distribution; and
the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other patent-related costs.

If 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. If we raise 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, pursuing acquisition opportunities or declaring dividends. If we raise 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.

We are not restricted under the terms of the indenture governing our senior convertible notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing our notes that could have the effect of diminishing our ability to make payments on our indebtedness.

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.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTRY DATA

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, 2013 and 2012, 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, 2013. 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, 2013 and 2012, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2013, 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, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework) and our report dated March 10, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia
March 10, 2014

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

	December 31, 2013	2012
ASSETS		
Current assets:		
Cash and cash equivalents	$179,338	$141,666
Accounts receivable	60,587	96,043
Inventories	14,643	15,161
Deferred tax assets, net	-	1,264
Income tax receivable, net	5,651	-
Prepaid expenses and other current assets	12,896	9,213
Total current assets	273,115	263,347
Property, plant and equipment, net	264,240	241,764
In-process research and development	41,800	41,800
Intangible assets, net	30,148	-
Goodwill	13,954	5,502
Deferred tax assets, net	-	11,087
Other assets	3,373	730
Total assets	$626,630	$564,230
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$27,521	$31,297
Accrued expenses and other current liabilities	1,252	1,488
Accrued compensation	24,615	22,726
Contingent purchase consideration, current portion	1,341	$-
Income tax payable, net	-	115
Deferred tax liability, net	88	-
Long-term indebtedness, current portion	-	4,470
Deferred revenue	1,834	1,811
Total current liabilities	56,651	61,907
Contingent purchase consideration, net of current portion	15,278	-
Long-term indebtedness, net of current portion	62,000	58,304
Deferred tax liability, net	1,419	-
Other liabilities	2,117	1,891
Total liabilities	137,465	122,102
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2013 and December 31, 2012, respectively	-	-
Common stock, $0.001 par value; 100,000,000 shares authorized, 37,036,996 shares issued and 36,624,043, shares outstanding at December 31, 2013; 36,272,550 shares issued and	37	36

35,869,392, shares outstanding at December 31, 2012		
Treasury stock, at cost, 412,953 and 403,158 common shares at December 31, 2013 and 2012, respectively	(6,119)	(5,906)
Additional paid-in capital	247,637	230,964
Accumulated other comprehensive loss	(3,465)	(4,129)
Retained earnings	251,528	220,393
Total Emergent BioSolutions Inc. stockholders' equity	489,618	441,358
Noncontrolling interest in subsidiaries	(453)	770
Total stockholders' equity	489,165	442,128
Total liabilities and stockholders' equity	$626,630	$564,230

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,		
	2013	2012	2011
Revenues:			
Product sales	$257,922	$215,879	$202,409
Contracts and grants	54,823	66,009	70,975
Total revenues	312,745	281,888	273,384
Operating expense:			
Cost of product sales	62,127	46,077	42,171
Research and development	119,933	120,226	124,832
Selling, general and administrative	87,883	76,018	74,282
Impairment of in-process research and development	$-	9,600	-
Income from operations	42,802	29,967	32,099
Other income (expense):			
Interest income	139	134	105
Interest expense	$-	(6)	-
Other income (expense), net	426	1,970	(261)
Total other income (expense)	565	2,098	(156)
Income before provision for income taxes	43,367	32,065	31,943
Provision for income taxes	13,108	13,922	15,830
Net income	30,259	18,143	16,113
Net loss attributable to noncontrolling interest	876	5,381	6,906
Net income attributable to Emergent BioSolutions Inc.	$31,135	$23,524	$23,019
Earnings per share - basic	$0.86	$0.65	$0.65
Earnings per share - diluted	$0.85	$0.65	$0.64
Weighted-average number of shares - basic	36,201,283	36,080,495	35,658,907
Weighted-average number of shares - diluted	36,747,556	36,420,662	36,206,052

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,		
	2013	2012	2011
Net income attributable to Emergent BioSolutions Inc.	$31,135	$23,524	$23,019
Reclassification of cummulative foreign currency translation adjustment to income, net of tax	58	-	-
Foreign currency translations, net of tax	606	(816)	(1,203)
Comprehensive income	$31,799	$22,708	$21,816

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,		
	2013	2012	2011
Cash flows from operating activities:			
Net income	$30,259	$18,143	$16,113
Adjustments to reconcile to net cash provided by operating activities:			
Stock-based compensation expense	11,238	11,115	10,739
Depreciation and amortization	18,958	11,197	9,355
Deferred income taxes	13,858	3,383	20,188
Non-cash development expenses from joint venture	(347)	3,670	5,290
Change in fair value of contingent obligations	735	(3,005)	221
Impairment of in-process research and development	-	9,600	-
Impairment of long-lived assets	1,172	-	976
Excess tax benefits from stock-based compensation	(3,099)	(1,588)	(4,608)
Other	51	(40)	392
Changes in operating assets and liabilities:			
Accounts receivable	35,456	(21,890)	(34,873)
Inventories	518	(500)	(1,939)
Income taxes	(7,179)	8,055	1,422
Prepaid expenses and other assets	(6,226)	(1,038)	660
Accounts payable	(551)	274	2,510
Accrued expenses and other liabilities	7	169	(95)
Accrued compensation	2,092	1,649	(3,303)
Deferred revenue	26	449	(10,863)
Net cash provided by operating activities	96,968	39,643	12,185
Cash flows from investing activities:			
Purchases of property, plant and equipment	(42,021)	(53,845)	(54,026)
Proceeds from sale of assets	-	11,765	-
Proceeds from maturity of investments	-	1,966	4,250
Purchase of investments	-	-	(4,187)
Acquisition of Healthcare Protective Products Division	(25,873)	-	-
Net cash used in investing activities	(67,894)	(40,114)	(53,963)
Cash flows from financing activities:			
Proceeds from borrowings on long-term indebtedness	62,000	13,547	27,522
Issuance of common stock subject to exercise of stock options	6,848	761	10,026
Excess tax benefits from stock-based compensation	3,099	1,588	4,608
Principal payments on long-term indebtedness and line of credit	(62,774)	(10,227)	(15,494)
Contingent obligation payments	(348)	(1,748)	(10,000)
Purchase of treasury stock	(213)	(5,906)	-
Restricted cash deposit	-	220	(3)
Net cash provided by (used in) financing activities	8,612	(1,765)	16,659
Effect of exchange rate changes on cash and cash equivalents	(14)	1	1
Net increase (decrease) in cash and cash equivalents	37,672	(2,235)	(25,118)
Cash and cash equivalents at beginning of year	141,666	143,901	169,019
Cash and cash equivalents at end of year	$179,338	$141,666	$143,901

Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$2,055	$2,137	$1,740
Cash paid during the year for income taxes	$6,331	$6,537	$4,280
Supplemental information on non-cash investing and financing activities:			
Purchases of property, plant and equipment unpaid at year end	$2,755	$5,612	$13,509

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, 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
Foreign currency translation, net of tax	-	-	-	-	-	(1,203)	-	-	(1,203)
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	-	-	-	-	-	(816)	-	-	(816)

translation, net of tax									
Balance at December 31, 2012	36,272,550	$ 36	$ 230,964	(403,158)	$ (5,906)	$ (4,129)	$ 770	$ 220,393	$ 442,128
Employee equity award plans activity	764,446	1	16,673	-	-	-	-	-	16,674
Non-cash development expenses from joint venture	-	-	-	-	-	-	(347)	-	(347)
Net loss attributable to noncontrolling interest	-	-	-	-	-	-	(876)	-	(876)
Treasury stock	-	-	-	(9,795)	(213)	-	-		(213)
Net income	-	-	-	-	-	-	-	31,135	31,135
Foreign currency translation, net of tax	-	-	-	-	-	664	-	-	664
Balance at December 31, 2013	37,036,996	$ 37	$ 247,637	(412,953)	$ (6,119)	$ (3,465)	$ (453)	$ 251,528	$ 489,165

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 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; which includes acquired 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. In August 2013, the Company acquired substantially all of the assets of the Health Protective Products Division ("HPPD") of Bracco Diagnostics Inc. ("Bracco") for cash along with contingent purchase consideration obligations.

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.

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 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.

Significant customers and accounts receivable

For the years ended December 31, 2013, 2012 and 2011, the Company's primary customer was the U.S. Department of Health and Human Services ("HHS"). For the years ended December 31, 2013, 2012 and 2011, revenues from HHS and HHS agencies comprised 95.5%, 97.9% and 91.3%, respectively, of total revenues and are included in the Company's Biodefense segment. As of December 31, 2013 and 2012, the Company's receivable balances were comprised of 96.2% and 99.9%, respectively, from this customer. Unbilled accounts receivable, included in accounts receivable, as of December 31, 2013 and 2012 were $14.8 million and $19.9 million, respectively, relates 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, 2013 and 2012, 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 to the CDC. In addition, the Company has generated sales under its indefinte delivery/indefinete quantity contract with the U.S. government and recogonizes revenue upon delivery.

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 costs 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, 2013, the costs incurred under the contracts and grants approximated the revenue earned.

The Company analyzes its multiple element revenue-generating arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. An item can generally be considered a separate unit of accounting if both of the following criteria are met: the delivered item(s) has value to the customer on a stand-alone basis and if the arrangement includes a general right of return and delivery or performance of the undelivered item(s) is considered probable and substantially in the 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 unit's selling price and is recognized in full when the criteria are met. The Company deems services to be rendered if no continuing obligation exists on the part of the Company.

The Company's contract with the Biomedical Advanced Research and Development Authority ("BARDA") to establish a Center for Innovation in Advanced Development and Manufacturing ("CIADM") is a service arrangement that includes multiple elements. The CIADM contract requires the Company to provide a flexible infrastructure to supply medical countermeasures to the U.S. government over the contract period and includes such items as construction and facility design, workforce development and licensure of a pandemic flu vaccine. Since none of the individual elements by themselves satisfy the purpose of the contract, the Company has concluded that the CIADM contract elements cannot be separated as they do not have stand-alone value to the U.S. government. Therefore, the Company has concluded that there is a single unit of accounting associated with the CIADM contract. The Company recognizes revenue under the CIADM contract on a straight-line basis, based upon its estimate of the total payments to be received under the contract. The Company analyzes the estimated payments to be received on a quarterly basis to determine if an adjustment to revenue is required. Changes in estimates attributed to modifications in the estimate of total payments to be received are recorded prospectively

Contingent purchase consideration obligations

In accordance with the terms of the Company's August 2013 acquisition of HPPD, the Company may be required to make additional payments on a quarterly basis to Bracco, based on achievement of certain net sales thresholds of RSDL through 2028. The Company records this obligation at fair value. Contingent purchase consideration is based on a percentage of future net RSDL sales. The fair value model used to calculate this obligation is based on the income approach (a discounted cash flow model) that has been risk adjusted based on the probability of achievement of net sales.

The inputs the Company uses for determining the fair value of the contingent purchase consideration are Level 3 fair value measurements. The Company re-evaluates the fair value of the contingent purchase consideration obligation on a quarterly basis. Changes in the fair value can result from adjustments to the discount rates and updates in the assumed timing of or achievement of net sales. Any future increase in the fair value of the contingent purchase consideration obligation is based on an increased likelihood that the underlying net sales will be achieved and the associated payment or payments which will therefore become due and payable. These increases in the fair value of the contingent purchase consideration obligation will result in a charge to cost of product sales in the period in which the increase is determined. Similarly, any future decrease in the fair value of the contingent purchase consideration obligation will result in a reduction in cost of product sales.

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.

Intangible assets and acquired in-process research and development

Intangible assets represent the fair value assigned to products and medical devices that the Company acquired. The value assigned to intangible assets is determined by estimating the revenues and costs from these products and medical devices, and discounting the net cash flows to present value. The revenue and cost projections used to value intangibles assets are, as applicable, reduced based on the probability of achieving sales and cost forecasts.

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 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. 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 acquired intangible and IPR&D assets are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition date. If these assets are not successful or successfully developed, sales and profitability will be adversely affected in future periods, and as a result, the value of the assets may become impaired.

The Company amortizes intangible assets based on the estimated useful life.

Intangible assets are tested for impairment whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. The Company assesses IPR&D assets for impairment on an annual basis or more

frequently if indicators of impairment are present. The Company's annual assessment includes a comparison of the fair value of IPR&D assets to existing carrying value, and recognizes an impairment when the carrying value is greater than the determined fair value. The Company believes that the assumptions used in valuing the intangible and IPR&D assets are reasonable and are based upon its best estimate of likely outcomes of sales and clinical development. The underlying assumptions and estimates used to value these assets are subject to change in the future, and actual results may differ significantly from the assumptions and estimates. The Company has selected October 1st as its annual impairment test date for indefinite-lived intangible assets.

