

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

Emergent BioSolutions Inc.
Form 10-K
March 06, 2015
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, 2014

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

Commission file number: 001-33137

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

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

400 Professional Drive, Gaithersburg , Maryland 20879
(Address of Principal Executive Offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: (240) 631-3200
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

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

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, 2014 was approximately \$659 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 27, 2015, the registrant had 37,918,377 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2015 annual meeting of stockholders scheduled to be held on May 21, 2015, 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, 2014, 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 2015 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, 2014

INDEX

PART I

- Item 1. Business
- Item 1A. Risk Factors
- Item 1B. Unresolved Staff Comments
- Item 2. Properties
- Item 3. Legal Proceedings
- Item 4. Mine Safety Disclosures

PART II

- Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities
- Item 6. Selected Financial Data
- Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations
- Item 7A. Quantitative and Qualitative Disclosures About Market Risk
- Item 8. Financial Statements and Supplementary Data
- Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure
- Item 9A. Controls and Procedures
- Item 9B. Other Information

PART III

- Item 10. Directors, Executive Officers and Corporate Governance
- Item 11. Executive Compensation
- Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters
- Item 13. Certain Relationships and Related Transactions, and Director Independence
- Item 14. Principal Accountant Fees and Services

PART IV

- Item 15. Exhibits and Financial Statement Schedules
- Signatures
- Exhibit Index

BioThrax® (Anthrax Vaccine Adsorbed), RSDL® (Reactive Skin Decontamination Lotion Kit), BAT™ [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)], Anthrasil™ (Anthrax Immune Globulin Intravenous [human]), HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)], VARIZIG® [Varicella Zoster Immune Globulin (Human)], WinRho® SDF [Rh₀ (D) Immune Globulin Intravenous (Human)], NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), PreviThrax™ (recombinant protective antigen anthrax vaccine, purified) and any and all Emergent BioSolutions Inc. brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent BioSolutions Inc. or its subsidiaries in the United States or other countries. episil® (oral liquid) is a trademark of Camurus AB. All rights reserved. All other brands, products, services and feature names or trademarks are the property of their respective owners.

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, including our current investigation involving our operations and those of our suppliers and contract manufacturers regarding a discovery of foreign particles in two lots of BioThrax, 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:

- § the potential outcome of our current investigation of foreign particles discovered in two lots of BioThrax;
- § appropriations for the procurement of BioThrax® (Anthrax Vaccine Adsorbed), our FDA-licensed anthrax vaccine;
- § our ability to successfully integrate our acquisition of Cangene Corporation, 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;
- § our ability to realize synergies and benefits from acquisitions or in-licenses within expected time periods or at all;
- § our ability to selectively enter into collaboration arrangements;
- § our ability to achieve milestones in our out-license and collaboration contracts;
- § 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 and the ability of our contractors and suppliers to maintain compliance with cGMP and other regulatory obligations;
- § the results of regulatory inspections;
- § 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, non-clinical activities and clinical trials of our product candidates;

§ the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;

§ the success of our commercialization, marketing and manufacturing capabilities and strategy; and

§ the accuracy of our estimates regarding future revenues, expenses, 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 global specialty biopharmaceutical company seeking to protect and enhance life by offering specialized products to healthcare providers and governments to address 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 400 Professional Drive, Gaithersburg, Maryland 20879. Our telephone number is (240) 631-3200, 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 CBRNE (Chemical, Biological, Radiological, Nuclear and Explosives) 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 and various investigational stage product candidates.

Our Biodefense division marketed products are:

BioThrax[®] (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or the FDA, for the prevention of anthrax disease;

BAT[™] (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-Equine), the only heptavalent therapeutic licensed by the FDA for the treatment of botulinum disease*;

Anthrasil[™] (Anthrax Immune Globulin Intravenous (Human)), which has a pending Biologics License Application, or BLA, with the FDA and, if approved, would be the only polyclonal antibody therapeutic licensed by the FDA for the treatment of anthrax infection*;

VIGIV (Vaccinia Immune Globulin Intravenous (Human)), the only therapeutic licensed by the FDA to address adverse events from smallpox vaccination*;

RSDL[®] (Reactive Skin Decontamination Lotion Kit), the only device cleared by the FDA for the removal or neutralization of chemical agents, T-2 toxin and many pesticide-related chemicals from the skin.

* Denotes products acquired through our acquisition of Cangene Corporation in February 2014.

Our Biodefense division investigational stage product candidates are:

NuThrax[™] (anthrax vaccine adsorbed with CPG 7909 adjuvant), a next generation anthrax vaccine;

PreviThrax[™] (recombinant protective antigen anthrax vaccine, purified), a next generation anthrax vaccine;

GC-072, the lead compound in the EV-035 series of broad spectrum antibiotics, which we acquired from Evolva SA in December 2014; and

Other Biodefense product candidates.

Our Biodefense division also has programs aimed at providing solutions to the current Ebola outbreak in West Africa, including an MVA-Ebola vaccine candidate, anti-Ebola monoclonal antibody product candidates and an Ebola hyperimmune product candidate. We have responded to Task Order Requests issued by the Biomedical Advanced Research and Development Authority, or BARDA, for the manufacture of Ebola medical countermeasures as part of our Center for Innovation in Advanced Development and Manufacturing, or CIADM, program. In addition, we have a license agreement for the manufacture of VAX161C, a clinical stage recombinant pandemic influenza vaccine product candidate being developed by VaxInnate, Inc., in the event of a surge order from BARDA.

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, infectious disease and autoimmunity. Our Biosciences portfolio consists of four revenue generating products, all of which were acquired through our acquisition of Cangene Corporation in February 2014, as well as various investigational stage product candidates and a contract manufacturing services business.

Our Biosciences division marketed products are:

WinRho[®] SDF [Rh₀(D) Immune Globulin Intravenous (Human)], 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[®] [(Hepatitis B Immune Globulin Intravenous (Human)], for post-exposure prophylactic treatment of hepatitis-B*;

VARIZIG[®] [Varicella Zoster Immune Globulin (Human)], for post-exposure prophylactic treatment of varicella zoster virus, which causes chickenpox and shingles*;

episil[®] (oral liquid), for relief of pain and soothing oral lesions of various etiologies, including oral mucositis/stomatitis caused by chemotherapy or radio therapy*.

* Denotes products acquired through our acquisition of Cangene Corporation.

Our Biosciences division investigational stage product candidates include:

IXINITY[®] (coagulation factor IX (recombinant)), being developed for the prevention of bleeding episodes in people with hemophilia B;

ES414, now known as MOR209/ES414, being developed for metastatic castration resistant prostate cancer under our collaboration with MorphoSys AG entered into in August 2014;

otlertuzumab, formerly known as TRU-016, being developed for Chronic Lymphocytic Leukemia; and

Other Biosciences product candidates.

In addition, our Biosciences division includes several platform technologies, including our ADAPTIR[™] (modular protein technology) platform, our MVAtor[™] (modified vaccinia virus Ankara vector) platform, and our hyperimmune specialty plasma product manufacturing platform.

Operations that support this division include manufacturing, quality, regulatory affairs, 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 plan goals will further require that we marshal our core competencies across the following key objectives: driving organic growth, acquiring revenue generating assets, focusing on controlling research and development costs by securing external funding for our development programs and building the Biosciences division into a profitable business.

RECENT ACQUISITIONS AND COLLABORATIONS

Acquisition of Cangene Corporation

In February 2014, we acquired Cangene Corporation, or Cangene, for a total all-cash purchase price of approximately \$222 million. In this acquisition we gained seven revenue generating products, three of which were added to our Biodefense division and four of which were added to our Biosciences division. Specifically, the Biodefense products include: BAT for treatment of botulinum disease; Anthrasil for treatment of anthrax infection; 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.

Collaboration with MorphoSys AG to develop MOR209/ES414

In August 2014, we entered into an agreement with MorphoSys AG to co-develop and commercialize our novel oncology immunotherapeutic, MOR 209/ES414, targeting prostate cancer. Under the terms of the agreement, we received an upfront payment of \$20 million and are eligible to receive milestone payments of up to \$163 million, linked to specific events, including the initiation of a Phase 1 clinical study, successful development of MOR 209/ES414 in several indications and securing approval in certain territories. MorphoSys will bear 64% and Emergent 36% of the total development costs. We will retain commercialization rights in the United States and Canada, with a tiered royalty obligation to MorphoSys, from mid-single digit up to 20%. MorphoSys will gain worldwide commercialization rights excluding the United States and Canada, with a low single digit royalty obligation to us. We will manufacture and supply clinical material from our manufacturing facilities in Baltimore, Maryland.

Acquisition of EV-035 from Evolva Holding SA

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

In December 2014, we acquired the EV-035 series of molecules from Evolva Holding SA. EV-035 is a series of novel small molecules in the 4-oxoquinolizine class and targets bacterial type IIa topoisomerase. The lead molecule, GC-072, is being developed as a potential oral and IV treatment for *B. pseudomallei* and has demonstrated protection in vivo when administered orally in animals. GC-072 is being developed under a three-year, \$15 million contract with the Defense Threat Reduction Agency, or DTRA, of the U.S. Department of Defense. In vitro models have shown activity of the EV-035 series of molecules in gram-negative and gram-positive bacteria, including multi-drug resistant and quinolone-resistant bacteria. The scope of the DTRA contract also includes conducting formulation, manufacturing and toxicology studies, exploring efficacy in additional multi-drug resistant biodefense and commercial pathogens, and preparing an Investigational New Drug application, or IND, for submission to the FDA.

MARKETED PRODUCT PORTFOLIO

BIODEFENSE

| <u>Product</u> | <u>Indication</u> | <u>Regulatory Approvals</u> |
|--|--|--|
| 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 |
| Anthrasil (Anthrax Immune Globulin Intravenous (Human)) | Treatment of toxemia associated with inhalational anthrax | Anthrasil is an investigational product, but is procured by U.S. Health & Human Services, or HHS, for inclusion into the Strategic National Stockpile, or SNS, for use in an emergency under an Emergency Use Authorization, or EUA. |
| VIGIV (Vaccinia Immune Globulin Intravenous (Human)) | Post-exposure prophylaxis of vaccinia (a common virus used to vaccinate against small pox) | United States Canada |
| RSDL® (Reactive Skin Decontamination Lotion Kit) | Removal or neutralization of chemical warfare agents, T-2 toxin and many pesticide-related chemicals from the skin | United States 510(k) United Kingdom Australia Canada |

BIOSCIENCES

| <u>Product</u> | <u>Indication(s)</u> | <u>Regulatory Approvals</u> |
|---|--|---|
| WinRho® SDF [(Rh ₀ (D) Immune Globulin Intravenous (Human))] | ITP – immune thrombocytopenic purpura HDN – hemolytic disease of the newborn Preventing Rh ₀ (D) immunization in Rh ₀ (D)(-) women [1] Treating Rh ₀ (D)(-) patients after transfusions with incompatible Rh ₀ (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] | United States – [1] Canada – [2] |

| | | |
|-----------------------|---|---|
| | Prevention and reduction of severity in maternal infections within four days of exposure to Varicella zoster virus [2] | |
| episil® (oral liquid) | Relief of pain, soothing oral lesions of various etiologies, including oral mucositis/stomatitis caused by chemotherapy and radio therapy | United States (exclusive commercialization rights in the United States) |

BIODEFENSE DIVISION

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

Marketed Products

BioThrax® (Anthrax Vaccine Adsorbed). BioThrax is the only vaccine licensed 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 completion of this three dose primary series. 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, 2014, \$911 million in funding has been committed, of which approximately \$722 million has been delivered, which represents approximately 27 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 seeking to expand the BioThrax label to include a post-exposure prophylaxis, or PEP, indication for BioThrax administered in combination with antimicrobial therapy. With funding from a multi-year development contract with BARDA, an agency within HHS, we have completed the last licensure-enabling study in the PEP program, known as the antibiotic non-interference study, and have submitted the clinical study report to the FDA. Data from this study, coupled with data from previously completed studies also funded by BARDA, were used to support our supplemental Biologics License Application, or sBLA, for the PEP indication that we filed with the FDA in October 2014. Additionally, the FDA granted Orphan Drug designation to BioThrax for post-exposure prophylaxis of anthrax disease in April 2014.

BAT®™ [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-Equine)]. BAT is the only heptavalent therapeutic licensed by the FDA for botulinum disease. 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). We are currently delivering under a five-year, \$362 million contract with BARDA, which calls for delivery of up to 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, subject to availability of funding to BARDA. In addition to domestic government sales, BAT has been sold to several foreign governments.

Anthrasil™ (Anthrax Immune Globulin Intravenous (Human)). Anthrasil is an investigational product candidate that is a mixture of purified polyclonal human immune globulins (antibodies) directed to the toxins produced by *Bacillus anthracis*. It is being developed to treat toxemia associated with inhalational anthrax. Anthrasil is procured by HHS into the SNS for use in an emergency under an EUA. To date, the principal customer for Anthrasil 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. Under this contract, in August 2014, we submitted to the FDA a Biologics License Application, or BLA, for licensure of Anthrasil. The contract also provides for the collection of Anthrasil 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 four-year period through September 2017. The maximum amount that could be paid to us under this contract is approximately \$264 million, subject to availability of funding to BARDA. We are currently delivering under a task 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.

VIGIV [Vaccinia Immune Globulin Intravenous (Human)]. VIGIV is the only therapeutic licensed by the FDA to address adverse events from smallpox vaccination. 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 a therapeutic approved in the United States 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 the CDC) and the DoD. The CDC contract is for the supply of VIGIV to the Strategic National Stockpile. In August 2014, we entered into a contract extension with the CDC, which includes the performance of work required to maintain FDA licensure and to collect plasma for future manufacturing, increasing the total contract value to up to \$36.6 million.

RSDL® (Reactive Skin Decontamination Lotion Kit). RSDL is the only medical device licensed by the FDA to remove or neutralize chemical warfare agents, including nerve agents, mustard gas and T-2 toxin (a myco toxin capable of being weaponized) and organophosphate based pesticides from the skin. RSDL has been cleared as a medical device by the FDA and Health Canada, has a current CE mark under European Directives, and is licensed as a Therapeutic Good by 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 indefinite delivery/indefinite quantity contract, including option years, that expires in June 2017. The maximum amount that could be paid to us under this contract is approximately \$243 million, subject to availability of funding to DoD. In addition to domestic government sales, we have also made sales into 35 foreign countries since launch. Our current strategy is to expand the market for RSDL by expanding the uses and indications which may include treatment of toxic industrial chemicals and removal of radioactive metal exposure. In February, 2014 we expanded the indication for use to organophosphate based pesticides. We continue to strategize on how best to expand sales due to this new indication.

Product Candidates

NuThrax™ (anthrax vaccine adsorbed with 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 Diseases, or NIAID. We are developing NuThrax to potentially elicit a more rapid onset of immune response using fewer doses to provide protective immunity in patients than BioThrax. In September 2010, we obtained additional funding for this product candidate 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 2 clinical trial lots, process characterization, assay validation and clinical trial preparation. Using funds from the 2010 contract, in October 2014, we completed a Phase 2 safety, immunogenicity and dose ranging clinical trial of NuThrax in which all endpoints were successfully met, including that it may require fewer vaccine doses and shorten the recommended antibiotic (60-day) regimen for anthrax post-exposure prophylaxis. NuThrax is now positioned for a Phase 3 clinical trial. We continue to seek additional government funding for NuThrax to advance it toward FDA approval. In September 2014, we also obtained additional funding for this product through a five-year development contract with NIAID of up to \$29 million to support the development of a dry formulation of NuThrax, including: manufacturing, assay development and non-clinical activities through the preparation of an Investigational New Drug application to the FDA. The dry formulation of NuThrax is intended to increase stability of the vaccine candidate at ambient and higher temperatures, with the objective of eliminating the need for cold chain during shipping and storage.

GC-072. We are developing GC-072, a novel bacterial type II topoisomerase inhibitor, belonging to the chemical class of 4-oxoquinolizine as a potential oral and IV treatment for *B. pseudomallei* under a three-year, \$15 million contract with DTRA. GC-072 has demonstrated protection in vivo from lethal *B. pseudomallei* infection when administered orally, and it shows activity not only on drug-sensitive strains, but also on those resistant to marketed antibiotics (including quinolones). It has a favorable safety profile and has demonstrated efficacy when dosed intravenously or orally in animals. The scope of the DTRA contract includes investigating GC-072 as a treatment for *B. pseudomallei* in preclinical in vitro and in vivo studies, conducting formulation, manufacturing and toxicology studies, exploring efficacy in additional multi-drug resistant biodefense and commercial pathogens, and preparing an Investigational New Drug application for submission to the FDA. Furthermore, GC-072 has also demonstrated broad-spectrum activity against pathogens such as *S. aureus*, *S. pneumoniae*, *E. faecalis*, *E. coli*, *P. aeruginosa*, *A. baumannii* and *H. influenzae*, as well as several potential biodefense pathogens such as *B. pseudomallei*, *B. anthracis*, *F. tularensis*, and *Y. pestis*.