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 Company evaluates goodwill using the qualitative assessment method which permits companies to qualitatively assess whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount. The Company considers developments in its operations, the industry in which it operates and overall macroeconomic factors that could have affected the fair value of the reporting unit since the date of the most recent calculation of a reporting unit's fair value when evaluating whether to perform a quantitative evaluation.

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, 2013, 2012 and 2011, the Company incurred interest of $2.0 million, $2.2 million and $1.7 million, respectively. Of these amounts, the Company capitalized $2.0 million, $2.2 million and $1.7 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 may not be able to manufacture BioThrax consistently in accordance with FDA specifications.

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, 2013, an aggregate of 11,178,826 shares of common stock were authorized for issuance under the 2006 Plan, of which a total of 2,387,463 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,		
	2013	2012	2011
Expected dividend yield	0%	0%	0%
Expected volatility	39-49%	41-52%	60%
Risk-free interest rate	0.32-0.70%	0.36-0.54%	0.35-1.04%
Expected average life of options	4.4 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.

3. Acquisition of Healthcare Protective Products Division

On August 1, 2013, the Company acquired substantially all of the assets of the HPPD, a division of Bracco, for approximately $25.9 million in cash along with contingent purchase consideration obligations to Bracco. The assets acquired in this acquisition include HPPD's product, RSDL, and a majority of the customer and distributor agreements associated with RSDL along with approximately $1.5 million of manufacturing equipment. The acquisition diversifies the Biodefense segment by adding product sales from RSDL.

The contingent purchase consideration obligation is based on a percentage of RSDL net sales, ranging from 0-10%, for the period August 1, 2013 through July 31, 2028. At August 1, 2013, the contingent purchase consideration obligation was recorded at a fair value of $16.2 million. The Level 3 fair value of this obligation is based on management's assessment of the potential future realization of the contingent purchase consideration payments. This assessment is based on inputs that have no observable market. The obligation is measured using the income approach (a discounted cash flow model).

The total purchase price is summarized below:

(in thousands)	
Amount of cash paid to Bracco Diagnostics Inc.	$25,873
Fair value of contigent purchase consideration	16,232
Total purchase price	$42,105

The table below summarizes the allocation of the purchase price based upon fair values of assets acquired and liabilities assumed at August 1, 2013.

(in thousands)	
Acquired intangible assets	32,099
Goodwill	8,452
Acquired equipment	1,543
Other	11
Total purchase price	$42,105

A substantial portion of the assets acquired from Bracco consisted of intangible assets associated with the RSDL product. As of the date of acquisition, the Company has recorded intangible assets of approximately $28.6 million related to RSDL, which is being amortized over 8 years, and $3.5 million related to a manufacturing agreement with Bracco, which is being amortized over 3 years. For the year ended December 31, 2013, the Company recorded $2.0 million in amortization for intangible assets, which have been recorded in cost of product sales within the Company's Biodefense segment. The weighted average amortization period for the intangible assets is 89 months.

Intangible assets consist of the following:

(in thousands)	RSDL	Manufacturing Agreement	Total
Cost Basis			
Balance at December 31, 2012	$–	$ –	$–
Additions	28,621	3,478	32,099
Balance at December 31, 2013	$28,621	$ 3,478	$32,099
Accumulated Amortization			
Balance at December 31, 2012	$–	$ –	$–
Amortization	(1,468)	(483)	(1,951)
Balance at December 31, 2013	$(1,468)	$ (483)	$(1,951)
Net book value at December 31, 2013	$27,153	$ 2,995	$30,148

Future amortization expense as of December 31, 2013 is as follows:

(in thousands)	
2014	$4,737
2015	4,737
2016	4,255
2017	3,587
2018 and beyond	12,832
Total remaining amortization	$30,148

The Company recorded approximately $8.5 million in goodwill related to the HPPD acquisition representing the purchase price paid in the acquisition in excess of the fair value of the tangible and intangible assets acquired. This goodwill is included in the Company's biodefense segment. None of the goodwill generated from the HPPD acquisition is expected to be deductible for tax purposes.

For the year ended December 31, 2013, $11.2 million of revenue and $1.9 million of revenue and net income, respectively, has been included in the Company's statements of operations.

The Company incurred transaction costs related to the HPPD acquisition of approximately $600,000 for the year ended December 31, 2013, which have been recorded in selling, general and administrative expenses within the Company's Biodefense segment.

The Company has determined the historical results of HPPD were not significant to the Company's results of operations, and as such no proforma disclosures have been presented.

4. 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, 2013			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Investment in money market funds (1)	$37,701	$ -	$-	$37,701
Total assets	$37,701	$ -	$-	$37,701
Liabilities:				
Contingent purchase consideration	$-	$ -	$16,619	$16,619
Total liabilities	$-	$ -	$16,619	$16,619

	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

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

As of December 31, 2013 and 2012, the Company did not have any transfers between Level 1 and Level 2 assets or liabilities.

The fair value of contingent purchase consideration obligations are based on management's assessment of changes as a result of adjustments to the discount rates and updates in the assumed and actual achievement of net sales for RSDL, which are inputs that have no observable market (Level 3). For the year ended December 31, 2013, the contingent purchase consideration obligation increased by $735,000 primarily due to an adjustment to the actual and expected timing of RSDL sales. The adjustment to fair value is classified in the Company's statement of operations as cost of product sales within the Company's Biodefense segment.

The fair value of 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. As of December 31, 2013 and 2012, respectively, the Company had no CVR obligations. For the year ended December 31, 2012, the Company recorded a decrease in the CVR obligations of $3.0 million due to Pfizer Inc. ("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 Laboratories ("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 years ended December 31, 2013 and 2012.

(in thousands)	
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	$-
Expense (income) included in earnings	735
Settlements	(348)
Purchases, sales and issuances	16,232
Transfers in/(out) of Level 3	-
Balance at December 31, 2013	$16,619

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. For the year ended December 31, 2013, some of the Company's equipment was measured at fair value on a non-recurring basis (see Note 7), which is categorized as a Level 3 fair value measurement. 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, 2013 and 2012, the Company had no other assets or liabilities that were measured at fair value on a nonrecurring basis.

5. Accounts receivable

Accounts receivable consist of the following:

	December 31,	
(in thousands)	2013	2012
Billed	$45,757	$76,155
Unbilled	14,830	19,888
Total	$60,587	$96,043

6. Inventories

Inventories consist of the following:

	December 31,

(in thousands)	2013	2012
Raw materials and supplies	$2,656	$2,733
Work-in-process	9,819	9,813
Finished goods	2,168	2,615
Total inventories	$14,643	$15,161

7. Property, plant and equipment

Property, plant and equipment consist of the following:

	December 31,	
(in thousands)	2013	2012
Land and improvements	$10,605	$4,839
Buildings, building improvements and leasehold improvements	83,823	66,953
Furniture and equipment	107,006	91,772
Software	21,832	15,691
Construction-in-progress	98,345	105,452
	321,611	284,707
Less: Accumulated depreciation and amortization	(57,371)	(42,943)
Total property, plant and equipment, net	$264,240	$241,764

For the years ended December 31, 2013 and 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.

During the year ended December 31, 2013, the Company recorded an impairment related to idle equipment of $1.2 million. The fair value of the asset group was determined via observable prices for similar equipment along with the estimated prices for scrap (salvage value). The impairment is classified in the Company's statements of operations as selling, general and administrative expense with in the Company's Biodefense segment. The impairment reflects management's assessment of the estimated recoverability of the equipment.

Depreciation and amoritization expense was $19.0 million, $11.2 million and $9.4 million for the years ended December 31, 2013, 2012 and 2011, respectively. The increase in depreciation expense as compared to December 31, 2012 was primarily due to the Company's Baltimore facility being placed-in-service in December 2012. As of December 31, 2013, 2012 and 2011 there was no unamortized internal use software-cost.

8. In-process research and development and goodwill

The Company completed its annual impairment assessments for its IPR&D asset and goodwill as of October 1, 2013 and 2012, respectively, and determined that the fair value of the IPR&D asset and goodwill was in excess of carrying value. The Company has determined its IPR&D assets and $5.5 million of goodwill is included in the Biosciences therapeutics reporting unit, a component of the Biosciences business segment. The remainder of goodwill, $8.5 million, is related to the HPPD acquisition and is included in the Company's Biodefense segment. The Company performed a quantitative assessment of goodwill associated with the Bioscience segment and a qualitative assesment of goodwill associated with the Biodefense segment.

During the year ended December 31, 2012, Pfizer Inc. ("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.

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 a sales price of $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 included recent purchase offers less estimated selling costs.

10. Long-term debt

The components of long-term indebtedness are as follows:

	December 31,	
(in thousands)	2013	2012
Construction loan dated July 2011; one month LIBOR plus 3%, repaid in December 2013	$-	$ 29,375
Equipment loan dated August 2011; one month LIBOR plus 3%, repaid in December 2013	-	11,068
Term loan dated December 2009; three month LIBOR plus 3.25%, repaid in December 2013	-	18,200
Term loan dated November 2009; three month LIBOR plus 3.25%, repaid in December 2013	-	4,131
Revolving credit loan dated December 2013; one month LIBOR plus 2.75%; due in December 2018	62,000	-
Total long-term indebtedness	62,000	62,774
Less current portion of long-term indebtedness	-	(4,470)
Noncurrent portion of long-term indebtedness	$62,000	$ 58,304

On December 11, 2013, the Company entered into a senior secured credit agreement ("Credit Agreement") with three lending financial institutions (the "Lenders"), led by Bank of America, N.A., as administrative agent for certain other lending financial institutions. The Credit Agreement provides for a revolving credit facility of up to $100 million through December 11, 2018 (or such earlier date required by the terms of the Credit Agreement) and a term loan facility of up to $125 million to be drawn in full, if at all, on or prior to March 31, 2014. In connection with the entry into the Credit Agreement, borrowed $62.0 million under the revolving credit facility primarily to repay obligations under existing loan agreements. As of December 31, 2013, $62.0 million was outstanding under the revolving credit facility. Debt issuance costs of $3.5 million have been capitalized and are being amortized over the term of the Credit Agreement, with an unamortized balance of $3.4 million at December 31, 2013.

The Company's payment obligations under the Credit Agreement are secured by a lien on substantially all of the Company's assets, including the stock of all of the Company's subsidiaries, and the assets of the subsidiary guarantors, including mortgages over certain of their real properties, including the Company's large-scale vaccine manufacturing facility in Lansing, Michigan and the Company's product development and manufacturing facility in Baltimore, Maryland.

Under the Credit Agreement, the Company is required to make quarterly interest payments calculated using a combination of conventional base-rate measures plus a margin over those rates. The base rates consist of LIBOR rates and prime rates. The actual rates will depend on the level of these underlying rates plus a margin based on the Company's leverage, on a consolidated basis, from quarter to quarter.

The Credit Agreement contains affirmative and negative covenants customary for financings of this type. Negative covenants in the Credit Agreement, among other things, limit the Company's ability to incur indebtedness (other than the issuance of the notes in this offering) and liens; dispose of assets; make investments including loans, advances or guarantees; and enter into certain mergers or similar transactions. The Credit Agreement also contains financial covenants, tested quarterly and in connection with any triggering events under the Credit Agreement: (1) a minimum consolidated debt service coverage ratio of 2.50 to 1.00, (2) a maximum consolidated leverage ratio of 3.50 to 1.00, (3) a maximum consolidated senior leverage ratio of 2.00 to 1.00 (when no term loan is outstanding) and (4) a minimum liquidity requirement of $50 million. Upon the occurrence and continuance of an event of default under the Credit Agreement, the commitments of the lenders to make loans under the Credit Agreement may be terminated (other than commitments to make the term loan, which may only be terminated upon the occurrence and continuance of certain specified defaults) and the Company's payment obligations under the Credit Agreement may be accelerated. The events of default under the Credit Agreement include, among others, subject in some cases to specified cure periods, payment defaults; inaccuracy of representations and warranties in any material respect; defaults in the observance or performance of covenants; bankruptcy and insolvency related defaults; the entry of a final judgment in excess of a threshold amount; change of control; and the invalidity of loan documents relating to the Credit Agreement. The Company was in compliance with these covenants as of December 31, 2013.

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 loan was repaid in December 2013.

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. 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. This loan was repaid in December 2013.

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. Payment of the loan was 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 Company repaid the loan in December 2013.

In October 2009, the Company acquired a research and development facility in Gaithersburg, Maryland. The loan was collateralized by the facility. The Company repaid the loan in December 2013.