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 identified CPG 7909 as a potential adjuvant for this product candidate and are currently finalizing a thermostable formulation to progress towards initiating a Phase 1 study.

Our Biodefense division also has programs aimed at providing solutions to the current Ebola outbreak in West Africa, including an MVA-Ebola vaccine candidate, anti-Ebola monoclonal antibody product candidates and an Ebola hyperimmune product candidate. We have responded to Task Order Requests issued by BARDA for the manufacture of Ebola medical countermeasures as part of our Center for Innovation in Advanced Development and Manufacturing, or CIADM, program. In addition, we entered into a license agreement in 2012 with VaxInnate, Inc., under the auspices of our existing CIADM program, to manufacture VAX161C, a clinical stage recombinant pandemic influenza vaccine product candidate that is being developed by VaxInnate in part with funding from BARDA. VAX161C is an *E. coli*-expressed fusion protein product that fuses segments of the hemagglutinin (HA) protein from influenza to a bacterial protein and has been shown to induce a durable immune response to the particular HA protein, thus imparting protection. VAX161C is expressed at relatively high levels and, based on preclinical data, requires relatively small amounts of protein to be efficacious.

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. However, to offset these expenditures, we receive significant development funding through U.S. government contracts and grants, specifically from HHS (including BARDA and NIAID). Gross research and development expenses for the Biodefense division for the years ended December 31, 2014, 2013 and 2012 totaled approximately \$82.0 million, \$62.7 million and \$68.6 million, respectively. Net research and development expenses (net of contracts, grants and collaborations revenue) for the Biodefense division for the years ended December 31, 2013 and 2012 totaled approximately \$9.0 million and \$8.6 million, respectively. For the year ended December 31, 2014, contracts, grants and collaborations revenue exceeded research and development expenses by \$10.4 million. 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 material research and development activities.

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 CBRNE 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 CBRNE threat countermeasures increases.

Competition

Our products and product candidates intended for the treatment or prevention of CBRNE 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 are 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 vaccine licensed by the FDA for the prevention of anthrax disease, 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 Public Health England manufactures an anthrax vaccine for use by the United Kingdom government. Other countries may also have anthrax vaccines in development for their own internal use.

§ BAT. Our botulinum immune globulin product is the only heptavalent therapeutic licensed by the FDA for the § treatment of botulinum disease. Other companies may be in stages of developing therapies aimed at treating or preventing botulism infections, however, direct competition is currently limited.

§ Anthrasil. 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 therapeutic licensed by the FDA to address adverse events from smallpox vaccination. 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.

RSDL. In the United States, 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.

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

§ GC-072. Basilea Pharmaceutica Ltd., The Medicines Company, Rempex Pharmaceuticals, Inc., Cempra, Inc., Tetrphase Pharmaceuticals, Inc., Achaogen, Inc., GlaxoSmithKline plc and others are each currently developing broad spectrum antibiotic product candidates with funding provided by DTRA, NIAID and BARDA.

VAX161C Pandemic Flu Vaccine. FluBlok® (Protein Sciences Corporation), Pandemrix™ (GlaxoSmithKline plc), § Emerflu® (Sanofi Pasteur Inc.) are licensed vaccines. Nanotherapeutics Inc., CSL Behring, and other companies are developing pandemic influenza vaccines that are not dependent on egg-based manufacturing.

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. In 2014, Biodefense division product revenues were \$278.3 million, consisting of \$267.0 million from sales to the U.S. government and \$11.3 million from international and other domestic customers. In 2013, Biodefense division product revenues were \$257.9 million, consisting of \$254.0 million from sales to the U.S. government and \$3.9 million from international and other domestic customers. In 2012, Biodefense division product revenues were \$215.9 million, consisting of \$215.3 million from sales to the U.S. government and \$546,000 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 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, grants, and collaborations 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 \$92.1 million in 2014, \$54.6 million in 2013 and \$60.5 million in 2012. 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, infectious disease and autoimmunity. 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 Rh₀(D)(+) red blood cells. As antibodies that are directed to the Rh₀(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 United States 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 United States 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 United States, 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 United States. for the liver transplant-related indication. 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 United States 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 United States 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 United States 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. We hold the exclusive rights to commercialize episil in the United States under an agreement with Camurus AB.

Product Candidates

Our Biosciences portfolio also includes investigational product candidates, including:

IXINITY[®] (coagulation factor IX (recombinant)). IXINITY is an intravenous recombinant human coagulation factor IX therapeutic that is being developed for the prevention of bleeding episodes in people with hemophilia B. We submitted a BLA, which is currently under review by the FDA with a Prescription Drug User Fee Act, or PDUFA, action date in the second quarter of 2015. Hemophilia B, also known as Christmas disease, is a rare, inherited bleeding disorder. 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.

MOR209/ES414. MOR209/ES414 is a targeted immunotherapeutic protein under development for metastatic castration resistant prostate cancer. MOR209/ES414, a bispecific protein constructed using our ADAPTIR technology platform, activates host T-cell immunity specifically against cells expressing Prostate Specific Membrane Antigen (PSMA), an antigen commonly overexpressed on prostate cancer cells. MOR209/ES414 selectively binds to the T cell receptor on cytotoxic T cells and PSMA on tumor cells. MOR209/ES414 contains two pairs of binding domains, each targeting a unique antigen, linked to opposite ends of an immunoglobulin Fc domain to extend the half-life and enable use of a purification process typical of Ig-based molecules. In preclinical studies, MOR209/ES414 has been shown to redirect T-cell cytotoxicity towards prostate cancer cells expressing PSMA. According to the American Cancer Society, prostate cancer is the most common cancer in men in the United States. Screening, radiation, surgery and hormone ablation therapy have greatly improved the detection and treatment of early stage prostate cancer. However, the new therapies only improve life expectancy by a few months for patients with metastatic castration-resistant prostate cancer.

Otlertuzumab. 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. 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. We completed a Phase 2 study evaluating the combination of otlertuzumab and bendamustine (a chemotherapy agent) versus bendamustine alone in people with relapsed CLL (Study 16201). We amended our Phase 1b single-arm, open-label study evaluating the safety and efficacy of otlertuzumab in combination with rituximab, an anti-CD-20 directed biologic, to include evaluating otlertuzumab in combination with obinutuzumab in people with previously untreated CLL (Study 16009). The preliminary data showed that the combination was active and well tolerated. We continue to evaluate opportunities for this product candidate in CLL.

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. To the extent which we can offset these expenditures, we pursue partnerships with various third parties. Gross research and development expenses for the Biosciences division for the years ended December 31, 2014, 2013 and 2012 totaled approximately \$60.8 million, \$50.7 million and \$44.6 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, 2014, 2013 and 2012 totaled approximately \$42.3 million, \$48.6 million and \$33.2 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 material research and development activities.

Contract Manufacturing Services

Our Biosciences division 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 pharmaceutical 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, final packaging and accelerated and ongoing stability studies. We manufacture both vial and pre-filled syringe formats for a wide variety of drug products — small molecule and biological — 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 clinical and 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 United States,

Canada, Japan, Brazil, the Middle East and several countries in the European Union.

Distribution

Our products are sold in the United States by our commercial sales force and distributed to end-users through major U.S. distributors and wholesalers, including Cardinal Health, Inc., McKesson Corporation, AmerisourceBergen Corporation and other specialty distributors. 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

We have 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 hospitals, hematology clinics, medical 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 the United States, our products are sold through a network of regional independent distributors. 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 pharmacovigilance 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 United States, the use of WinRho SDF is primarily for the ITP indication. In the U.S. ITP market, WinRho SDF competes with 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 United States 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.

IXINITY. If approved, we anticipate that IXINITY would compete with Rixubis (Baxter International Inc.) and Alprolix (Biogen Idec Inc.) recombinant FIX products as well as Benefix (Pfizer Inc.), AlphaNine (Grifols USA, LLC) and MonoNine (CSL Behring, a subsidiary of CSL Limited), which are FIX preparations derived from human plasma. We expect that Novo Nordisk Inc. and CSL Behring will also launch additional long acting recombinant factor IX agents in the future.

MOR209/ES414. If approved, we anticipate that MOR209/ES414 would compete with Taxotere (Sanofi), Jevtana (Sanofi), Zytiga (Janssen), Xtandi (Astellas), Xofigo (Bayer/Algeta), Provenge (Dendreon) and potentially other products currently under development.

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), Gayzva™ (Genentech USA, Inc., a member of the Roche Group) and Zydelig® (Gilead Sciences, Inc.). In addition, Boehringer Ingelheim GmbH and ImmunoGen, Inc. are in early stage development for monoclonal antibodies directed to CD37. AbbVie Inc. is developing ABT-199, a B-cell lymphoma 2 inhibitor, for treatment of CLL in collaboration with Genentech, Inc.

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, Par Pharmaceutical Companies, Inc., 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 adjacent to Building 12 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. In April 2014, we manufactured BioThrax consistency lots in Building 55 that were used in the pivotal non-clinical efficacy study initiated in September 2014. The efficacy study was designed to demonstrate that BioThrax manufactured at large scale in Building 55 is comparable to the BioThrax currently manufactured in its approved facility, Building 12. The in-life phase of this study has been completed and the interim analysis of data shows that the primary endpoints were met. Data from this study will be used to support an sBLA to the FDA for Building 55 licensure, which is anticipated in late 2015 or early 2016. Building 12 produces 7 to 9 million doses of BioThrax annually. Building 55 has the potential to triple manufacturing capacity to an estimated 20 to 25 million doses annually.

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 manufacture products 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, nuclear and explosive 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. in August 2013, we acquired rights to a packaging facility at The University of Southern Mississippi's Accelerator, a technology innovation and commercialization center. This facility is equipped to package RSDL. A significant portion of the doses of RSDL that we sell to domestic customers can be packaged at this facility. In connection with this acquisition, we also entered into a three-year Contract Manufacturing Organization, or CMO, agreement with Bracco Diagnostics Inc., and its wholly-owned subsidiary, E-Z-EM Canada Inc. (dba Therapex), to manufacture bulk quantities of RSDL's active ingredient and to package RSDL units. 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 in February 2014, 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 for our Biosciences division, WinRho SDF, HepaGam B and VARIZIG, and for our Biodefense division, BAT, Anthrasil and VIGIV.

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 pharmaceutical 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, final packaging and accelerated and ongoing stability studies 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 United States. 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, Anthrasil, 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 United States 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 United States, 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 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 United States 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 United States. 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.

Our products with current Orphan Drug exclusivity include the following:

BioThrax for post-exposure prophylaxis for patients with known or suspected exposure to B. anthracis administered in combination with antimicrobial therapy;

Anthraxil for the treatment of toxemia associated with inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs;

BAT with exclusivity through March 2020 for treatment of suspected or documented exposure to botulinum neurotoxin A, B, C, D, E, F or G; and

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.

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

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, or FDCA. 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:

- fining, 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 United States, 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 United States 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, including 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 United States 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 United States 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 United States 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

Currently, we maintain a commercial presence in the United States and Canada as well as in select foreign countries. In the future, we may further expand our commercial presence to additional foreign countries and territories. In the European Union, medicinal products are authorized following a process similarly demanding as the process required in the United States. 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 United States (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. Manufacturers of drugs are required to publicly report payments and transfers of value made to physicians and teaching hospitals. This information is 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. As a public company, the FCPA also requires us 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 are 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 product development, are or may be applicable to our activities.

EMPLOYEES

As of February 27, 2015, we had 1,280 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 are represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

AVAILABLE INFORMATION

We maintain a website at www.emergentbiosolutions.com. We make available, free of charge on our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, 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 of BioThrax, our FDA-licensed anthrax vaccine, to the U.S. government. 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, 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, Anthrasil, 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 \$110 million. If levels of government expenditures and authorizations for biodefense decrease or shift to programs in areas where we do not offer products or are not developing product candidates, or if the U.S. government otherwise declines to exercise its options under our contracts, 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. Legislation has been enacted 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 unique risks and requirements.

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 and 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 procurement, 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 the U.S. Health & Human Services, or HHS, and the Department of Defense, or 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. 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 and transplantation markets include: Amgen Inc., Baxter International Inc., CSL Behring, a subsidiary of CSL Limited, GlaxoSmithKline plc, Grifols USA LLC and Biotest Pharmaceuticals Corporation, a subsidiary of Biotest AG.

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, only two distributors have 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 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 revenues from product sales.

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.

Changes in health care systems and payer reimbursement 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, the 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 United States 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, Anthrasil, HepaGam B, VARIZIG and VIGIV, or our "Biologic Products," may be affected by follow-on biologics, or "biosimilars," in the United States and other jurisdictions. Regulatory and legislative activity in the United States 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 could 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 CBRNE (Chemical, Biological, Radiological, Nuclear and Explosives) 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. If

the threat of terrorism were to decline, then the public perception of the risk of bioterrorism may be 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. Except under limited circumstances related to certain government sales, 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 3 safety and efficacy trials conducted in patients with the disease or condition being targeted.

However, Anthrasil, 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 instead of testing in humans. This is known as the FDA's "Animal Rule." We cannot guarantee that the FDA will permit us to proceed with licensure of Anthrasil, 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 is 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, current good manufacturing practices, or 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 and our Winnipeg manufacturing facility was inspected most recently in July 2014. 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 are 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, Anthrasil, HepaGam B, VARIZIG, VIGIV and many 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, contamination, 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.

For example, FDA approval is required for the release of each lot of BioThrax. A "lot" is approximately 186,000 doses. 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.

Prior to release of lots of BioThrax, we visually inspect each vial. Beginning on January 28, 2015, during standard quality inspections performed in accordance with customary procedures, we discovered foreign particles in a limited number of vials in two manufactured lots of BioThrax. In order to determine the source of the foreign particles, we have been investigating our operations as well as those of our suppliers and contract manufacturers. Under our quality standards, these two BioThrax lots will be rejected. Currently, there is no evidence that any other BioThrax lots have been affected, but as a precautionary measure, we have quarantined 13 additional lots in inventory pending the findings of our investigation. It is our goal to complete this investigation within the next 60 days. Consequently, no BioThrax deliveries will be made in the first quarter. Based upon current information and depending on the disposition of the quarantined lots, the impact on previously forecasted 2015 BioThrax revenues is anticipated to be between \$0 and \$65 million. Furthermore, there is no current evidence that product in distribution is impacted. Since the investigation is ongoing and the full scope of the issue has not been determined with certainty, the actual impact may be greater than anticipated. As the company is unable to definitively assess the impact to 2015 financial results, it is suspending previously issued 2015 guidance.

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 impact our future 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 to fund the scale-up, qualification and validation of manufacturing BioThrax at an expanded scale. Additionally, in 2009, we acquired a facility in Baltimore, Maryland, which we intend 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 future 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 contamination or 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 key 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 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, pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act, we are required to register with 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 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 a number of factors, including the success of our development programs, the U.S. government's interest in providing development funding for or procuring certain of our Biodefense division product candidates, 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 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 biologics 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 arrangements; establishment and training of a commercial sales force for the product, whether alone or in collaboration with others; successful registration and maintenance of relevant patent and/or other proprietary protection; and acceptance of the product by potential government customers, physicians, patients, healthcare payers and others in the medical community.

If we are delayed or prevented from developing or commercializing a product candidate in a profitable 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 in these trials, which may not yield viable products.

Before obtaining regulatory approval for the sale of our product candidates, we and our collaborative partners where applicable 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 regulatory 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, which could delay or prevent our ability to receive regulatory approval for a product candidate, 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 2b 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 prove to 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 business, will depend, in large part, on our ability to obtain and maintain protection in the United States 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. In the past, we have abandoned the prosecution and/or maintenance of a family of patent applications in the ordinary course of business. We may in the future choose to abandon such prosecution and/or maintenance in a similar fashion. 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 United States and in 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 from Pfizer, Inc. an oligonucleotide adjuvant, CPG 7909, for use in our anthrax vaccine product candidate NuThrax. 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 materially affect our business.

Our development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents and other intellectual property rights of third parties under which we do not hold 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 United States and abroad. These third parties may have substantially greater financial resources than us and could bring claims against us that could 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, which could cause us to 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 an acquisition 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 acquisition of Cangene Corporation could adversely affect our ability to grow our business.

We may not be able to integrate any acquired business successfully, including our recent acquisition of Cangene Corporation, 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 or future acquisitions with our existing businesses, or operate any acquired business profitably, we may not obtain the advantages that the acquisitions were intended to create, which may materially adversely affect the growth of our business.

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, our humanized anti-CD37 therapeutic (formerly known as TRU-016), we plan to evaluate the merits of entering into collaboration arrangements with third parties, including leading biopharmaceutical companies or non-governmental organizations. We expect to selectively pursue collaboration arrangements with third parties 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 are 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, 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, in 2011, our previous collaboration partner Abbott Laboratories terminated its collaboration with us for the development of otlertuzumab (formerly TRU-016) following a portfolio reprioritization process by Abbott.

Failure of any of our future collaboration 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 December 31, 2014, our total consolidated indebtedness was \$251 million, including \$250 million 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 initiatives;
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 ability to grow our business, results of operations and financial condition.

We may require significant additional funding to grow our business, including 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, 2014, we had approximately \$280.5 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, 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; and
- the costs of commercialization activities, including product marketing, sales and distribution

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 a shelf registration statement on file with the Securities and Exchange Commission, effective until June 2015 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 quarters of 2014, 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, Anthrasil and VIGIV as covered countermeasures. These declarations expire in 2015. 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.

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, Anthrasil 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 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, and any failure to attract or retain key personnel may negatively affect 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 are unable to retain 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 substantial beneficial ownership of our common stock, including an ability to 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 substantial beneficial ownership of our common stock. As of February 27, 2015, Mr. El-Hibri was the beneficial owner of approximately 15% of our outstanding common stock. As a result, Mr. El-Hibri could 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 in 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 27, 2015, our common stock has traded as high as \$30.74. per share and as low as \$4.40 per share. The stock market in general as well as 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;
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 currently do not pay dividends, investors will benefit from an investment in our common stock only if it appreciates in value.

We currently do not pay dividends on our common stock. 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 27, 2015, 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 | Owned/leased |
|----------|-----|---------|--------------|
|----------|-----|---------|--------------|

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

| | | | Approximate square feet Owned/leased | |
|----------------------------|--|------------------------|--|--------------------|
| Lansing, Michigan | Manufacturing operations facilities, office space and laboratory space | Biodefense | 336,000 | Owned |
| Baltimore, Maryland | Manufacturing facilities and office and laboratory space | Biodefense | 56,000 | Owned |
| Gaithersburg, Maryland | Office and laboratory space | Biodefense | 48,000 | Owned |
| 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 |
| Seattle, Washington | Office and laboratory space | Biosciences | 51,000 | Leases expire 2020 |
| Gaithersburg, Maryland | Office space/rental real estate | Biodefense/Biosciences | 130,000 | Owned |

Biodefense

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.

Gaithersburg, Maryland. Our facility in Gaithersburg, Maryland is approximately 48,000 square feet and contains a combination of laboratory and office space.

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, a technology innovation and commercialization center. This facility is equipped to manufacture and package RSDL.

Biosciences

Winnipeg, Manitoba, Canada. 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.

Baltimore, Maryland. Additionally, as part of the Cangene acquisition, we acquired a manufacturing facility focused on pharmaceutical 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, final packaging and accelerated and ongoing stability studies 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.

Seattle, Washington. Our facility in Seattle, Washington is approximately 51,000 square feet and contains a combination of laboratory and office space.

Biodefense and Biosciences

Gaithersburg, Maryland. In 2013, we acquired a 130,000 square foot building in Gaithersburg, Maryland, a portion of which we utilize as our corporate headquarters, while continuing to rent a portion of the remainder of the space to third parties.

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 December 31, 2014:

| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
|------------------------------|------------------|-------------------|------------------|-------------------|
| Year Ended December 31, 2014 | | | | |
| High | \$ 28.48 | \$ 27.17 | \$ 25.41 | \$ 28.08 |
| Low | \$ 21.72 | \$ 20.04 | \$ 20.11 | \$ 19.31 |
| Year Ended December 31, 2013 | | | | |
| High | \$ 16.99 | \$ 15.89 | \$ 19.53 | \$ 24.04 |
| Low | \$ 13.75 | \$ 13.02 | \$ 14.49 | \$ 17.31 |

As of February 27, 2015, the closing price per share of our common stock on the New York Stock Exchange was \$29.97 and we had 30 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, 2014 (1) | 7,236 | 27.64 | 0 | \$ 0.00 |
| Total | 7,236 | \$27.64 | 0 | \$ 0.00 |

(1)In December 2014, 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 our chief executive office in which we acquired 7,236 shares of common stock as payment for the exercise price of 11,536 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, 2014, 2013, and 2012 and the consolidated balance sheet data as of December 31, 2014, and 2013 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, 2011, and 2010 and the consolidated balance sheet data as of December 31, 2012, 2011, and 2010 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.

| (in thousands, except share and per share data) | Year Ended December 31, | | | | |
|---|-------------------------|------------|------------|------------|------------|
| | 2014 | 2013 | 2012 | 2011 | 2010 |
| Statements of operations data: | | | | | |
| Revenues: | | | | | |
| Product sales | \$308,345 | \$257,922 | \$215,879 | \$202,409 | \$251,381 |
| Contract manufacturing | 30,944 | - | - | - | - |
| Contracts, grants and collaborations | 110,849 | 54,823 | 66,009 | 70,975 | 34,790 |
| Total revenues | 450,138 | 312,745 | 281,888 | 273,384 | 286,171 |
| Operating expenses: | | | | | |
| Cost of product sales and contract manufacturing | 118,412 | 62,127 | 46,077 | 42,171 | 47,114 |
| Research and development | 150,829 | 119,933 | 120,226 | 124,832 | 89,295 |
| Selling, general & administrative | 122,841 | 87,883 | 76,018 | 74,282 | 76,205 |
| Impairment of in-process research and development | - | - | 9,600 | - | - |
| Total operating expenses | 392,082 | 269,943 | 251,921 | 241,285 | 212,614 |
| Income from operations | 58,056 | 42,802 | 29,967 | 32,099 | 73,557 |
| Other income (expense): | | | | | |
| Interest income | 320 | 139 | 134 | 105 | 832 |
| Interest expense | (8,240) | - | (6) | - | - |
| Other income (expense), net | 2,926 | 426 | 1,970 | (261) | (1,023) |
| Total other income (expense) | (4,994) | 565 | 2,098 | (156) | (191) |
| Income before provision for income taxes | 53,062 | 43,367 | 32,065 | 31,943 | 73,366 |
| Provision for income taxes | 16,321 | 13,108 | 13,922 | 15,830 | 26,182 |
| Net income | 36,741 | 30,259 | 18,143 | 16,113 | 47,184 |
| Net loss attributable to noncontrolling interest | - | 876 | 5,381 | 6,906 | 4,514 |
| Net income attributable to Emergent BioSolutions Inc. | \$36,741 | \$31,135 | \$23,524 | \$23,019 | \$51,698 |
| Earnings per share — basic | \$0.98 | \$0.86 | \$0.65 | \$0.65 | \$1.63 |
| Earnings per share — diluted | \$0.88 | \$0.85 | \$0.65 | \$0.64 | \$1.59 |
| Weighted average number of shares — basic | 37,344,891 | 36,201,283 | 36,080,495 | 35,658,907 | 31,782,286 |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

Weighted average number of shares — diluted 45,802,807 36,747,556 36,420,662 36,206,052 32,539,500

(in thousands) As of December 31,
2014 2013 2012 2011 2010

Balance Sheet Data:

| | | | | | |
|-----------------------------|-----------|-----------|-----------|-----------|-----------|
| Cash and cash equivalents | \$280,499 | \$179,338 | \$141,666 | \$143,901 | \$169,019 |
| Working capital | 339,239 | 216,464 | 201,440 | 183,364 | 167,774 |
| Total assets | 945,262 | 626,630 | 564,230 | 546,864 | 500,319 |
| Total long-term liabilities | 299,125 | 80,814 | 60,195 | 59,083 | 51,039 |
| Total stockholders' equity | 553,201 | 489,165 | 442,128 | 416,727 | 373,561 |

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 CBRNE (Chemical, Biological, Radiological, Nuclear and Explosives) threats. The U.S. government is the primary purchaser of our Biodefense products and often provides us with substantial funding for the development of our 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. Our Biodefense portfolio consists of five marketed products, three of which were acquired in our acquisition of Cangene Corporation, or Cangene, in February 2014 and various investigational stage product candidates.

Our Biodefense division marketed products are:

§ BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or the FDA, for the prevention of anthrax disease;

§ BAT™ (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-Equine), the only heptavalent therapeutic licensed by the FDA for the treatment of botulinum disease*;

§

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

Anthrasil™ (Anthrax Immune Globulin Intravenous (Human)), which has a pending Biologics License Application, or BLA, with the FDA and, if approved, would be the only polyclonal antibody therapeutic licensed by the FDA for the treatment of anthrax infection*;

§ VIGIV (Vaccinia Immune Globulin Intravenous (Human)), the only therapeutic licensed by the FDA to address adverse events from smallpox vaccination*; and

§ RSDL® (Reactive Skin Decontamination Lotion Kit), the only device cleared by the FDA for the removal or neutralization of chemical agents, T-2 toxin and many pesticide-related chemicals from the skin.

Our Biodefense division primarily consists of the following investigational stage product candidates:

§ NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), a next generation anthrax vaccine;

§ PreviThrax™ (recombinant protective antigen anthrax vaccine, purified), a next generation anthrax vaccine; and

§ GC-072, the lead compound in the EV-035 series of broad spectrum antibiotics, which we acquired from Evolva SA in December 2014.

Our Biodefense division also has programs aimed at providing solutions to the current Ebola outbreak in West Africa, including an MVA-Ebola vaccine candidate, anti-Ebola monoclonal antibody product candidates and an Ebola hyperimmune product candidate. We have responded to Task Order Requests issued by BARDA for the manufacture of Ebola medical countermeasures as part of our Center for Innovation in Advanced Development and Manufacturing, or CIADM, program. In addition, we have a license agreement for the manufacture of VAX161C, a clinical stage recombinant pandemic influenza vaccine product candidate being developed by VaxInnate, Inc., in the event of a surge order from the Biomedical Advanced Research and Development Authority, or BARDA.

Our Biosciences division is a specialty pharmaceutical business focused on therapeutics and vaccines in hematology/oncology, transplantation, infectious disease and autoimmunity. Our Biosciences portfolio consists of marketed products, which were acquired through our acquisition of Cangene, as well as various investigational stage product candidates and a contract manufacturing services business. Operations that support this division include manufacturing, quality, regulatory affairs, 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.

Our Biosciences division marketed products are:

§ WinRho® SDF [Rh₀(D) Immune Globulin Intravenous (Human)], 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® [(Hepatitis B Immune Globulin Intravenous (Human))], for post-exposure prophylactic treatment of hepatitis-B*;

§ VARIZIG® [Varicella Zoster Immune Globulin (Human)], for post-exposure prophylactic treatment of varicella zoster virus, which causes chickenpox and shingles*;

§ episil® (oral liquid), for relief of pain and soothing oral lesions of various etiologies, including oral mucositis/stomatitis caused by chemotherapy or radio therapy*.

Our Biosciences division primarily consist of the following investigational stage product candidates:

§ IXINITY® (coagulation factor IX (recombinant)), being developed for the prevention of bleeding episodes in people with hemophilia B;

§ ES414, now known as MOR209/ES414, being developed for metastatic castration resistant prostate cancer under our collaboration with MorphoSys AG entered into in August 2014; and

§ otlertuzumab, formerly known as TRU-016, being developed for Chronic Lymphocytic Leukemia.

In addition, our Biosciences division includes several platform technologies, including our ADAPTIR™ (modular protein technology) platform, our MVAtor™ (modified vaccinia virus Ankara vector) platform, and our hyperimmune specialty plasma product manufacturing platform.

Our Biodefense segment has generated net income for each of the last five years. Our Biosciences segment has generated revenue over this timeframe through product sales, development contracts and collaborative funding but has incurred a net loss for each of the last five years.

Product Sales

We have derived a majority 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. Our total revenues from BioThrax sales were \$245.9 million, \$246.7 million and \$215.9 million for the years ended December 31, 2014, 2013 and 2012, respectively. We expect to continue to derive a majority of our product sales revenues from sales of BioThrax to the U.S. government. We are focused on increasing the sales of our Biodefense products to U.S. government customers and expanding the market for our product portfolio to other customers domestically and internationally.

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 a number of our development programs. 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 BARDA which provides funding to support the work needed to approve manufacturing of BioThrax at the larger 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, nuclear and explosive threat countermeasures, as well as our current and future non-CIADM product development and manufacturing needs.

In connection with our August 2013 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, a technology innovation and commercialization center. 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. 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 Cangene acquisition, we acquired a manufacturing facility located in Baltimore, Maryland focused on pharmaceutical 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, final packaging and accelerated and ongoing stability studies 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 United States. 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 United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses.

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

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

Revenue Recognition

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

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

All revenues from product sales are recorded net of applicable allowances for sales, rebates, special promotional programs, and discounts. We estimate allowances for revenue reducing obligations using a combination of information received from third parties including market data, inventory reports from major wholesalers, historical information and analysis. These estimates are subject to the inherent limitations of estimates that rely on third-party

data, as certain third-party information may itself rely on estimates and reflect other limitations. Provisions for estimated rebates and other allowances, such as discounts and promotional and other credits, are estimated based on historical payment experience, historical relationship to revenues, estimated customer inventory levels and contract terms, and actual discounts offered.

We market and sell our Biosciences products through commercial wholesalers (direct customers) who purchase the products at a price referred to as the wholesale acquisition cost, or WAC. Additionally, we enter into agreements with indirect customers for a contracted price that is less than the WAC. The indirect customers, such as group-purchasing organizations, physician practice-management groups and hospitals, purchase our products from the wholesalers. Under these agreements with the wholesalers, we guarantee to credit them for the difference between the WAC and the indirect customers' contracted price. This credit is referred to as a chargeback. Adjustments to our chargeback provisions are made periodically to reflect new facts and circumstances that may indicate that historical experience may not be indicative of current and/or future results. We make subjective judgments primarily based on evaluation of current market conditions and trade inventory levels related to the products. This evaluation may result in an increase or decrease in the experience rate that is applied to current and future sales, or as an adjustment to past sales, or both.

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 RSDL 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 and grants for development services by 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: (1) the delivered item(s) has value to the customer on a stand-alone basis and (2) if the arrangement includes a general right of return and delivery or performance of the undelivered item(s) is considered probable and substantially in our control. 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 relative selling price and is recognized in full when the appropriate revenue recognition criteria are met. We deem services to be rendered if no continuing obligation exists on our part.

Revenue associated with non-refundable upfront license fees that can be treated as a single unit of accounting is recognized when all ongoing obligations have been delivered. Revenue associated with non-refundable upfront license fees under arrangements where the license fees and any 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 our continued

involvement in the research and development process or based on the proportional performance of our 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, we recognize such milestone as revenue on a straight-line basis over the remaining expected term of continued involvement in the research and development process or based on the proportional performance of our expected future obligations under the contract.

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.

Stock-based Compensation

In accordance with stock-based compensation accounting guidance, all equity awards, 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.

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 and foreign jurisdictions. 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.

Mergers and Acquisitions

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the merger or acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are recognized at fair value if fair value can reasonably be estimated. If the acquisition date fair value of an asset acquired or liability assumed that arises from a contingency cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. 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. Accordingly, we may be required to value assets at fair value measures that do not reflect our intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in our consolidated financial statements after the date of the merger or acquisition. If we determine the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded. The fair values of intangible assets, including acquired in-process research and development, or IPR&D, are determined utilizing information available near the merger or acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, we typically obtain assistance from third-party valuation specialists for significant items. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets. Upon successful completion of each project, we will make a separate determination as to the then useful life of the asset and begin amortization. The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect the Company's results of operations.

The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an "income approach" through which fair value is estimated based on each asset's discounted projected net cash flows. Our estimates of market participant net cash flows consider historical and projected pricing, margins and expense levels; the performance of competing products where applicable; relevant industry and therapeutic area growth drivers and factors; current and expected trends in technology and product life cycles; the time and investment that will be required to develop products and technologies; the ability to obtain marketing and regulatory approvals; the ability to manufacture and commercialize the products; the extent and timing of potential new product introductions by the Company's competitors; and the life of each asset's underlying patent, if any. The net

cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to IPR&D are determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate. Intangible assets are tested for impairment whenever events or changes in circumstances indicate that its carrying amount may not be recoverable.

Contingent Purchase Consideration Obligations

In accordance with the terms our August 2013 acquisition of the Health Protective Products Division, or HPPD, from Bracco Diagnostics 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.

Contingent Value Rights

We record contingent value right, or 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.

We believe that the inputs it uses for determining the fair value of the CVR obligations are Level 3 fair value measurements. We re-evaluate 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.