Scheduled principal repayments and maturities on long-term debt as of December 31, 2013 are as follows:

(in thousands)	
2014	-
2015	-
2016	-
2017	-
2018 and thereafter	62,000
	$62,000

On January 29, 2014, the Company issued $250.0 million aggregate principal amount of 2.875% Convertible Senior Notes due 2021 ("Notes"). The Notes will bear interest at a rate of 2.875% per year, payable semi-annually in arrears on January 15 and July 15 of each year, commencing July 15, 2014. The Notes will mature on January 15, 2021, unless earlier purchased by us, redeemed or converted. The conversion rate will initially equal 30.8821 shares of common stock per $1,000 principal amount of notes (which is equivalent to an initial conversion price of approximately $32.38 per share of common stock). The conversion rate will be subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest.

On January 29, 2014, in connection with the Company's issuance of the Notes, the unused $125 million term loan portion of the Company's Credit Agreement terminated automatically in accordance with the terms of the senior secured credit agreement, dated December 11, 2013, with the Lenders. In addition, following the closing of the Notes offering, we repaid the $62.0 million outstanding indebtedness under the revolving credit portion of the credit facility, which restored the full $100.0 million revolving credit capacity under this facility.

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 Company repurchased 398,481 shares for $5.8 million during the year ended December 31, 2012. There were no repurchases under the plan during the year ended December 31, 2013. The repurchase program terminated on December 31, 2013. In addition, the Company has acquired 14,472 shares, through December 31, 2013, from members of senior management for $287,000.

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 ESPP share is estimated at the beginning of each plan period. During the year ended December 31, 2013, the Company issued 52,768 shares under the ESPP plan. During the year ended December 31, 2013, the Company recorded stock-based compensation expense of $128,000 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, 2012	3,549,842	$ 17.08	53,156	$ 8.86	$4,801,378
Exercisable at December 31, 2012	2,144,732	$ 16.25	53,156	$ 8.86	$4,476,830
Granted	993,544	15.21	-	-	
Exercised	(481,549)	12.61	-	-	
Forfeited	(419,742)	18.34	-	-	
Outstanding at December 31, 2013	3,642,095	$ 17.01	53,156	$ 8.86	$23,148,738
Exercisable at December 31, 2013	2,074,772	$ 17.44	53,156	$ 8.86	$12,685,394
Options expected to vest at December 31, 2013	1,171,171	$ 16.44	-	$ -	$7,820,256

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, 2012	715,276	$ 18.41	$11,473,027
Granted	496,771	15.21	
Vested	(337,498)	14.91	
Forfeited	(80,873)	16.72	
Outstanding at December 31, 2013	793,676	$ 16.52	$18,246,611

The weighted average remaining contractual term of options outstanding as of December 31, 2013 and 2012 was 4.1 and 4.2 years, respectively. The weighted average remaining contractual term of options exercisable as of December 31, 2013 and 2012 was 3.4 and 3.5 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2013, 2012 and 2011 was $5.38, $5.16 and $10.09 respectively. The total intrinsic value of options exercised during the years ended December 31, 2013, 2012 and 2011 was $6.9 million, $589,000 and $10.2 million, respectively. The total fair value of awards vested during 2013, 2012 and 2011 was $9.1 million, $10.3 million and $7.9 million, respectively.

Stock-based compensation expense from the 2006 Plan was recorded in the following financial statement line items:

	Years Ended December 31,		
(in thousands)	2013	2012	2011
Cost of product sales	$575	$513	$466
Research and development	3,283	3,451	3,203
General and administrative	7,252	7,151	7,070
Total stock-based compensation expense	$11,110	$11,115	$10,739

12. Income taxes

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

	Year ended December 31,		
(in thousands)	2013	2012	2011
Current			
Federal	$(878)	$11,481	$11,481
State	(173)	(1,045)	(1,045)
International	300	103	103
Total current	(751)	10,539	10,539
Deferred			
Federal	12,679	3,758	3,758
State	1,028	(375)	(375)
International	152	-	-
Total deferred	13,859	3,383	3,383
Total provision for income taxes	$13,108	$13,922	$13,922

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

	December 31,	
(in thousands)	2013	2012
Net operating loss carryforward	$23,256	$26,102
Research and development carryforward	7,395	3,556
Stock compensation	6,378	5,289
Foreign deferrals	64,090	64,009
Deferred revenue	-	-
Other	4,522	9,005
Deferred tax asset	105,641	107,961
Fixed assets	(32,588)	(22,040)
Other	(5,714)	(6,158)
Deferred tax liability	(38,302)	(28,198)
Valuation allowance	(68,846)	(67,412)
Net deferred tax (liabilities)/assets	$(1,507)	$12,351

The Company currently has approximately $34.1 million in net operating loss carryforwards along with $7.4 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 $211.5 million in state net operating loss carryforwards, primarily in Maryland, that will begin to expire in 2018. The Company has approximately $227.6 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 as their realization is not more-likely-than-not. The use of any of these net operating losses 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)	2013	2012	2011

US	$52,749	$52,391	$66,756
International	(8,506)	(14,945)	(27,907)
Earnings before taxes on income	44,243	37,446	38,849
Federal tax at statutory rates	$15,485	$13,106	$13,597
State taxes, net of federal benefit	538	(2,079)	46
Impact of foreign operations	(1,116)	(3,604)	(2,371)
Change in valuation allowance	1,434	4,629	3,193
Effect of foreign rates	-	(22)	(12)
Tax credits	(5,918)	(2,904)	(1,405)
Other differences	(227)	139	556
Permanent differences	2,912	4,657	2,226
Provision for income taxes	$13,108	$13,922	$15,830

The effective annual tax rate for the years ended December 31, 2013, 2012 and 2011 was 30%, 37% and 41%, respectively. The decrease in the effective annual tax rate in 2013 from 2012 is primarily related to research and development tax credits and orphan drug tax credits related to our otlertuzumab (formely TRU-016) product candidate. The decrease in the effective annual tax rate in 2012 from 2011 is primarily related to orphan drug tax credits related to our otlertuzumab (formerly TRU-016) product candidate.

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 $15,000 and $25,000 for the payment of interest and penalties as of December 31, 2013 and 2012, respectively. Of the total unrecognized tax benefits recorded at December 31, 2013 and 2012, $132,000 and $153,000, respectively, is classified as a current liability and $991,000 and $863,000, respectively, is classified as a non-current liability on the balance sheet. As of December 31, 2013 and 2012, $152,000 and $75,000, respectively, of unrecognized tax benefits will reverse within the next twelve months.