Provision for Chargebacks

We record sales for our Bioscience products, primarily WinRho and HepaGam, net of provisions for chargebacks, administration fees, rebates and other adjustments. These provisions are primarily estimated based on historical experience, future expectations, contractual arrangements with wholesalers and indirect customers, and other factors known to management at the time of accrual. Provisions for chargebacks, administration fees, rebates and other

adjustments require varying degrees of subjectivity. While rebates generally are based on contractual terms and require minimal estimation, chargebacks require management to make more subjective assumptions.

The provision for chargebacks is a significant and complex estimate used in the recognition of revenue. We sell our products directly primarily to large commercial wholesale distributors. We also sell our products indirectly to group-purchasing organizations, physician practice-management groups and hospitals, collectively referred to as "indirect customers." We enter into agreements with our indirect customers to establish pricing for certain of our products. The indirect customers then independently select a wholesaler from which to purchase the products. If the price paid by the indirect customers is lower than the price paid by the wholesaler, we will provide a credit, called a chargeback, to the wholesaler for the difference between the contractual price with the indirect customers and the wholesaler purchase price. The provision for chargebacks is based on expected sell-through levels by our wholesale customers to the indirect customers and estimated wholesaler inventory levels.

As sales to the large wholesale customers fluctuate the reserve for chargebacks will also generally fluctuate in the same direction. However, the degree of the fluctuation depends on product mix and the amount of sales made to indirect customers with which we have specific chargeback agreements.

On a quarterly basis management reviews actual payments for provisions, wholesaler and distributor sales to our indirect customers, inventory balances at the wholesalers and distributors, as well as any known market factors that may impact our estimate, and we make adjustments when we believe that actual expected chargebacks may differ from the actual chargeback reserve.

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 \$911 million for the procurement of BioThrax doses under this contract. Through December 31, 2014, we have delivered and, upon CDC acceptance, recognized revenue on approximately 27 million doses, representing approximately \$722 million in revenue under this contract.

Beginning on January 28, 2015, during standard quality inspections performed in accordance with customary procedures, we discovered foreign particles in a limited number of vials in two manufactured lots of BioThrax. In order to determine the source of the foreign particles, we have been investigating our operations as well as those of our suppliers and contract manufacturers. Under our quality standards, these two BioThrax lots will be rejected. Currently, there is no evidence that any other BioThrax lots have been affected, but as a precautionary measure, we have quarantined 13 additional lots in inventory pending the findings of the investigation. It is our goal to complete this investigation within the next 60 days. Consequently, no BioThrax deliveries will be made in the first quarter. Based upon current information and depending on the disposition of the quarantined lots, the impact on previously forecasted 2015 BioThrax revenues is anticipated to be between \$0 and \$65 million. Additionally, we estimate that the cost of inventory for which there is a reasonable possibility of loss is approximately \$2 million to \$15 million. This ongoing investigation does not impact any of the company's other products or manufacturing operations, including the company's operations and plans for licensure for Building 55, our large-scale vaccine manufacturing facility in Lansing, Michigan. Furthermore, there is no current evidence that product in distribution is impacted. Since the investigation is ongoing and the full scope of the issue has not been determined with certainty, the actual impact may be greater than anticipated.

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

We have received contract and grant funding from the CDC, 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 — 4/2015 |
| PreviThrax | BARDA | 9/2010 | 9/2010 — 9/2015 |
| CIADM | BARDA | 6/2012 | 6/2012 — 6/2037 |
| BAT | CDC | 1/2003 | 1/2003 — 1/2015 |
| BAT | BARDA | 5/2006 | 5/2006 — 5/2026 |
| Anthraxil | BARDA | 9/2005 | 9/2005 — 4/2021 |
| Anthraxil | BARDA | 9/2002 | 9/2002 — 12/2015 |
| Anthraxil | BARDA | 9/2013 | 9/2013 — 9/2018 |
| VIGIV | CDC | 8/2012 | 8/2012 — 8/2017 |
| NuThrax Dry Formulation | NIAID | 8/2014 | 8/2014 — 10/2019 |

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 and Contract Manufacturing

The primary expense that we incur to deliver our vaccines and therapeutics to our customers is manufacturing costs, consisting of fixed and variable costs. Variable manufacturing costs consist primarily of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff, contract manufacturing and filling operations, and sales-based royalties. Fixed manufacturing costs include facilities, utilities and amortization of intangible assets. We determine the cost of product sales for products sold during a reporting period based on the average manufacturing cost per unit in the period those units were manufactured. In addition to the fixed and variable manufacturing costs described above, the cost of product sales depends on utilization of available manufacturing capacity.

The primary expense that we incur to deliver our medical device, RSDL, to our customers is the cost per unit of production from our third-party contract manufacturer. Other associated expenses include sales-based royalties, amortization 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; and
costs of materials used in clinical trials and research and development.

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 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 personnel-related costs and professional fees in support of our executive, sales and marketing, business development, government affairs, finance, accounting, information technology, legal and human resource functions. Other costs include facility costs not otherwise included in cost of product sales and contract manufacturing or research and development expense.

Collaboration with MorphoSys AG

In August 2014, we entered into a collaboration agreement, the MorphoSys Agreement, with MorphoSys AG, or MorphoSys, for the joint worldwide development and commercialization of MOR209/ES414, a targeted immunotherapeutic proteins constructed using our proprietary ADAPTIR platform technology, which activates host T-cell immunity specifically against cells expressing prostate specific membrane antigen, an antigen commonly overexpressed on prostate cancer cells.

In accordance with the terms of this agreement, we received a nonrefundable \$20 million upfront payment and may receive up to \$163 million in additional contingent payments upon the achievement of specified development and regulatory milestones. We will jointly fund MOR209/ES414 development; we are responsible for 36% of the total development cost and MorphoSys is responsible for the remainder. Our funding requirement is capped at \$186 million. We will retain commercialization rights in the United States and Canada, with a tiered royalty obligation to MorphoSys, ranging from mid-single digits up to 20%. MorphoSys will gain worldwide commercialization rights excluding the United States and Canada, with a low single digit royalty obligation to us. We will manufacture and supply clinical material.

We evaluated the MorphoSys agreement and have determined that it is a revenue arrangement with multiple deliverable or performance obligations. We determined that there were two units of accounting under MorphoSys Agreement: (1) the license to further develop and commercialize MOR209/ES414 and (2) development services. We determined the license has standalone value as the drug candidate has been (1) developed and is currently Phase 1 clinical trial ready; (2) MorphoSys possesses the knowledge, technology, skills, experience and infrastructure necessary for all further development of the drug through commercialization; and (3) MorphoSys has the right to sublicense the product. We allocated the \$20 million upfront payment to the two units of accounting using the relative selling price method. We determined the estimated selling price of the license using the income approach. The estimated selling price includes unobservable inputs such as estimates revenues and operating margins; the time and resources needed to complete the development and approval; and risks related to the viability of and potential for alternative treatments. The estimated selling price of the development services is based on the estimated number of full-time equivalent personnel at a contracted rate defined in the MorphoSys Agreement, which are approximate terms of other service related contracts both entered into by us and observed generally through other collaboration negotiations.

During the year ended December 31, 2014, we recorded revenue of \$15.6 million from the upfront payment pursuant to the MorphoSys Agreement, which is included in contracts, grants and collaborations revenues within our Biosciences segment.

In-process Research and Development and Goodwill

EV-035

The intangible asset associated with IPR&D acquired from Evolva Holdings SA, or Evolva, in December 2014, is the EV-035 product candidate. As part of the preliminary purchase price allocation, management determined that the estimated acquisition date fair value related to EV-035 IPR&D asset was \$27.7 million. The estimated fair value was determined using the income approach, which discounts expected future cash flows to present value. We estimated the fair value using a present value discount rate of 12%. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would likely use to value the EV-035 asset. The projected cash flows from the EV-035 project were based on key assumptions, including: estimates of revenues and operating profits considering its stage of development on the acquisition date; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential alternative treatments in any future target markets. The EV-035 asset is considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts.

IXINITY

The intangible asset associated with IPR&D in the acquisition of Cangene is the IXINITY product candidate. As part of the purchase price allocation with respect to the Cangene acquisition, our management determined that the estimated acquisition date fair value related to the IXINITY IPR&D asset was \$8.3 million. The estimated fair value was determined using the income approach, which discounts expected future cash flows to present value. We estimated the fair value using a present value discount rate of 16%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of Cangene. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would likely use to value this type of IPR&D asset. The projected cash flows from the IXINITY project were based on key assumptions, including: estimates of revenues and operating profits considering its stage of development on the acquisition date; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential alternative treatments in any future target markets. The IXINITY asset is considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts.

On July 29, 2014, the FDA issued a complete response letter for the New Drug Application, or NDA, of IXINITY. The complete response letter requested additional analyses of data from completed studies and noted deficiencies in the chemistry, manufacturing, and controls section of the license application, all of which must be resolved before approval can be granted by FDA. We determined the FDA's response to our NDA is a potential indicator of impairment of the related IXINITY IPR&D asset. We have completed our interim impairment assessment and concluded the estimated fair value of the IXINITY IPR&D asset was in excess of the carrying value, therefore we determined there was no impairment. We determined the fair value based on inputs, such as estimated future revenue and operating profits, probabilities of successful commercialization and discount rates.

We have completed our annual impairment assessments for the IPR&D assets and goodwill as of October 1, 2014 and 2013, respectively, and determined that the fair value of the IPR&D assets and goodwill were in excess of carrying value. The following table summarizes our IPR&D and goodwill by reporting unit:

| Reporting unit | December 31, 2014 | | December 31, 2013 | |
|-------------------------------------|-------------------|-----------|-------------------|----------|
| | IPR&D | Goodwill | IPR&D | Goodwill |
| Biosciences therapeutics | \$50,100 | \$ 13,902 | \$41,800 | \$ 5,502 |
| Biosciences contracts manufacturing | - | 6,736 | - | - |
| Biosciences subtotal | 50,100 | 20,638 | 41,800 | 5,502 |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

| | | | | |
|--------------------------------------|----------|----------|----------|----------|
| Biodefense therapeutics and vaccines | 27,700 | 11,430 | - | - |
| Biodefense medical device(s) | - | 9,916 | - | 8,452 |
| Biodefense subtotal | 27,700 | 21,346 | - | 8,452 |
| Total | \$77,800 | \$41,984 | \$41,800 | \$13,954 |

Results of Operations

Year Ended December 31, 2014 Compared to Year Ended December 31, 2013

Revenues

Product Sales:

Product sales revenues increased by \$50.4 million, or 20%, to \$308.3 million for 2014 from \$257.9 million in 2013. Product sales revenues included:

BioThrax - \$245.9 million for 2014 as compared to \$246.7 million for 2013;
 Other Biodefense products - \$32.4 million for 2014 (which includes RSDL and products we acquired from Cangene in February 2014) as compared to \$11.2 million for 2013; and
 Biosciences product sales (acquired in February 2014) - \$30.1 million for 2014.

BioThrax product sales revenues during the year ended December 31, 2014 consisted of sales to the CDC of \$242.2 million and aggregate international and other sales of \$3.7 million. BioThrax product sales revenues during the year ended December 31, 2013 consisted primarily of BioThrax sales to the CDC of \$244.1 million and aggregate international and other sales of \$2.5 million.

Contract Manufacturing:

Contract manufacturing revenue was \$30.9 million for 2014. Contract manufacturing (acquired in February 2014) revenues primarily consists of contract services to third parties.

Contracts, Grants and Collaborations:

Contracts, grants and collaborations revenues increased by \$56.0 million, or 102%, to \$110.8 million for 2014 from \$54.8 million for 2013. The increase in contracts, grants and collaboration revenues was primarily due to the following:

§ development funding of \$27.8 million for Anthrasil (acquired in February 2014);
 § development funding of \$17.0 million for BAT (acquired in February 2014); and
 § recognition of \$15.6 million, primarily related to license fee revenue, from our collaboration with MorphoSys (executed in August 2014).

These increases were partially offset by decreased revenue of \$12.6 million under our development contracts for PreviThrax and large-scale manufacturing of BioThrax, primarily due to the timing of development efforts.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by \$56.3 million, or 91%, to \$118.4 million 2014 from \$62.1 million for 2013. The increase was primarily attributable to the following:

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

product and contract manufacturing costs of \$48.6 million for 2014 associated with revenues acquired in February, 2014 as part of the Cangene acquisition; and increased costs of \$9.4 million for RSDL, which we acquired in August 2013.

Research and Development Expense

Research and development expenses increased by \$30.9 million, or 26%, to \$150.8 million for 2014 from \$119.9 million for 2013. This increase primarily reflects higher contract service costs and includes increased expenses of \$19.3 million for product candidates and manufacturing development categorized in the Biodefense division, increased expenses of \$10.2 million for product candidates and technology platform development activities categorized in the Biosciences division and increased expenses of \$1.4 million in other research and development, which are in support of central research and development activities. Net of contract, grants and collaborations revenues along with the net loss attributable to noncontrolling interests, we incurred research and development expenses of \$40.0 million and \$64.2 million, during 2014 and 2013, respectively.

Our principal research and development expenses for 2014 and 2013 are shown in the following table:

| (in thousands) | Year ended | |
|--|--------------|-----------|
| | December 31, | |
| | 2014 | 2013 |
| Biodefense: | | |
| Large-scale manufacturing for BioThrax | \$13,625 | \$17,876 |
| BioThrax related programs | 7,157 | 10,613 |
| PreviThrax | 10,737 | 14,953 |
| NuThrax | 9,428 | 9,236 |
| Botulinum antitoxin | 7,351 | - |
| Anthrasil | 19,513 | - |
| Pandemic influenza | - | 2,545 |
| Other Biodefense | 14,164 | 7,440 |
| Total biodefense | 81,975 | 62,663 |
| Biosciences: | | |
| ES414 (formerly T-Scorp) | 11,818 | 7,719 |
| IXINITY | 17,456 | - |
| otlertuzumab (formerly TRU-016) | 8,818 | 27,035 |
| Tuberculosis vaccine | - | 4,882 |
| Other Biosciences | 22,729 | 11,016 |
| Total biosciences | 60,821 | 50,652 |
| Other | 8,033 | 6,618 |
| Total | \$150,829 | \$119,933 |

The decrease in spending for large-scale manufacturing for BioThrax was primarily due to the timing of manufacturing development activities. The decrease in spending for BioThrax related programs was primarily related to the timing of clinical studies to support applications for label expansion for BioThrax. The decrease in spending for PreviThrax was primarily due to the timing of stability and non-clinical studies. The spending for NuThrax was primarily due to clinical trial activities. The spending for our Botulinum Antitoxin program (which we acquired from Cangene) was primarily due to plasma collection services and stability testing. The spending for our Anthrasil program (which we acquired from Cangene) was due to plasma collection services and manufacturing activities. The decrease in spending for pandemic influenza was related to a license fee for the rights to manufacture and sell pandemic influenza products during 2013. The increase in spending for Other Biodefense activities was primarily due to increased spending related to manufacturing development.

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

The increase in spending for our ES414 (formerly T-Scorp) product candidate was primarily due to ongoing manufacturing development. The spending for our IXINITY product candidate in 2014 was primarily for clinical trial and manufacturing activities. The decrease in spending for our otlertuzumab (formerly TRU-016) product candidate was primarily related to the timing of clinical trial activities. The spending for our tuberculosis vaccine product candidate during 2013 was for manufacturing development activities. The increase in spending for Other Biosciences activities was primarily due to increased costs associated with the development of platform technologies.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by \$35.0 million, or 40%, to \$122.8 million for 2014 from \$87.9 million for 2013. This increase included increased spending for professional services of \$8.1 million associated with acquisition and integration activities, along with ongoing post-acquisition selling, general and administrative costs of \$26.2 million associated with the operations of Cangene and in support of RSDL.

Selling, general and administrative expenses attributable to the Biodefense division increased by \$8.7 million, or 14%, to \$69.6 million during 2014 from \$60.9 million during 2013. The increase in Biodefense selling, general and administrative expense was primarily due to post acquisition costs associated with our acquisitions of Cangene and the RSDL product from Bracco. Selling, general and administrative expenses related to our Biosciences division increased by \$26.3 million, or 97%, to \$53.3 million during 2014 from \$27.0 million during 2013. The increase in the Biosciences selling, general and administrative expense was due to professional services to support due diligence along with other acquisition-related activities and post-acquisition operations associated with our acquisition of Cangene.

Total Other Income (Expense)

Total net other income (expense) decreased by \$5.6 million to a net other expense of \$5.0 million for 2014, from a net other income of \$565,000 for 2013. The decrease was primarily due to interest expense of \$5.0 million that was not capitalized in 2014, \$1.8 million of costs associated with the termination of our \$125 million term loan facility and \$1.4 million of loan fee amortization expense associated with our 2.875% Convertible Senior Notes due 2021, or the Notes, and our revolver loan facility, partially offset by \$3.1 million in rental income.

Income Taxes

Provision for income taxes increased by \$3.2 million, or 25%, to \$16.3 million for 2014 from \$13.1 million for 2013. The provision for income taxes for 2014 resulted primarily from our income before provision for income taxes and the loss attributable to noncontrolling interest of \$53.1 million and an effective annual tax rate of approximately 31%. 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 2014 and 2013, respectively, reflects net tax credits associated with research and developments activities of \$6.0 million and \$5.9 million, respectively.

Net Loss Attributable to Noncontrolling Interest

Net loss attributable to noncontrolling interest decreased to \$0 for 2014 from \$876,000 for 2013. The decrease resulted from the liquidation of our noncontrolling interest in the Oxford Emergent Tuberculosis Consortium during 2013.

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

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. 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.

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:

| (in thousands) | Year ended | |
|--|----------------------|----------|
| | December 31, 2013 | 2012 |
| Biodefense: | | |
| Large-scale manufacturing for BioThrax | \$17,876 | \$18,908 |
| BioThrax related programs | 10,613 | 10,934 |
| PreviThrax | 14,953 | 19,805 |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

| | | |
|---------------------------------|------------|------------|
| NuThrax | 9,236 | 8,591 |
| Pandemic influenza | 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 (formerly TRU-016) | 27,035 | 13,585 |
| ES414 (formerly T-Scorp) | 7,719 | 4,673 |
| ES-301 (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 2b 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 1b/2 relapsed refractory and Phase 1 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 2012. The impairment charge for 2012 resulted from the full impairment of our SBI-087 in-process research and development asset due to our decision to no longer pursue further development of this asset due to reduced overall probability of success and increased development costs for the product candidate.

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 2013 and 2012, 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 2014 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 convertible debt and common stock offerings and proceeds received upon exercise of stock options. We have operated profitably for each of the five years ended December 31, 2014.

As of December 31, 2014, we had cash and cash equivalents of \$280.5 million.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2014, 2013 and 2012.

| (in thousands) | Year ended December 31, | | |
|---------------------------------|-------------------------|------|------|
| | 2014 | 2013 | 2012 |
| Net cash provided by (used in): | | | |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

| | | | |
|--------------------------------------|------------|-----------|-------------|
| Operating activities(1) | \$ 112,339 | \$ 96,954 | \$ 39,644 |
| Investing activities | (210,052) | (67,894) | (40,114) |
| Financing activities | 198,874 | 8,612 | (1,765) |
| Total net cash provided by (used in) | \$ 101,161 | \$ 37,672 | \$ (2,235) |

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

Net cash provided by operating activities of \$112.3 million in 2014 was primarily due to our net income of \$36.7 million, a decrease in accounts receivable of \$21.4 million related to the timing of collection of amounts billed primarily to the CDC, along with the effect of non-cash charges of \$12.8 million for stock-based compensation and \$32.5 million for depreciation and amortization.

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 IPR&D, 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 used in investing activities of \$210.1 million in 2014 was primarily due to the acquisition of Cangene for \$177.9 million, which is net of \$43.6 million of acquired cash and capital expenditures of \$30.7 million for infrastructure and equipment investments.

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 provided by financing activities of \$198.9 million in 2014 was primarily due to net proceeds from our Convertible Senior Notes of \$241.6 million, \$14.1 million in proceeds from the issuance of common stock pursuant to employee equity plans and \$6.0 million in excess tax benefits from the exercise of stock options, partially offset by a principal payment on indebtedness of \$62.0 million under our revolving credit facility.

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

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

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.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2014:

| (in thousands) | Payments due by period | | | | |
|--|------------------------|------------------------|-----------------|-----------------|-------------------------|
| | Total | Less than 1 year | 1 to 3 Years | 4 to 5 Years | More than 5 years |
| Contractual obligations: | | | | | |
| 2.875% Convertible Senior Notes due 2021 (Notes) | \$250,000 | \$- | \$- | \$- | \$250,000 |
| Contractual interest due on Notes | 43,424 | 7,188 | 14,376 | 14,376 | 7,484 |
| Long-term indebtedness (excluding Notes) | 1,000 | - | - | - | 1,000 |
| Purchase commitments | 11,248 | 3,648 | 7,600 | - | - |
| Operating lease obligations | 11,126 | 2,558 | 4,154 | 3,510 | 904 |
| Total contractual obligations | \$316,798 | \$13,394 | \$26,130 | \$17,886 | \$259,388 |

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 \$166 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 and adversely 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 January 29, 2014, we issued \$250.0 million aggregate principal amount of our Notes. The Notes 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 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 is 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. As of December 31, 2014, no amounts were drawn under the revolving credit facility.

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.

Our payment obligations under the Credit Agreement are secured by a lien on substantially all of our assets, including the stock of all of 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.

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. However, our credit facility restricts our ability to incur additional indebtedness, including secured indebtedness.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is currently confined to our cash and cash equivalents. 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.

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. and subsidiaries

We have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. and subsidiaries as of December 31, 2014 and 2013, 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, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Emergent BioSolutions Inc. and subsidiaries at December 31, 2014 and 2013, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Emergent BioSolutions Inc. and subsidiaries' internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 6, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia
March 6, 2015

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

| | December 31, | |
|--|--------------|-----------|
| | 2014 | 2013 |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$280,499 | \$179,338 |
| Accounts receivable | 58,834 | 60,587 |
| Inventories | 65,674 | 14,643 |
| Deferred tax assets, net | 1,710 | - |
| Income tax receivable, net | 1,357 | 5,651 |
| Prepaid expenses and other current assets | 24,101 | 12,896 |
| Total current assets | 432,175 | 273,115 |
| Property, plant and equipment, net | 313,979 | 264,240 |
| In-process research and development | 77,800 | 41,800 |
| Intangible assets, net | 58,344 | 30,148 |
| Goodwill | 41,984 | 13,954 |
| Deferred tax assets, net | 12,764 | - |
| Other assets | 8,216 | 3,373 |
| Total assets | \$945,262 | \$626,630 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$40,930 | \$27,521 |
| Accrued expenses and other current liabilities | 6,274 | 1,252 |
| Accrued compensation | 31,654 | 24,615 |
| Contingent purchase consideration, current portion | 6,487 | 1,341 |
| Provisions for chargebacks | 2,246 | - |
| Deferred tax liability, net | - | 88 |
| Deferred revenue | 5,345 | 1,834 |
| Total current liabilities | 92,936 | 56,651 |
| Contingent consideration, net of current portion | 41,170 | 15,278 |
| Long-term indebtedness | 251,000 | 62,000 |
| Deferred revenue, net of current portion | 5,713 | - |
| Deferred tax liability, net of current portion | - | 1,419 |
| Other liabilities | 1,242 | 2,117 |
| Total liabilities | 392,061 | 137,465 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, \$0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2014 and 2013, respectively | - | - |
| Common stock, \$0.001 par value; 100,000,000 shares authorized, 38,129,872 shares issued and 37,709,683, shares outstanding at December 31, 2014; 37,036,996 shares issued and | 38 | 37 |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

36,624,043, shares outstanding at December 31, 2013

Treasury stock, at cost, 420,189 and 412,953 common shares at December 31, 2014 and 2013, respectively

| | | |
|---|-----------|-----------|
| Additional paid-in capital | 274,222 | 247,637 |
| Accumulated other comprehensive loss | (3,008) | (3,465) |
| Retained earnings | 288,269 | 251,528 |
| Total Emergent BioSolutions Inc. stockholders' equity | 553,201 | 489,618 |
| Noncontrolling interest in subsidiaries | - | (453) |
| Total stockholders' equity | 553,201 | 489,165 |
| Total liabilities and stockholders' equity | \$945,262 | \$626,630 |

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

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

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

| | Year Ended December 31, | | |
|---|-------------------------|------------|------------|
| | 2014 | 2013 | 2012 |
| Revenues: | | | |
| Product sales, net | \$308,345 | \$257,922 | \$215,879 |
| Contract manufacturing | 30,944 | - | - |
| Contracts, grants and collaborations | 110,849 | 54,823 | 66,009 |
| Total revenues | 450,138 | 312,745 | 281,888 |
| Operating expense: | | | |
| Cost of product sales and contract manufacturing | 118,412 | 62,127 | 46,077 |
| Research and development | 150,829 | 119,933 | 120,226 |
| Selling, general and administrative | 122,841 | 87,883 | 76,018 |
| Impairment of in-process research and development | - | - | 9,600 |
| Income from operations | 58,056 | 42,802 | 29,967 |
| Other income (expense): | | | |
| Interest income | 320 | 139 | 134 |
| Interest expense | (8,240) | - | (6) |
| Other income (expense), net | 2,926 | 426 | 1,970 |
| Total other income (expense) | (4,994) | 565 | 2,098 |
| Income before provision for income taxes | 53,062 | 43,367 | 32,065 |
| Provision for income taxes | 16,321 | 13,108 | 13,922 |
| Net income | 36,741 | 30,259 | 18,143 |
| Net loss attributable to noncontrolling interest | - | 876 | 5,381 |
| Net income attributable to Emergent BioSolutions Inc. | \$36,741 | \$31,135 | \$23,524 |
| Earnings per share - basic | \$0.98 | \$0.86 | \$0.65 |
| Earnings per share - diluted | \$0.88 | \$0.85 | \$0.65 |
| Weighted-average number of shares - basic | 37,344,891 | 36,201,283 | 36,080,495 |
| Weighted-average number of shares - diluted | 45,802,807 | 36,747,556 | 36,420,662 |

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, | | |
|--|--------------|----------|----------|
| | 2014 | 2013 | 2012 |
| Net income attributable to Emergent BioSolutions Inc. | \$36,741 | \$31,135 | \$23,524 |
| Reclassification of cumulative foreign currency translation adjustment to income, net of tax | - | 58 | - |
| Foreign currency translations, net of tax | 457 | 606 | (816) |
| Comprehensive income | \$37,198 | \$31,799 | \$22,708 |

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

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

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

| | Year Ended December 31, | | |
|--|-------------------------|-----------|-----------|
| | 2014 | 2013 | 2012 |
| Cash flows from operating activities: | | | |
| Net income | \$36,741 | \$30,259 | \$18,143 |
| Adjustments to reconcile to net cash provided by operating activities: | | | |
| Stock-based compensation expense | 12,829 | 11,238 | 11,115 |
| Depreciation and amortization | 32,453 | 18,958 | 11,197 |
| Deferred income taxes | 16,493 | 13,858 | 3,383 |
| Non-cash development expenses from joint venture | - | (347) | 3,670 |
| Change in fair value of contingent obligations | 3,133 | 735 | (3,005) |
| Write off of debt issuance costs | 1,831 | - | - |
| Impairment of in-process research and development | - | - | 9,600 |
| Impairment of long-lived assets | - | 1,172 | - |
| Excess tax benefits from stock-based compensation | (5,987) | (3,099) | (1,588) |
| Other | 1,284 | 51 | (40) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | 21,405 | 35,456 | (21,890) |
| Inventories | 4,229 | 518 | (500) |
| Income taxes | (4,711) | (7,179) | 8,055 |
| Prepaid expenses and other assets | (8,472) | (6,226) | (1,038) |
| Accounts payable | (9,279) | (551) | 274 |
| Accrued expenses and other liabilities | 2,685 | 7 | 169 |
| Accrued compensation | 4,539 | 2,092 | 1,649 |
| Provision for chargebacks | 299 | - | - |
| Deferred revenue | 2,846 | 26 | 449 |
| Net cash provided by operating activities | 112,318 | 96,968 | 39,643 |
| Cash flows from investing activities: | | | |
| Purchases of property, plant and equipment | (30,673) | (42,021) | (53,845) |
| Proceeds from sale of assets | - | - | 11,765 |
| Proceeds from maturity of investments | - | - | 1,966 |
| Acquisitions, net of acquired cash | (179,379) | (25,873) | - |
| Net cash used in investing activities | (210,052) | (67,894) | (40,114) |
| Cash flows from financing activities: | | | |
| Proceeds from long-term debt obligations | 241,588 | - | - |
| Proceeds from borrowings on long-term indebtedness | 1,000 | 62,000 | 13,547 |
| Issuance of common stock subject to exercise of stock options | 14,078 | 6,848 | 761 |
| Excess tax benefits from stock-based compensation | 5,987 | 3,099 | 1,588 |
| Principal payments on long-term indebtedness and line of credit | (62,000) | (62,774) | (10,227) |
| Contingent obligation payments | (1,579) | (348) | (1,748) |
| Purchase of treasury stock | (200) | (213) | (5,906) |
| Restricted cash deposit | - | - | 220 |
| Net cash provided by (used in) financing activities | 198,874 | 8,612 | (1,765) |
| Effect of exchange rate changes on cash and cash equivalents | 21 | (14) | 1 |
| Net increase (decrease) in cash and cash equivalents | 101,161 | 37,672 | (2,235) |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

| | | | |
|--|-----------|-----------|-----------|
| Cash and cash equivalents at beginning of year | 179,338 | 141,666 | 143,901 |
| Cash and cash equivalents at end of year | \$280,499 | \$179,338 | \$141,666 |
| Supplemental disclosure of cash flow information: | | | |
| Cash paid during the year for interest | \$3,761 | \$2,055 | \$2,137 |
| Cash paid during the year for income taxes | \$4,711 | \$6,331 | \$6,537 |
| Supplemental information on non-cash investing and financing activities: | | | |
| Purchases of property, plant and equipment unpaid at year end | \$5,394 | \$2,755 | \$5,612 |

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

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

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 Capital | Treasury Stock | | Accumulated Other Comprehensive Loss | Noncontrolling Interest in Subsidiary | Retained Earnings | Total Stockholders' Equity |
|---|-----------------------------------|--------|----------------------------------|----------------|-----------|---|--|----------------------|----------------------------------|
| | Shares | Amount | Capital | Shares | Amount | Loss | Earnings | Equity | |
| Balance at December 31, 2011 | 36,002,698 | \$ 36 | \$220,654 | - | \$- | \$ (3,313) | \$ 2,481 | \$196,869 | \$416,727 |
| Employee equity award plans activity | 269,852 | - | 10,310 | - | - | - | - | - | 10,310 |
| Non-cash development expenses from joint venture | - | - | - | - | - | - | 3,670 | - | 3,670 |
| Net loss attributable to noncontrolling interest | - | - | - | - | - | - | (5,381) | - | (5,381) |
| Treasury stock | - | - | - | (403,158) | (5,906) | - | - | - | (5,906) |
| Net income | - | - | - | - | - | - | - | 23,524 | 23,524 |
| Foreign currency translation, net of tax | - | - | - | - | - | (816) | - | - | (816) |
| Balance at December 31, 2012 | 36,272,550 | \$ 36 | \$230,964 | (403,158) | \$(5,906) | \$ (4,129) | \$ 770 | \$220,393 | \$442,128 |
| 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 |
| | - | - | - | - | - | 664 | - | - | 664 |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

Foreign
currency
translation, net
of tax

Balance at
December 31,
2013

37,036,996 \$ 37 \$ 247,637 (412,953) \$(6,119) \$(3,465) \$(453) \$ 251,528 \$ 489,165

Employee
equity award
plans activity

1,092,876 1 26,585 - - - - - 26,586

Non-cash
development
expenses from
joint venture

- - - - - - 453 - 453

Treasury stock

- - - (7,236) (201) - - (201)

Net income

- - - - - - - 36,741 36,741

Foreign
currency
translation, net
of tax

- - - - - 457 - - 457

Balance at
December 31,
2014

38,129,872 \$ 38 \$ 274,222 (420,189) \$(6,320) \$(3,008) \$ - \$ 288,269 \$ 553,201

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 markets and develops 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. In February 2014, the Company acquired all the shares of Cangene Corporation ("Cangene") for cash.

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.

Significant customers and accounts receivable

For the years ended December 31, 2014, 2013 and 2012, the Company's primary customer was the U.S. Department of Health and Human Services ("HHS"). For the years ended December 31, 2014, 2013 and 2012, revenues from HHS and HHS agencies comprised 74.3%, 95.5% and 97.9%, respectively, of total revenues and are included in the Company's Biodefense segment. As of December 31, 2014 and 2013, the Company's receivable balances were comprised of 40.4% and 96.2%, respectively, from this customer. The overall decrease in the percentage of receivables attributed to HHS was due to the additional non-U.S. government revenue generating products from the Company's acquisition of Cangene in February 2014. Unbilled accounts receivable, included in accounts receivable, as of December 31, 2014 and 2013 were \$18.9 million and \$14.8 million, respectively, relates to various service contracts for which work has been performed, though invoicing has not yet occurred. 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, 2014 and 2013, 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 accounts receivable. The Company places its cash and cash equivalents with high quality financial institutions. Management believes that the financial risks associated with its cash and cash equivalents 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 (including fixed production-overhead costs) 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. Costs of purchased inventories are recorded using weighted-average costing. The Company determines normal capacity for each production facility and allocates fixed production-overhead costs on that basis.