The table below presents the gross unrecognized tax benefits activity for 2013, 2012 and 2011:

(in thousands)	
Gross unrecognized tax benefits at January 1, 2011	$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
Increases for tax positions for prior years	165
Decreases for tax positions for prior years	-
Increases for tax positions for current year	15
Settlements	-
Lapse of statute of limitations	(75)
Gross unrecognized tax benefits at December 31, 2013	$1,121

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 2010 to 2012 remain open to examination. The Company's tax returns in the United Kingdom remain open to examination for the tax years 2006 to 2013, and tax returns in Germany remain open indefinitely.

As of December 31, 2013, the Company's 2008, 2009 and 2010 federal income tax returns are in appeals with 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"). As a result of clinical trial data for the Company's tuberculosis vaccine product candidate published in February 2013, 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, 2013 and 2012, respectively, assets of $305,000 and $2.0 million and liabilities of $249,000 and $2.0 million related to OETC were included within the Company's consolidated balance sheets. During the year ended December 31, 2013, 2012 and 2011, OETC incurred a net loss of $1.8 million, $10.7 million and $13.2 million, respectively, of which, $910,000, $5.4 million and $6.7 million, respectively, is included in the Company's consolidated statement of operations. In addition, the Company reclassified $83,000 of accumulated translation adjustments. This reclassification was recorded as selling, general and administrative expense within the Company's Biosciences segment.

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, 2013 and 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 otlertuzumab (formerly TRU-016). The collaboration agreement covered otlertuzumab (formerly 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 otlertuzumab (formerly TRU-016) and other CD37-directed protein therapeutics under the collaboration agreement reverted back to the Company.

During the year ended December 31, 2012 and 2011, the Company recorded revenue of $2.7 million and $17.7 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.

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 May 2011, the Company and Pfizer entered into an amendment to the Pfizer Agreement which released certain restrictions related to the devleopment and commercialization of Biosilimiar CD-20 antibodies ("Biosimilar Agreement"). In September 2012, the Pfizer Agreement was terminated. The Company's right to receive royalty payments under the Biosiliar Agreement survives termination of the Pfizer Agreement.

During the year ended December 31, 2012 and 2011, the Company recorded revenue of $1.2 million and $1.9 million, 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.

15. Restructuring

In February 2013, the Company adopted a plan to restructure the operations of Emergent Product Development UK Limited ("EPDU") and OETC due to the results of the Phase IIb clinical trial for the Company's tuberculosis vaccine product candidate. The Company completed this restructuring as of June 30, 2013, except for the payment of certain termination benefit obligations that remain payable as of December 31, 2013.

The restructuring plan included a headcount reduction of 14 employees at EPDU, the termination of a facility lease, and the impairment of leasehold improvements and equipment. These costs, which are included in selling, general and administrative expense in the Company's statement of operations and are included within the Biosciences segment, are detailed below:

(in thousands)	Incurred during the year ended December 31, 2013
Termination benefits	$ 2,114
Contract termination costs	431
Other costs	261
Total	$ 2,806

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

(in thousands)	Termination Benefits	Contract Termination Costs	Other Costs	Total
Balance at December 31, 2012	$ -	-	$-	$-

Expenses incurred	2,114	431	134	2,679
Amount paid	(1,660)	(431)	(134)	(2,225)
Other adjustments	-	-	-	-
Balance at December 31, 2013	$ 454	$ -	-	$454

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, 2013, 2012 and 2011, the Company made matching contributions of approximately $2.0 million, $1.9 million and $1.8 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 contains a 3% annual escalation clause, which expires in December 2016, and includes an early termination date of January 2014. 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, 2013, 2012 and 2011, total lease expense was $3.9 million, $3.6 million and $3.8 million, respectively. For the year ended December 31, 2013, the Company recorded lease income of $446,000.

Future minimum lease payments under operating lease obligations as of December 31, 2013 were as follows:

(in thousands)	
2014	3,151
2015	1,981
2016	1,217
2017	-
Total minimum lease payments	6,349
Minimum lease receipts	(5,938)
Total net minimum lease payments	$411

18. Business interruption insurance recovery

During the year ended December 31, 2012, the Company recorded a $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 2013 and 2012.

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, the Company incurred approximately $35,000 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 year ended 2011, the Company incurred approximately $225,000 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 per share:

	Year Ended December 31,		
(in thousands, except share and per share data)	2013	2012	2011
Numerator:			
Net income	$31,135	$23,524	$23,019
Denominator:			
Weighted-average number of shares—basic	36,201,283	36,080,495	35,658,907
Dilutive securities—equity awards	546,273	340,167	547,145
Weighted-average number of shares—diluted	36,747,556	36,420,662	36,206,052
Earnings per share-basic	$0.86	$0.65	$0.65
Earnings per share-diluted	$0.85	$0.65	$0.64

For the years ending December 31, 2013, 2012 and 2011, outstanding stock options to purchase approximately 1.5 million, 2.9 million and 746,000 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.

	Reportable Segments			
(in thousands)	Biodefense	Biosciences	All Other	Total
Year Ended December 31, 2013				
External revenue	$311,564	$ 1,181	$-	$312,745
Intersegment revenue (expense)	-	-	-	-
Research and development	62,663	50,652	6,618	119,933
Interest income	-	-	139	139
Interest expense	-	-	-	-
Depreciation and amortization	17,534	1,238	186	18,958
Net income (loss)	87,289	(50,925)	(5,229)	31,135
Intangible assets	30,148	-	-	30,148
In-process research and development assets	-	41,800	-	41,800
Goodwill	8,452	5,502		13,954
Total assets	331,827	98,510	196,293	626,630
Expenditures for long-lived assets	30,700	1,343	9,978	42,021
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 income	-	-	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 income	-	-	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

22. Quarterly financial data (unaudited)

Quarterly financial information for the years ended December 31, 2013 and 2012 is presented in the following tables:

	Three months ended			
(in thousands)	March 31,	June 30,	September 30,	December 31,
Fiscal year 2013				

Revenue	$43,100	$82,436	$ 89,102	$ 98,107
Income (loss) from operations	(13,350)	14,712	18,147	23,293
Net income (loss)	(8,062)	10,484	13,491	15,222
Net income (loss) per share, basic	(0.22)	0.29	0.37	0.42
Net income (loss) per share, diluted	(0.22)	0.29	0.36	0.41
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

23. Subsequent events

On December 11, 2013, the Company entered into an arrangement agreement with Cangene Corporation ("Cangene") pursuant to which one of Emergent's wholly-owned subsidiaries will acquire all of the outstanding common shares of Cangene (the "Arrangement"), for $3.24 per share in cash (on a fully diluted basis), which represents a total purchase price of $222 million. This transaction will be accounted for by the Company under the acquisition method of accounting, with the Company as the acquiror. Under the acquisition method of accounting, the assets and liabilities of Cangene will be recorded as of the acquisition date, at their respective fair values, and combined with those of the Company. The Arrangement closed on February 21, 2014.