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
collectibility is reasonably assured.

All revenues from product sales are recorded net of applicable allowances for sales rebates, special promotional programs, and discounts. The Company estimates allowances for revenue reducing obligations using a combination of information received from third parties including market data, inventory reports from major wholesalers, historical information and analysis. These estimates are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information may itself rely on estimates and reflect other limitations. Provisions for estimated rebates and other allowances, such as discounts and promotional and other credits, are estimated based on historical payment experience, historical relationship to revenues, estimated customer inventory levels and contract terms, and actual discounts offered.

The Company markets and sells its Biosciences products through commercial wholesalers (direct customers) who purchase the products at a price referred to as the wholesale acquisition cost ("WAC"). Additionally, the Company enters into agreements with indirect customers for a contracted price that is less than the WAC. The indirect customers, such as group-purchasing organizations, physician practice-management groups and hospitals, purchase the Company's products from the wholesalers. Under these agreements with wholesalers, the Company guarantees to credit the wholeseller for the difference between the WAC and the indirect customers' contracted price. This credit is referred to as a chargeback. Adjustments to the Company's chargeback provisions are made periodically to reflect new facts and circumstances that may indicate that historical experience may not be indicative of current and/or future results. The Company makes subjective judgments primarily based on its evaluation of current market conditions and trade inventory levels related to the Company's products. This evaluation may result in an increase or decrease in the experience rate that is applied to current and future sales, or as an adjustment to past sales, or both.

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 RSDL sales under its indefinite delivery, indefinite quantity contract with the U.S. government and recognizes revenue upon delivery.

Collaborative research and development agreements can provide for one or more of upfront license fees, research payments, and milestone payments. 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 relative selling price and is recognized when the appropriate revenue recognition criteria are met. The Company deems services to be 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 recognizes 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, 2014, the costs incurred under the contracts and grants approximated the revenue earned.

Revenue associated with non-refundable upfront license fees that can be treated as a single unit of accounting are recognized when all ongoing obligations have been delivered. 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 are 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 obligations 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 recognizes such milestone as revenue on a straight-line basis over the remaining expected term of continued involvement in the research and development process or based on the proportional performance of the Company's expected future obligations under the contract.

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.

Mergers and Acquisitions

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the merger or acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are recognized at fair value if fair value can reasonably be estimated. If the acquisition date fair value of an asset acquired or liability assumed that arises from a contingency cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. 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. Accordingly, the Company may be required to value assets at fair value measures that do not reflect our intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in our consolidated financial statements after the date of the merger or acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded. The fair values of intangible assets, including acquired in-process research and development, or IPR&D, are determined utilizing information available near the merger or acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, the Company typically obtains assistance from third-party valuation specialists for significant items. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets. Upon successful completion of each project, the Company will make a separate determination as to the then useful life of the asset and begin amortization. The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect the Company's results of operations.

The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an "income approach" through which fair value is estimated based on each asset's discounted projected net cash flows. Our estimates of market participant net cash flows consider historical and projected pricing, margins and expense levels; the performance of competing products where applicable; relevant industry and therapeutic area growth drivers and factors; current and expected trends in technology and product life cycles; the time and investment that will be required to develop products and technologies; the ability to obtain marketing and regulatory approvals; the ability to manufacture and commercialize the products; the extent and timing of potential new product introductions by the Company's competitors; and the life of each asset's underlying patent, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to IPR&D are determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate. Indefinite-lived intangible assets are tested for impairment annually or whenever events or changes in circumstances indicate that its carrying amount may not be recoverable.

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 recognized. 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 also evaluates goodwill for certain reporting units 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 quantitative analysis of a reporting unit's fair value.

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.

Contingent purchase consideration obligations

The Company records contingent purchase obligations at fair value. Obligations are based on sales royalties, primarily for RSDL. 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.

Impairment of in process research and development and long-lived assets

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.

The Company assesses the recoverability of its long-lived assets or asset groups 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 of the assets or asset groups.

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

Except for the Company's Canadian subsidiaries, 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. The Company's Canadian subsidiaries local currency is U.S. dollars due to substantially all the transactions of the subsidiaries being denominated in U.S. dollars.

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, 2014, 2013 and 2012, the Company incurred interest of \$7.5 million, \$2.0 million and \$2.2 million, respectively. Of these amounts, the Company capitalized \$2.5 million, \$2.0 million and \$2.2 million, respectively.

Certain risks and uncertainties

The Company has derived a majority of 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

The Company calculates basic earnings per share by dividing net income by the weighted average number of shares of common stock outstanding during the period.

During the year ended December 31, 2014, the Company issued 2.875% Convertible Senior Notes due 2021 (the "Notes"). Due to the issuance, the Company calculates diluted earnings per share using the if-converted method by dividing the adjusted net income by the weighted average number of shares of common stock outstanding during the period. The adjusted net income is adjusted for interest expense and amortization of debt issuance cost, both net of tax, associated with the Notes. The weighted average number of shares-diluted is adjusted for the potential dilutive effect of the exercise of stock options and the vesting of restricted stock units along with the assumption of the conversion of the Notes, at the beginning of the period.

For the years ended December 31, 2013 and 2012, diluted earnings per share is computed using the treasury method by dividing net income by the weighted average number of shares of common stock outstanding during the period, adjusted for the potential dilutive effect of other securities if such securities were converted or exercised.

Accounting for stock-based compensation

The Company has two stock-based employee compensation plans, the Third 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 22, 2014, the Company's shareholders approved an amendment to the 2006 Plan, which increased the number of shares of common stock available for issuance under plan awards by 4,000,000. As part of this amendment, awards of restricted stock units granted after May 22, 2014 are counted against the maximum aggregate number of shares of common stock available for issuance under the 2006 Plan as 2.3 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 1,000,000.

As of December 31, 2014, an aggregate of 15,178,826 shares of common stock were authorized for issuance under the 2006 Plan, of which a total of 4,461,925 shares of common stock remain available for future awards to be made to plan participants. 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.

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 authorized for issuance under 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.

The Company determines the fair value of restricted stock units and stock options 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. 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, | | |
|----------------------------------|-------------------------|------------|------------|
| | 2014 | 2013 | 2012 |
| Expected dividend yield | 0% | 0% | 0% |
| Expected volatility | 35-38% | 39-49% | 41-52% |
| Risk-free interest rate | 1.14-1.65% | 0.32-0.70% | 0.36-0.54% |
| Expected average life of options | 4.5 years | 4.4 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. Acquisitions

Cangene Corporation

On February 21, 2014, the Company acquired 100% of the voting interest of Cangene for \$3.24 per share in cash (on a fully-diluted basis), which represents a total purchase price of \$221.5 million. This transaction was accounted for by the Company under the acquisition method of accounting, with the Company as the acquirer. Under the acquisition method of accounting, the assets and liabilities of Cangene were recorded as of the acquisition date, at their respective fair values, and combined with those of the Company. This acquisition diversified the product portfolio of the Company's Biodefense and Biosciences divisions and expanded the Company's manufacturing capabilities.

The table below summarizes the allocation of the purchase price based upon estimated fair values of assets acquired and liabilities assumed at February 21, 2014.

(in thousands)

Fair value of tangible assets acquired and liabilities assumed:

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

| | |
|--|-----------|
| Cash | \$43,631 |
| Accounts receivable | 19,652 |
| Inventory (i) | 55,259 |
| Prepaid expenses and other assets | 2,375 |
| Property, plant and equipment | 40,264 |
| Deferred taxes, net | 21,337 |
| Income tax receivable | 2,452 |
| Accounts payable and accrued liabilities | (22,918) |
| Provision for chargebacks | (1,946) |
| Contingent purchase consideration | (1,284) |
| Deferred revenue | (6,378) |
| Total fair value of tangible assets acquired and liabilities assumed | 152,444 |
| Acquired in-process research and development | 8,300 |
| Acquired intangible assets | 36,200 |
| Goodwill | 24,566 |
| Total purchase price | \$221,510 |

(i) Acquired inventory reflects a \$8.8 million adjustment to record inventory at fair value, referred to as a step-up adjustment. The \$8.8 million step-up is estimated to be amortized through cost of product sales and contract manufacturing over the next five years based on expected inventory turnover, which will increase cost of product sales and contract manufacturing 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 | \$2,800 | 5.0 |
| Marketed Products | 8,100 | 10.0 |
| Licensed Products | 3,100 | 7.0 |
| Biodefense Products | 16,700 | 12.0 |
| Contract Manufacturing | 5,500 | 8.0 |
| Total identified intangible assets | \$36,200 | |

The Company determined the estimated fair value of the intangible 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.

A portion of the assets acquired from Cangene consisted of intangible assets. The Marketed Products intangible asset consists of WinRho[®] SDF [Rh₀(D) Immune Globulin Intravenous (Human)] and VARIZIG[®] (Varicella Zoster Immune Globulin (Human)). The Licensed Products intangible asset primarily consists of HepaGam B[®] (Hepatitis B Immune Globulin Intravenous (Human)). The Biodefense intangible asset consist of BAT[™] [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G)-Equine], Anthrasil (Anthrax Immune Globulin Intravenous (Human)) and VIGIV (Vaccinia Immune Globulin Intravenous (Human)). The Contract Manufacturing intangible asset is primarily related

to contract manufacturing contracts with current and expected future third-party customers.

The Company estimated the fair value of the Marketed, Licensed and Biodefense Product intangible assets using the income approach with a present value discount rate of 15%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of Cangene. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value these intangible assets. The projected cash flows from these Marketed, Licensed and Biodefense Product intangible assets were based on key assumptions including: estimates of revenues and operating profits; the life of the potential commercialized product and associated risks; and risks related to the viability of and potential alternative treatments in any future target markets.

The Company estimated the fair value of the Contract Manufacturing intangible asset using the income approach with a present value discount rate of 15%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of Cangene. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value this intangible asset. The projected cash flows from the Contract Manufacturing intangible asset were based on key assumptions including: estimates of revenues and operating profits; and viability of attaining/maintaining future third-party manufacturing relationships with the Company's customers.

The Company estimated the fair value of the Corporate Trade Name intangible asset using the relief of royalty method with a present value discount rate of 15%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of Cangene. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value this intangible asset.

The weighted average amortization period of the intangible assets from the Cangene acquisition is 110 months. For the year ended December 31, 2014, the Company recorded amortization expense of \$3.3 million for intangible assets acquired from Cangene, of which \$478,000 and \$2.8 million, respectively, has been recorded in selling, general and administrative and cost of product sales and contract manufacturing. Amortization expense of \$2.1 million and \$1.2 million, respectively, was recorded within the Biosciences and Biodefense segments for the year ended December 31, 2014.

The intangible asset associated with IPR&D acquired from Cangene is the IXINITY product candidate. Management determined that the estimated acquisition-date fair value of intangible assets related to IPR&D was \$8.3 million. The estimated fair value was determined using the income approach, which discounts expected future cash flows to present value. The Company estimated the fair value using a present value discount rate of 16%, which is based on the estimated weighted-average cost of capital for companies with that profiles substantially similar to that of Cangene and IPR&D assets at a similar stage of development as IXINITY. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value the IPR&D. The projected cash flows for IXINITY was based on key assumptions including: estimates of revenues and operating profits, considering its stage of development on the acquisition date; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate, such as obtaining marketing approval from the U.S. Food and Drug Administration ("FDA") and other regulatory agencies; and risks related to the viability of and potential for alternative treatments in any future target markets. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts (see Note 9).

The Company recorded approximately \$24.6 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.

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

The Company has incurred transaction costs related to the Cangene acquisition of approximately \$3.7 million and \$3.3 million for the years ended December 31, 2014 and 2013, respectively, which has been recorded in selling, general and administrative expenses within the Company's Biosciences segment.

The following pro forma information is presented as if the acquisition had occurred on January 1, 2013, and combines the historical results of operations of the Company and Cangene for the year ended December 31, 2014 and 2013.

| (in thousands) | December 31, | |
|----------------------|--------------|-----------|
| | 2014 | 2013 |
| Pro forma revenue | \$462,446 | \$428,194 |
| Pro forma net income | \$34,624 | \$10,994 |

EV-035 Molecules

On December 17, 2014, the Company acquired the EV-035 series of molecules from Evolva Holding SA ("Evolva") for approximately \$1.5 million in cash along with contingent purchase consideration obligations to Evolva. EV-035 is a series of novel small molecule broad spectrum antibiotics of the 4-oxoquinolizine class and targets bacterial type IIa topoisomerase. The lead molecule in the series, GC-072, has demonstrated protection in vivo from lethal *B. pseudomallei* infection when administered orally. GC-072 is being developed as a potential oral and IV treatment for *B. pseudomallei* under a three-year, \$15 million contract with the Defense Threat Reduction Agency ("DTRA") of the U.S. Department of Defense. *B. pseudomallei* is a gram-negative pathogen classified by the CDC as a Category B bioterrorism agent and a priority threat capable of being easily weaponized and disseminated. The acquisition diversifies the Biodefense segment by adding a clinical stage product that is currently being funded through preclinical development and has been accounted for a business acquisition.

The contingent values rights are based on the novation of the DTRA contract (\$4.0 million) along with the achievement of certain development (\$15.0 million) and regulatory filing (\$50.0 million) milestones. In addition, the Company is required to make sales-based royalty payments of between 5 %-10 % based on levels of annual net sales.

The total preliminary purchase price is summarized below:

| (in thousands) | |
|---|----------|
| Amount of cash paid to Evolva Holdings SA | \$1,500 |
| Fair value of contingent consideration | 28,200 |
| Total purchase price | \$29,700 |

The table below summarizes the preliminary allocation of the purchase price based upon fair values of assets acquired. As of the date of this filing, the valuation of acquired intangible assets and other fair value adjustments are not complete as the Company is obtaining and analyzing additional information related to the aforementioned items. As such, the purchase price allocation is subject to change.

| (in thousands) | |
|----------------------------|----------|
| Acquired intangible assets | \$27,700 |
| Goodwill | 2,000 |
| Total purchase price | \$29,700 |

The assets acquired from Evolva consisted of the EV-035 molecules IPR&D asset. Management determined that the estimated acquisition-date fair value of intangible assets related to IPR&D was \$27.7 million. The estimated fair value was determined using the income approach, which discounts expected future cash flows to present value. The Company estimated the fair value using a present value discount rate of 12%. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value the

IPR&D. The projected cash flows for EV-035 was based on key assumptions including: estimates of revenues and operating profits, considering its stage of development on the acquisition date; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate, such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential for alternative treatments in any future target markets. IPR&D assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. From the acquisition date through the year ended December 31, 2014, there were no indicators present that would require the Company to complete an interim impairment assessment.

Healthcare Protective Products Division

In August 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. In addition, the Company assumed a \$1.5 million liability associated with the Canadian Technology Development Fund ("TDF").

The contingent purchase consideration obligation is based on a percentage of RSDL net sales, ranging from 5 %-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 contingent 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 | 9,916 |
| Acquired equipment | 1,543 |
| Other | 11 |
| Assumed liabilities | (1,464) |
| Total purchase price | \$42,105 |

During the year ended December 31, 2014, the Company updated its purchase price to include an assumed liability from the TDF resulting in additional goodwill of \$1.5 million.

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, 2014 and 2013, respectively, the Company recorded \$4.7 million and \$2.0 million in amortization for intangible assets, which have been recorded in cost of product sales and contract manufacturing within the Company's Biodefense segment. The weighted average amortization period for the intangible assets is 72 months.

The Company recorded approximately \$9.9 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.

The Company has determined the historical results of the EV-035 Series and 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:

| (in thousands) | At December 31, 2014 | | | Total |
|--------------------------------------|----------------------|---------|-----------|------------|
| | Level 1 | Level 2 | Level 3 | |
| Assets: | | | | |
| Investment in money market funds (1) | \$ 111,912 | \$ - | \$ - | \$ 111,912 |
| Total assets | \$ 111,912 | \$ - | \$ - | \$ 111,912 |
| Liabilities: | | | | |
| Contingent consideration | \$ - | \$ - | \$ 47,657 | \$ 47,657 |
| Total liabilities | \$ - | \$ - | \$ 47,657 | \$ 47,657 |
| | | | | |
| (in thousands) | At December 31, 2013 | | | Total |
| | Level 1 | Level 2 | Level 3 | |
| Assets: | | | | |
| Investment in money market funds (1) | \$ 37,701 | \$ - | \$ - | \$ 37,701 |
| Total assets | \$ 37,701 | \$ - | \$ - | \$ 37,701 |
| Liabilities: | | | | |
| Contingent price consideration | \$ - | \$ - | \$ 16,619 | \$ 16,619 |
| Total liabilities | \$ - | \$ - | \$ 16,619 | \$ 16,619 |

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

As of December 31, 2014 and 2013, 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 future net sales for RSDL and HepaGam B, which are inputs that have no observable market (Level 3). For the years ended December 31, 2014 and 2013, the contingent purchase consideration obligation increased by \$3.1 million and \$735,000, respectively, primarily due to an adjustment to the actual and expected timing of RSDL and HepaGam B sales. This

increase resulted in a charge that is classified in the Company's statement of operations as cost of product sales and contract manufacturing. In addition, contingent value rights increased for the year ended December 31, 2014 due to the acquisition of EV-035 series (see Note 3).

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, 2014 and 2013.

(in thousands)

| | |
|---------------------------------------|----------|
| 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 |
| Expense (income) included in earnings | 3,133 |
| Settlements | (1,579) |
| Purchases, sales and issuances | 29,484 |
| Transfers in/(out) of Level 3 | - |
| Balance at December 31, 2014 | \$47,657 |

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis, as documented above, from those measured at fair value on a nonrecurring basis. During the year ended December 31, 2014, the assets acquired and liabilities assumed as part of the Cangene and EV-035 molecules acquisitions (Note 3) and the evaluation of the IXINITY IPR&D asset for impairment (Note 9) were 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.

5. MorphoSys collaboration agreement

In August 2014, the Company entered into a collaboration agreement ("MorphoSys Agreement") with MorphoSys AG ("MorphoSys") for the joint worldwide development and commercialization of MOR209/ES414, a targeted immunotherapeutic protein, constructed using the Company's proprietary ADAPTIR technology platform, which activates host T-cell immunity specifically against cells expressing prostate specific membrane antigen, an antigen commonly overexpressed on prostate cancer cells.

In accordance with the terms of the MorphoSys Agreement, the Company received a nonrefundable \$20 million upfront payment and may receive up to \$163 million in additional contingent payments, of which \$80.0 million and \$83.0 million, respectively, are due upon the achievement of specified development and regulatory milestones. The Company has determined that payments for the achievement of the development and regulatory milestones are substantive milestones and will be accounted for as revenue in the period in which the milestone is achieved.

MorphoSys and the Company will jointly fund further development of MOR209/ES414, with the Company responsible for 36% of the total development cost and MorphoSys responsible for the remainder. The Company's funding requirement is capped at \$186 million. The Company will retain commercialization rights in the U.S. and Canada, with a tiered royalty obligation to MorphoSys, ranging from mid-single digits up to 20%. MorphoSys will gain worldwide commercialization rights excluding the United States and Canada, with a low single digit royalty obligation to the Company. The Company's current obligations under the collaboration includes the performance of non-clinical, clinical, manufacturing and regulatory activities.

The Company has evaluated the MorphoSys Agreement and determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company determined there were two units of accounting under the collaboration agreement with MorphoSys: (1) the delivered license to further develop and commercialize MOR209/ES414 and (2) undelivered items related to development services. The Company determined that the license had standalone value as the drug candidate has been (1) developed and is currently Phase 1 clinical trial ready, (2) MorphoSys possesses the knowledge, technology, skills, experience and infrastructure necessary to complete all further development of the drug through commercialization, and (3) MorphoSys has the right to further sublicense the product. The Company allocated the \$20.0 million upfront payment to the two units of accounting using the relative selling price method. The Company determined the estimated selling price for the license using the income approach and a discount rate of 12%. The estimated selling price includes unobservable inputs (Level 3), such as estimates of revenues and operating margins; the time and resources needed to complete the development and approval of the product candidate; and the risk related to the viability of and potential for alternative treatments. The Company determined the estimated selling price of the development services unit of accounting based on the estimated number of full-time equivalent personnel at the contractual rate as defined in the MorphoSys Agreement, which represents the approximate terms of other service related contracts both entered by the Company and observed generally through other collaboration negotiations. The allocation resulted in \$15.3 million of the upfront payment being allocated to the license and \$4.7 million being allocated to the development services. The Company determined the license fee unit of accounting was delivered on the date the MorphoSys agreement was executed and therefore has recognized revenue of \$15.3 million, which is included in contracts, grants and collaborations revenues within the Company's Biosciences segment. Revenue related to the undelivered item will be recognized as the services are performed. The current estimated service period for the undelivered item under the MorphoSys Agreement is through 2022.

The amount allocable to the units of accounting is limited to the amount that is not contingent upon the delivery of additional items or meeting other specified performance conditions (the noncontingent amount). As such, the Company excluded from the allocable arrangement consideration the milestone payments and royalties regardless of the probability of receipt.

The collaboration provides for sharing of development and clinical costs, with the Company responsible for 36% of such costs and MorphoSys responsible for the remainder. In the event the Company's share of the total cost for a given quarter exceeds 36% of the total costs for the project, the Company records a net receivable in its financial statements equal to the difference between the Company's costs and 36% of the total costs for the period, and reduces research and development expense in this amount. For the year ended December 31, 2014, the Company has recorded a reduction to research and development expense of \$1.5 million. As of December 31, 2014, accounts receivable from MorphoSys was \$972,000.

As of December 31, 2014, deferred revenue related to the MorphoSys Agreement consisted of \$890,000 and \$3.5 million of current and long-term deferred revenue, respectively.

6. Accounts receivable

Accounts receivable consist of the following:

| | December 31, | |
|----------------|--------------|----------|
| (in thousands) | 2014 | 2013 |
| Billed | \$39,948 | \$45,757 |
| Unbilled | 18,886 | 14,830 |
| Total | \$58,834 | \$60,587 |

7. Inventories

Inventories consist of the following:

| (in thousands) | December 31, | |
|----------------------------|--------------|----------|
| | 2014 | 2013 |
| Raw materials and supplies | \$17,375 | \$2,656 |
| Work-in-process | 33,477 | 9,819 |
| Finished goods | 14,822 | 2,168 |
| Total inventories | \$65,674 | \$14,643 |

8. Property, plant and equipment

Property, plant and equipment consist of the following:

| (in thousands) | December 31, | |
|---|--------------|-----------|
| | 2014 | 2013 |
| Land and improvements | \$12,838 | \$10,605 |
| Buildings, building improvements and leasehold improvements | 107,202 | 83,823 |
| Furniture and equipment | 130,131 | 107,006 |
| Software | 25,354 | 21,832 |
| Construction-in-progress | 117,884 | 98,345 |
| | 393,409 | 321,611 |
| Less: Accumulated depreciation and amortization | (79,430) | (57,371) |
| Total property, plant and equipment, net | \$313,979 | \$264,240 |

For the years ended December 31, 2014 and 2013, 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 amortization expense was \$23.0 million, \$17.0 million and \$11.2 million for the years ended December 31, 2014, 2013 and 2012, respectively. The increase in depreciation expense as compared to December 31, 2013 was primarily due to the Company's Baltimore facility being placed-in-service in December 2013. As of December 31, 2014, 2013 and 2012 there was no unamortized internal use software-cost.

For the year ended December 31, 2014, the Company had \$2.4 million of capitalized software development costs.

9. Intangible assets, 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, 2014 and 2013, respectively, and determined that the fair value of the Company's IPR&D assets and reporting units was significantly in excess of carrying value. The Company performed a quantitative assessment of goodwill associated with the Bioscience Therapeutics and Contract Manufacturing reporting units, components of the Biosciences segment along with the Biodefense medical device reporting unit, a component of the Biodefense segment. The Company performed a qualitative assessment of goodwill associated with the Biodefense Therapeutics and Vaccines reporting unit, a component of the Biodefense segment.

On July 29, 2014, the FDA issued a complete response letter for the New Drug Application ("NDA") of IXINITY. The complete response letter requested additional analyses of data from completed studies and noted deficiencies in the chemistry, manufacturing, and controls section of the license application, all of which must be resolved before approval can be granted by the FDA. The Company determined that the FDA's response to its NDA is a potential indicator of impairment of the related IXINITY IPR&D asset. The Company performed its interim impairment analysis and concluded its estimated fair value for the IXINITY IPR&D asset was in excess of carrying value, therefore the Company determined there was no impairment of the IXINITY IPR&D asset as of December 31, 2014. The determination of fair value involved unobservable inputs, such as estimates of future revenues and operating profits, probabilities of success and discount rates. The Company believes these inputs represent the highest and best use of the IXINITY IPR&D asset.

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.

Intangible assets consist of the following:

| (in thousands) | RSDL | Manufacturing Agreement | Corporate Tradename | Marketed Products | Licensed Products | Biodefense Products | Contract Manufacturing | Total |
|-------------------------------------|-----------|-------------------------|---------------------|-------------------|-------------------|---------------------|------------------------|---------|
| Cost basis | | | | | | | | |
| Balance at December 31, 2013 | \$28,621 | \$ 3,478 | \$ - | \$ - | \$ - | \$ - | \$ - | 32,099 |
| Additions | - | - | 2,800 | 8,100 | 3,100 | 16,700 | 5,500 | 36,200 |
| Balance at December 31, 2014 | \$28,621 | \$ 3,478 | \$ 2,800 | \$ 8,100 | \$ 3,100 | 16,700 | \$ 5,500 | 68,299 |
| Accumulated amortization | | | | | | | | |
| Balance at December 31, 2013 | \$(1,468) | \$(483) | \$ - | \$ - | \$ - | \$ - | \$ - | (1,951) |
| Amortization | (3,519) | (1,159) | (478) | (692) | (378) | (1,191) | (587) | (8,004) |
| Balance at December 31, 2014 | \$(4,987) | \$(1,642) | \$(478) | \$(692) | \$(378) | \$(1,191) | \$(587) | (9,955) |
| Net book value at December 31, 2014 | \$23,634 | \$ 1,836 | \$ 2,322 | \$ 7,408 | \$ 2,722 | \$ 15,509 | 4,913 | 58,344 |

Future amortization expense as of December 31, 2014 is as follows:

| (in thousands) | |
|----------------|---------|
| 2015 | \$8,629 |
| 2016 | 8,146 |
| 2017 | 7,470 |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

| | |
|------------------------------|----------|
| 2018 | 7,470 |
| 2019 and beyond | 26,629 |
| Total remaining amortization | \$58,344 |

The following table is a summary of changes in goodwill by reporting unit:

| (in thousands) | Biosciences therapeutics | Biosciences contracts manufacturing | Biodefense therapeutics | Biodefense medical device(s) | Total |
|------------------------------|-----------------------------|---|----------------------------|------------------------------------|--------|
| Cost Basis | | | | | |
| Balance at December 31, 2013 | \$ 5,502 | - | - | 8,452 | 13,954 |
| Additions | 8,400 | 6,736 | 11,430 | 1,464 | 28,030 |
| Balance at December 31, 2014 | \$ 13,902 | 6,736 | 11,430 | 9,916 | 41,984 |

10. Long-term debt

On January 29, 2014, the Company issued \$250.0 million aggregate principal amount of 2.875% Convertible Senior Notes due 2021 (the "Notes"). The Notes bear interest at a rate of 2.875% per year, payable semi-annually in arrears on January 15 and July 15 of each year. The Notes mature on January 15, 2021, unless earlier purchased by the Company or converted. The conversion rate is equal to 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 is subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest. The Company incurred approximately \$8.3 million in debt issuance costs associated with the Notes, which has been capitalized on the consolidated balance sheets and is being amortized over seven years, using the effective interest method.

On December 11, 2013, the Company entered into a senior secured credit agreement (the "Credit Agreement") with three lending financial institutions (the "Lenders"), led by Bank of America, N.A., as administrative agent. The Credit Agreement originally provided 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 Credit Agreement, the Company borrowed \$62.0 million under the revolving credit facility primarily to repay obligations under existing loan agreements. On January 29, 2014, in connection with the Company's issuance of the Notes, the unused \$125.0 million term loan portion of the Credit Agreement terminated automatically in accordance with the terms of the Credit Agreement. In addition, following the closing of the Notes offering, the Company repaid the \$62.0 million outstanding indebtedness under the revolving credit facility, which restored the full \$100.0 million revolving credit capacity under this facility. Under the revolving credit facility, the Company is required to pay an unused fee of approximately 0.6% per quarter. In addition, during the year ended December 31, 2014, the Company expensed \$1.8 million of debt issuance cost associated with the term loan facility. As of December 31, 2014, no amounts were drawn under the revolving credit facility.

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.

The Credit Agreement, as amended, contains affirmative and negative covenants customary for financings of this type. Negative covenants in the Credit Agreement limit the Company's ability to, among other things: incur indebtedness (other than the issuance of the Notes) 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 that include the maintenance of: (1) a minimum consolidated debt service coverage ratio of 2.50 to 1.00, (2) a maximum consolidated leverage ratio for the period ending on or prior to September 30, 2014 of 4.00 to 1.00, for the measurement period ending December 31, 2014 of 3.75 to 1.00, and thereafter of 3.50 to 1.00, (3) a maximum consolidated senior leverage ratio of 2.00 to 1.00 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 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, 2014.

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 was terminated on December 31, 2013.

Stock options and restricted stock units

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

| | 2006 Plan | | 2004 Plan | | Aggregate |
|----------------------------------|-----------|------------------|-----------|------------------|--------------|
| | Number of | Weighted-Average | Number | Weighted-Average | Intrinsic |
| | Shares | Exercise Price | Shares | Exercise Price | Value |
| Outstanding at December 31, 2013 | 3,633,146 | \$ 17.01 | 53,156 | \$ 8.86 | \$23,148,738 |
| Granted | 1,125,321 | 27.46 | - | - | |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

| | | | | | |
|---|------------|----------|----------|----------|--------------|
| Exercised | (784,811) | 16.72 | (10,000) | 2.74 | |
| Forfeited | (135,663) | 19.96 | - | - | |
| Outstanding at December 31, 2014 | 3,837,993 | \$ 20.04 | 43,156 | \$ 10.28 | \$29,181,534 |
| Exercisable at December 31, 2014 | 1,993,261 | \$ 17.81 | 43,156 | \$ 10.28 | \$19,499,871 |
| Options expected to vest at December 31, 2014 | 1,158,434 | \$ 21.41 | - | \$ - | \$7,193,136 |

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, 2013 | 789,951 | \$ 16.53 | \$18,246,611 |
| Granted | 562,662 | 27.46 | |
| Vested | (361,010) | 17.79 | |
| Forfeited | (64,247) | 19.84 | |
| Outstanding at December 31, 2014 | 927,356 | \$ 22.44 | \$25,251,904 |

The weighted average remaining contractual term of options outstanding as of December 31, 2014 and 2013 was 4.0 and 4.1 years, respectively. The weighted average remaining contractual term of options exercisable as of December 31, 2014 and 2013 was 3.2 and 3.4 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2014, 2013 and 2012 was \$8.84, \$5.38 and \$5.16 respectively. The total intrinsic value of options exercised during the years ended December 31, 2014, 2013 and 2012 was \$7.5 million, \$6.9 million and \$589,000, respectively. The total fair value of awards vested during 2014, 2013 and 2012 was \$12.3 million, \$9.1 million and \$10.3 million, respectively.