The table below summarizes the preliminary allocation of the purchase price based upon estimated fair values of assets acquired and liabilities assumed at February 21, 2014. As of the date of this filing, the valuation of acquired intangible assets, inventory, deferred taxes, property plant and equipment, contingent purchase consideration and other fair value adjustments are not complete, and as such the purchase price allocation is subject to change.

(in thousands)	February 21, 2014
Estimated fair value of tangible assets acquired and liabilities assumed:	
Acquired tangible assets (i)	$202,500
Assumed tangible liabilities	(38,300)
Total estimated fair value of tangible assets acquired and liabilities assumed	164,200
Identified intangible assets	52,500
Deferred tax liability associated with identified intangible assets	(3,000)
	49,500
Goodwill	8,300
Total preliminary estimated purchase price	$222,000

(i) Acquired tangible assets reflect a $12.3 million adjustment to record inventory at fair value, referred to as a step-up adjustment. The $12.3 million step-up was estimated to be amortized through cost of product sales and contract manufacturing over the next five years based on estimated inventory turnover which, will increase costs of product sales during such period.

The table below summarizes the preliminary estimated fair value of intangible assets acquired and the estimated amortization periods:

($ in thousands)	Amount	Amortization Period in years
Corporate trade name	$2,600	5.0
Marketed products	5,100	15.0
Licensed products	1,900	3.0
Biodefense	34,400	15.0
Contract manufacturing	8,500	15.0
Total identified intangible assets	$52,500	

The Company determined the estimated fair value of the intangibles assets using the income approach, which is based on the present value of future cash flows. The fair value measurements are based on significant unobservable inputs, that are developed by the Company using estimates and assumptions of the respective market and market penetration of the Company's products.

The Company will record approximately $8.3 million in goodwill related to the Cangene acquisition representing the purchase price paid in the acquisition that was in excess of the fair value of the tangible and intangible assets acquired. None of the goodwill generated from the Cangene acquisition is expected to be deductible for tax purposes.

The Company has incurred transaction costs related to the Cangene acquisition of approximately $3.3 million for the year ended December 31, 2013, which have been recorded in selling, general and administrative expenses within the Company's Biosciences segment.

The following pro forma information is presented as if the acqusition had occurred on January 1, 2012, and combines the historical results of operations of the Company and Cangene for the years ended December 31, 2013 and 2012.

	December 31,	
(in thousands, except per share data)	2013	2012
Pro forma revenue	$440,320	$400,269
Pro forma net income	$13,914	$2,171

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, 2013. 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, 2013, 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, 2013. 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 (1992 Framework). Based on this assessment, our management concluded that, as of December 31, 2013, our internal control over financial reporting was effective based on those criteria.

Management's assessment of and conclusion on the effectiveness of disclosure controls and procedures and internal controls over financial reporting did not include the internal controls related to the operations acquired in the acquisition of the Health Protective Products Division which is included in the 2013 consolidated financial statements of Emergent BioSolutions Inc. and constituted total and net assests of $55.7 million and $26.0 million, respectively as of December 31, 2013 and $11.2 million and $1.9 million, respectively, of revenues and net income for the year then ended.

Ernst & Young LLP, the independent registered public accounting firm that has audited our consolidated financial statements included herein, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2013, a copy of which is included in this annual report on Form 10-K.

Changes in Internal Control Over Financial Reporting

The Company completed the HPPD acquisition on August 1, 2013. Management considers this transaction to be material to the Company's Consolidated Financial Statements and believes that the internal controls and procedures of HPPD has a material effect on the Company's internal control over financial reporting. We are currently in the process of incorporating the internal controls and procedures of HPPD into our internal controls over financial reporting and extending our compliance program under the Sarbanes-Oxley Act of 2002 ("ACT") to include HPPD. The Company has elected to exclude HPPD from the scope of its 2013 annual assessment of internal control over financial reporting as provided by the Act and the applicable SEC rules and regulations concerning business combinations.

Other than the HPPD acquisition noted above, there have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f)) identified in connection with the evaluation required by Rule 13a-15(d) of the Exchange Act that occurred during the period covered by this report that have materially affected, or are 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, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) (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.

As indicated in the accompanying Management's Report on Internal Controls Over Financial Reporting, management's assessment of and conclusions on the effectiveness of internal control over financial reporting did not include the internal controls of the Health Protective Products Division acquisition which is included in the 2013 consolidated financial statements of Emergent BioSolutions, Inc. and Subsidiaries and constituted total and net assets of $55.7 million and $26.0 million, respectively as of December 31, 2013 and $11.2 million and $1.9 million of revenues and net income, respectively, for the year then ended. Our audit of internal control over financial reporting of Emergent BioSolutions Inc. and Subsidiaries also did not include an evaluation of the internal control over financial reporting of the Health Protective Products Division of Bracco Diagnostics Inc.

In our opinion, Emergent BioSolutions Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Emergent BioSolutions Inc. as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2013 of Emergent BioSolutions, Inc. and our report dated March 10, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia
March 10, 2014

ITEM 9B. OTHER INFORMATION

On March 4, 2014, 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 2013 as follows: Daniel Abdun-Nabi, $459,190; Robert Kramer, $265,640; Adam Havey, $142,183; and Barry Labinger, $78,539.

The compensation committee also approved grants of equity awards to be made on March 11, 2014 to the following named executive officers in the following amounts: Fuad El-Hibri, based on a value of $2,100,000; Daniel J. Abdun-Nabi, based on a value of $2,300,000; Robert Kramer, based on a value of $972,000; Adam Havey, based on a value of $525,000 and Barry Labinger, based on a value of $525,000. 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 2014 for our named executive officers. Annualized base salaries and target bonus percentages for our named executive officers for fiscal year 2014 are as follows: Daniel Abdun-Nabi, $680,014 and 80%; Robert Kramer, $455,998 and 50%; Adam Havey, $385,008 and 50%; and Barry Labinger, $429,977 and 50%. In addition, the compensation committee approved a base salary of $900,016 for Fuad El-Hibri.

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 2014 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 2014 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 2014 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 2014 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 2014 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 in Part I, Item 8.

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets at December 31, 2013 and 2012
Consolidated Statements of Operations for the years ended December 31, 2013, 2012 and 2011
Consolidated Statements of Comprehensive Income for the years ended December 31, 2013, 2012 and 2011
Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011
Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2013, 2012 and 2011
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 10, 2014

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 10, 2014
/s/Robert G. Kramer Robert G. Kramer	Executive Vice President Corporate Services Division, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 10, 2014
/s/Fuad El-Hibri Fuad El-Hibri	Executive Chairman of the Board of Directors	March 10, 2014
/s/Zsolt Harsanyi Zsolt Harsanyi, Ph.D.	Director	March 10, 2014

/s/Dr. John Niederhuber Dr. John Niederhuber	Director	March 10, 2014
/s/Ronald B. Richard Ronald B. Richard	Director	March 10, 2014
/s/Louis W. Sullivan, M.D. Louis W. Sullivan, M.D.	Director	March 10, 2014
/s/Marvin White Marvin White	Director	March 10, 2014
/s/Dr.Sue Bailey Dr. Sue Bailey	Director	March 10, 2014
/s/George Joulwan George Joulwan	Director	March 10, 2014

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
2		Arrangement Agreement dated as of December 11, 2013, among Emergent BioSolutions Inc., 2396638 Ontario Inc. and Cangene Corporation (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K filed on December 12, 2013).
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) (Registration 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) (Registration 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) (Registration 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) (Registration No. 333-136622).
4.4		Indenture, dated as of January 29, 2014, between Emergent BioSolutions Inc. and Wells Fargo Bank, National Association, including the form of 2.875% Convertible Senior Notes due 2021 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 29, 2014).
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) (Registration No. 333-136622).
10.1		Credit Agreement, dated as of December 11, 2013, among Emergent BioSolutions Inc., as borrower, certain of its subsidiaries party thereto, as guarantors, Bank of America, N.A., as administrative agent, and certain financial institutions party thereto as lenders (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 12, 2013).
10.2	#	First Amendment to Credit Agreement, dated as of January 17, 2014, among Emergent BioSolutions Inc., as borrower, certain of its subsidiaries party thereto, as guarantors, Bank of America, N.A., as administrative agent, and certain financial institutions party thereto as lenders.
10.3	*	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) (Registration No. 333-136622).
10.4	*	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) (Registration No. 001-33137).
10.5	*	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).
10.6	*	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).
10.7	*	Form of Director Nonstatutory Stock Option Agreement (incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K filed on March 8, 2013).

10.8	*	Form of Director Restricted Stock Unit Agreement (incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K filed on March 8, 2013).
10.9	*	Form of Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on March 8, 2013).
10.10	*	Form of Restricted Stock Unit Agreement (incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K filed on March 8, 2013).
10.11	*	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).
10.12	*	Director Compensation Program (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K filed on March 8, 2013).
10.13	*	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).
10.14	*	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).
10.15	*	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).
10.16		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).
10.17	†	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).
10.18	†	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).
10.19	†	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).
10.2		Modification No. 3 to the CDC BioThrax Procurement Contract, effective April 5, 2013, between Emergent BioDefense Operations Lansing LLC and the Centers for Disease Control and Prevention (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 6, 2013).
10.21	†	Modification No. 4 to the CDC BioThrax Procurement Contract, effective June 1, 2013, 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 August 6, 2013).
10.22	†	Modification No. 5 to the CDC BioThrax Procurement Contract, effective June 1, 2013, 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 August 6, 2013).
10.23	†	Modification No. 6 to the CDC BioThrax Procurement Contract, effective June 1, 2013, between Emergent BioDefense Operations Lansing LLC and the Centers for Disease Control and Prevention (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 6, 2013).
10.24	†	Modification No. 7 to the CDC BioThrax Procurement Contract, effective September 26, 2013, between Emergent BioDefense Operations Lansing LLC and the Centers for Disease Control and Prevention (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 8, 2013).
10.25	†	

		Modification No. 8 to the CDC BioThrax Procurement Contract, effective September 30, 2013, 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 8, 2013).
10.26	#††	Modification No. 9 to the CDC BioThrax Procurement Contract, effective January 13, 2014, between Emergent BioDefense Operations Lansing LLC and the Centers for Disease Control and Prevention.
10.27	#††	Modification No. 10 to the CDC BioThrax Procurement Contract, effective January 22, 2014, between Emergent BioDefense Operations Lansing LLC and the Centers for Disease Control and Prevention.
10.28		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 Company's Registration Statement on Form S-1 filed on September 25, 2006) (Registration No. 333-136622).
10.29		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 Company's Annual Report on Form 10-K for the year ended December 31, 2011 filed on March 9, 2012).
10.3		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 Company's Annual Report on Form 10-K for the year ended December 31, 2011 filed on March 9, 2012).
10.31		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 Company's Annual Report on Form 10-K for the year ended December 31, 2011 filed on March 9, 2012).
10.32		Fourth Amendment to the Rockville Lease, dated March 27, 2013, between Brandywine Research LLC and the Company (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 3, 2013).
10.33		Fifth Amendment to the Rockville Lease, dated April 12, 2013, between Brandywine Research LLC and the Company (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 3, 2013).
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.
101.INS		XBRL Instance Doccument
101.SCH		XBRL Taxonomy Extension Schema Document
101.CAL		XBRL Taxonomy Calculation Linksbase Document
101.DEF		XBRL Taxonomy Definition Linksbase Document
101.LAB		XBRL Taxonomy Label Linksbase Document
101.PRE		XBRL Taxonomy Presentation Linksbase Document

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, 2013 and 2012, (ii) Consolidated

Statements of Operations for the Years Ended December 31, 2013, 2012 and 2011, (iii) Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2013, 2012 and 2011 (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2013, 2012 and 2011, (v) Consolidated Statements of Changes in Stockholders' Equity for the Years ended December 31, 2013, 2012 and 2011, and (vi) Notes to Consolidated Financial Statements.