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

| (in thousands) | Years Ended December 31, | | |
|--|-----------------------------|----------|----------|
| | 2014 | 2013 | 2012 |
| Cost of product sales | \$1,145 | \$575 | \$513 |
| Research and development | 3,606 | 3,283 | 3,451 |
| General and administrative | 8,078 | 7,380 | 7,151 |
| Total stock-based compensation expense | \$12,829 | \$11,238 | \$11,115 |

12. Income taxes

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

| (in thousands) | Year ended December 31, | | |
|----------------|-------------------------|----------|----------|
| | 2014 | 2013 | 2012 |
| Current | | | |
| Federal | \$10,412 | \$(878) | \$11,481 |
| State | 479 | (173) | (1,045) |
| International | 112 | 300 | 103 |
| Total current | 11,003 | (751) | 10,539 |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

| | | | |
|----------------------------------|-----------|-----------|-----------|
| Deferred | | | |
| Federal | 7,693 | 12,679 | 3,758 |
| State | 128 | 1,028 | (375) |
| International | (2,503) | 152 | - |
| Total deferred | 5,318 | 13,859 | 3,383 |
| Total provision for income taxes | \$ 16,321 | \$ 13,108 | \$ 13,922 |

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

| (in thousands) | December 31, | |
|--|--------------|-------------|
| | 2014 | 2013 |
| Net operating loss carryforward | \$20,530 | \$23,256 |
| Research and development carryforward | 8,049 | 7,395 |
| Scientific research and experimental development credit carryforward | 29,556 | - |
| Intangible assets | 5,689 | 3,300 |
| Stock compensation | 8,196 | 6,378 |
| Foreign deferrals | 75,511 | 64,090 |
| Inventory reserves | 4,122 | - |
| Deferred revenue | 244 | - |
| Other | 7,219 | 1,222 |
| Deferred tax asset | 159,116 | 105,641 |
| Fixed assets | (34,839) | (32,588) |
| Intangible assets | (6,538) | - |
| Other | (10,891) | (5,714) |
| Deferred tax liability | (52,268) | (38,302) |
| Valuation allowance | (92,374) | (68,846) |
| Net deferred tax (liabilities)/ asset | \$ 14,474 | \$ (1,507) |

The Company currently has approximately \$24.2 million in net operating loss carryforwards along with \$8.1 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 \$224.6 million in state net operating loss carryforwards, primarily in Maryland, that will begin to expire in 2018. The Company has approximately \$274.4 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. The Company currently has approximately \$9.3 million of Canadian federal scientific research and experimental development credit carryforwards that will begin to expire in 2032. In addition, the Company has approximately \$22.9 million in Manitoba scientific research and experimental development credit carryforwards that will begin to expire in 2019. Due to the timing of the expiry of the Manitoba credits, the Company has recorded a valuation allowance with respect to the Manitoba credits in the amount of \$22.9 million, as it is uncertain whether sufficient future taxable income will be generated in Manitoba during the carryforward period. The foreign and state 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:

| (in thousands) | Year ended December 31, | | |
|----------------|-------------------------|----------|----------|
| | 2014 | 2013 | 2012 |
| US | \$59,764 | \$52,749 | \$52,391 |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

| | | | |
|-------------------------------------|----------|----------|-----------|
| International | (6,702) | (8,506) | (14,945) |
| Earnings before taxes on income | 53,062 | 44,243 | 37,446 |
| Federal tax at statutory rates | \$18,572 | \$15,485 | \$13,106 |
| State taxes, net of federal benefit | 257 | 538 | (2,079) |
| Impact of foreign operations | 186 | (1,116) | (3,604) |
| Change in valuation allowance | 1,808 | 1,434 | 4,629 |
| Effect of foreign rates | - | - | (22) |
| Tax credits | (7,137) | (5,918) | (2,904) |
| Other differences | 124 | (227) | 139 |
| Permanent differences | 2,511 | 2,912 | 4,657 |
| Provision for income taxes | \$16,321 | \$13,108 | \$13,922 |

The effective annual tax rate for the years ended December 31, 2014, 2013 and 2012 was 31%, 30% and 37%, 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 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 \$26,000 and \$15,000 for the payment of interest and penalties as of December 31, 2014 and 2013, respectively. Of the total unrecognized tax benefits recorded at December 31, 2014 and 2013, \$183,000 and \$132,000, respectively, is classified as a current liability and \$1.1 million and \$991,000, respectively, is classified as a non-current liability on the balance sheet. As of December 31, 2014, \$140,000 of unrecognized tax benefits will reverse within the next twelve months.

The table below presents the gross unrecognized tax benefits activity for 2014, 2013 and 2012:

(in thousands)

| | |
|--|---------|
| 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 |
| Increases for tax positions for prior years | 150 |
| Decreases for tax positions for prior years | - |
| Increases for tax positions for current year | 102 |
| Settlements | - |
| Lapse of statute of limitations | (125) |
| Gross unrecognized tax benefits at December 31, 2014 | \$1,248 |

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 2011 to 2013 remain open to examination. The Company's tax returns in the United Kingdom remain open to examination for the tax years 2007 to 2013, and tax

returns in Germany remain open indefinitely. The Company's tax returns for Canada remains open to examination for the tax years 2009 to 2013.

As of December 31, 2014, the Company's 2009 and 2011 federal income tax returns are in appeals with the Internal Revenue service. The Company believes appropriate provisions have been made for any outstanding issues. As of December 31, 2014, the Company's 2011 and 2012 federal income tax returns are under audit.

13. 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 2b clinical trial for the Company's tuberculosis vaccine product candidate. The Company completed this restructuring in 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:

| | Incurred during the year ended December 31, 2013 |
|----------------------------|---|
| (in thousands) | |
| 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:

| | Termination Benefits | Contract Termination Costs | Other Costs | Total |
|------------------------------|-------------------------|----------------------------------|----------------|---------|
| (in thousands) | | | | |
| 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 |
| Expenses incurred | - | - | - | - |
| Amount paid | (454) | - | - | (454) |
| Other adjustments | \$ - | \$ - | \$- | \$- |
| Balance at December 31, 2014 | - | - | - | - |

14. Assets held for sale

The Company currently owns a manufacturing and development facility in Winnipeg, Manitoba, Canada that it is actively seeking to sell. In October 2014, the Company determined that this facility, along with associated equipment,

would not be placed into service and committed to a plan to sell the facility. Therefore, this facility and related equipment are classified on the Company's balance sheet as an asset held for sale within the prepaid and other current assets line item. The Company recorded the assets held for sale at fair market value of \$2.4 million, based on factors that include recent purchase offers less estimated selling costs.

15. Purchase commitment

During the year ended December 31, 2014, the Company entered into a contract with Norwood Laboratories Inc. ("Norwood") to purchase \$15.2 million of raw materials related to the Company's RSDL product. For the year ended December 31, 2014, the Company has purchased \$1.5 million of materials under this commitment.

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 U.S. 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, 2014, 2013, and 2012, the Company made matching contributions of approximately \$2.4 million, \$2.0 million and \$1.9 million, respectively.

17. Leases

The Company leases laboratory and office facilities, office equipment and vehicles under various operating lease agreements. The Company leases office and laboratory space in Seattle, Washington under a operating lease that contains a 2% escalation clause, which expires in April 2020. For the years ended December 31, 2014, 2013, and 2012, total lease expense was \$4.6 million, \$3.9 million and \$3.6 million, respectively. For the year ended December 31, 2014 and 2013, the Company recorded lease income of \$3.1 million and \$446,000, respectively.

Future minimum lease payments under operating lease obligations as of December 31, 2014 were as follows:

(in thousands)

| | |
|------------------------------|----------|
| 2015 | \$2,558 |
| 2016 | 2,204 |
| 2017 | 1,950 |
| 2018 | 1,813 |
| 2019 | 1,697 |
| 2020 and beyond | 904 |
| Total minimum lease payments | 11,126 |
| Minimum lease receipts | (1,388) |

Total minimum lease payments \$9,738

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

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

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 2014, 2013 and 2012.

20. Earnings per share

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

| (in thousands, except share and per share data) | 2014 | 2013 | 2012 |
|---|------------|------------|------------|
| Numerator: | | | |
| Net income | \$36,741 | \$31,135 | \$23,524 |
| Interest expense applicable to convertible debt, net of tax | 2,879 | - | - |
| Amortization of debt issuance costs, net of tax | 735 | - | - |
| Adjusted net income | 40,355 | 31,135 | 23,524 |
| Denominator: | | | |
| Weighted-average number of shares—basic | 37,344,891 | 36,201,283 | 36,080,495 |
| Dilutive securities—equity awards | 737,391 | 546,273 | 340,167 |
| Dilutive securities—convertible debt | 7,720,525 | - | - |
| Weighted-average number of shares—diluted | 45,802,807 | 36,747,556 | 36,420,662 |
| Earnings per share-basic | \$0.98 | \$0.86 | \$0.65 |
| Earnings per share-diluted | \$0.88 | \$0.85 | \$0.65 |

For the years ending December 31, 2014, 2013 and 2012, outstanding stock options to purchase approximately 1.4 million, 1.5 million and 2.9 million shares of common stock, respectively, are not considered in the diluted earnings per share calculation because the exercise price of these options is greater than the average per share closing price during the year.

21. Segment information

For financial reporting purposes, the Company reports financial information for two business segments: Biodefense and Biosciences. The Company's two business segments, or divisions, engage in business activities for which discrete financial information is provided to and resources are allocated 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 manufacturing and development processes, along with having separate and distinct sales and marketing processes.

The Biodefense division is a specialty biopharmaceutical business focused on countermeasures that address Chemical, Biological, Radiological, Nuclear and Explosive threats and consists of two business units: vaccines and therapeutics, and medical devices. 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 hematology/oncology, transplantation and infectious diseases, and consists of three business units: therapeutics, vaccines and contract manufacturing. 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. For the years ended December 31, 2014, 2013 and 2012, respectively, the

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

Company had total assets of \$242.5 million, \$56.7 million and \$5.5 million located in foreign jurisdictions.

| (in thousands) | Reportable Segments | | | Total |
|--|---------------------|-------------|-----------|-----------|
| | Biodefense | Biosciences | All Other | |
| Year Ended December 31, 2014 | | | | |
| External revenue | \$370,547 | \$79,591 | \$- | \$450,138 |
| Intersegment revenue (expense) | - | - | - | - |
| Research and development | 81,975 | 60,821 | 8,033 | 150,829 |
| Interest income | 62 | - | 258 | 320 |
| Interest expense | - | - | (8,240) | (8,240) |
| Depreciation and amortization | 17,669 | 5,070 | 267 | 23,006 |
| Net income (loss) | 96,966 | (51,300) | (8,925) | 36,741 |
| Intangible assets | 40,979 | 17,365 | - | 58,344 |
| In-process research and development assets | 27,700 | 50,100 | - | 77,800 |
| Goodwill | 20,638 | 21,346 | - | 41,984 |
| Total assets | 439,797 | 344,420 | 161,045 | 945,262 |
| Expenditures for long-lived assets | 26,736 | 2,444 | 1,493 | 30,673 |
| 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 | 15,584 | 1,238 | 186 | 17,008 |
| 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 |

22. Quarterly financial data (unaudited)

Quarterly financial information for the years ended December 31, 2013 and 2014 is presented in the following tables:

Three months ended

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

| (in thousands) | March 31, | June 30, | September 30, | December 31, |
|--------------------------------------|--------------|-----------|------------------|-----------------|
| Fiscal year 2014 | | | | |
| Revenue | \$53,884 | \$110,325 | \$137,954 | \$147,975 |
| Income (loss) from operations | (25,458) | 7,862 | 31,032 | 44,620 |
| Net income (loss) | (20,236) | 5,029 | 21,832 | 30,116 |
| Net income (loss) per share, basic | (0.55) | 0.13 | 0.58 | 0.80 |
| Net income (loss) per share, diluted | (0.55) | 0.13 | 0.49 | 0.66 |
| 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 |

23. Subsequent events

Beginning on January 28, 2015, during standard quality inspections performed in accordance with customary procedures, the Company discovered foreign particles in a limited number of vials in two manufactured lots of BioThrax. In order to determine the source of the foreign particles, the Company has been investigating its operations as well as those of its suppliers and contract manufacturers. Under the Company's quality standards, these two BioThrax lots will be rejected. Currently, there is no evidence that any other BioThrax lots have been affected, but as a precautionary measure, the Company has quarantined 13 additional lots in inventory pending the findings of its investigation. It is the Company's goal to complete this investigation within the next 60 days. Consequently, no BioThrax deliveries will be made in the first quarter. Based upon current information and depending on the disposition of the quarantined lots, the impact on previously forecasted 2015 BioThrax revenues is anticipated to be between \$0 and \$65 million. Additionally, the cost of inventory for which there is a reasonable possibility of loss is estimated to be approximately \$2 million to \$15 million. Since the investigation is ongoing and the full scope of the issue has not been determined with certainty, the actual impact may be greater than anticipated.

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, 2014. 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, 2014, 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, 2014. 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 (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2014, our internal control over financial reporting was effective based on those criteria.

Management's assessment of and conclusion on the effectiveness of (1) disclosure controls and procedures and (2) internal controls over financial reporting did not include the internal controls related to the operations acquired in the acquisition of Cangene, which is included in our 2014 consolidated financial statements and constituted total and net assets of \$247.1 million and \$44.7 million, respectively as of December 31, 2014 and \$123.5 million and \$0.3 million, respectively, of revenues and net loss for the year then ended.

Ernst & Young LLP, the independent registered public accounting firm that has audited our consolidated financial statements included herein, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2014, a copy of which is included in this annual report on Form 10-K.

Changes in Internal Control Over Financial Reporting

We completed the Cangene acquisition on February 21, 2014. Our management considers this transaction to be material to our consolidated financial statements and believes that the internal controls and procedures of Cangene have a material effect on our internal control over financial reporting. We are currently in the process of incorporating the internal controls and procedures of Cangene into our internal controls over financial reporting and extending our compliance program under the Sarbanes-Oxley Act of 2002, or the Act, to include Cangene. We have elected to exclude Cangene from the scope of our 2014 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 Cangene 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 Stockholders of Emergent BioSolutions Inc. and subsidiaries

We have audited Emergent BioSolutions Inc. and subsidiaries' internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). Emergent BioSolutions Inc. and subsidiaries' management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the

accompanying Managements 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 Managements Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Cangene Corporation, which are included in the 2014 consolidated financial statements of Emergent BioSolutions, Inc. and subsidiaries and constituted \$246.3 million and \$44.3 million of total and net assets, respectively, as of December 31, 2014 and \$123.5 million and \$0.3 million of revenues and net loss, respectively, for the year then ended. Our audit of internal control over financial reporting of Emergent BioSolutions Inc. and subsidiaries also did not include an evaluation of the internal control over financial reporting of Cangene Corporation.

In our opinion, Emergent BioSolutions, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, 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. and subsidiaries as of December 31, 2014 and 2013, 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, 2014 of Emergent BioSolutions Inc. and subsidiaries and our report dated March 6, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia
March 6, 2015

ITEM 9B. OTHER INFORMATION

Not applicable.

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 2015 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 2015 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 MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by Item 12 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2015 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 2015 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 2015 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, 2014 and 2013

Consolidated Statements of Operations for the years ended December 31, 2014, 2013 and 2012

Consolidated Statements of Comprehensive Income for the years ended December 31, 2014, 2013 and 2012

Consolidated Statements of Cash Flows for the years ended December 31, 2014, 2013 and 2012

Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2014, 2013 and 2012

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 6, 2015

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, Chief Executive Officer and Director (Principal Executive Officer) | March 6, 2015 |
| /s/Robert G. Kramer Robert G. Kramer | Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer) | March 6, 2015 |
| /s/Fuad El-Hibri Fuad El-Hibri | Executive Chairman of the Board of Directors | March 4, 2015 |
| /s/Zsolt Harsanyi Zsolt Harsanyi, Ph.D. | Director | March 6, 2015 |
| /s/Dr. John Niederhuber Dr. John Niederhuber | Director | |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

| | | |
|---|----------|------------------|
| | | March 6, 2015 |
| /s/Ronald B. Richard Ronald B. Richard | Director | March 6, 2015 |
| /s/Louis W. Sullivan, M.D. Louis W. Sullivan, M.D. | Director | March 6, 2015 |
| /s/Marvin White Marvin White | Director | March 6, 2015 |
| /s/Dr. Sue Bailey Dr. Sue Bailey | Director | March 4, 2015 |
| /s/George Joulwan George Joulwan | Director | March 6, 2015 |
| /s/Jerome Hauer Jerome Hauer | Director | March 6, 2015 |

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

| Exhibit Number | Description |
|----------------|---|
| 2 | Arrangement Agreement dated as of December 11, 2013, among the Company, 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 the Company 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). |

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

- 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 the Company, 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 the Company, 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 10.2 to the Company's Annual Report on Form 10-K filed on March 10, 2014).
- 10.3 Second Amendment to Credit Agreement, dated as of March 21, 2014, among the Company, 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 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2014).
- 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 Third 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 7, 2014).
- 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).
- 10.14 * 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

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

- (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 (incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K filed on March 10, 2014).
- 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 (incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed on March 10, 2014).
- 10.27 † Modification No. 11 to the CDC BioThrax Procurement Contract, effective September 18, 2014, between Emergent Biodefense Operations Lansing LLC and the Centers for Disease Control and Prevention (incorporated by reference to Exhibit 10 to the Company's Quarterly Report on Form 10-Q/A filed on January 23, 2015).
- 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 #

Edgar Filing: Emergent BioSolutions Inc. - Form 10-K

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 Document
101.SCH XBRL Taxonomy Extension Schema Document
101.CAL XBRL Taxonomy Calculation Linkbase Document
101.DEF XBRL Taxonomy Definition Linkbase Document
101.LAB XBRL Taxonomy Label Linkbase Document
101.PRE XBRL Taxonomy Presentation Linkbase 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, 2014 and 2013, (ii) Consolidated Statements of Operations for the Years Ended December 31, 2014, 2013 and 2012, (iii) Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2014, 2013 and 2012 (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2014, 2013 and 2012, (v) Consolidated Statements of Changes in Stockholders' Equity for the Years ended December 31, 2014, 2013 and 2012, and (vi) Notes to Consolidated Financial Statements.