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 ý No

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

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

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

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

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

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

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

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

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 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

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K and the documents we incorporate by reference include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. We generally identify forward-looking statements by using words like "believes," "expects," "anticipates," "intends," "plans," "forecasts," "estimates" and similar expressions in conjunction with, among other things, discussions of financial performance or financial condition, growth strategy, product sales, manufacturing capabilities, 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;
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- 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*; 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.

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

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* 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

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

Product	Indication	Regulatory Approvals
BioThrax® (Anthrax Vaccine Adsorbed)	Pre-exposure prophylaxis of anthrax disease	United States Germany Singapore
BAT™ [(Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)]	Treatment of suspected or documented exposure to botulinum neurotoxin A, B, C, D, E, F or G	United States
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

Product	Indication(s)	Regulatory Approvals
WinRho® SDF [(Rh_o(D) Immune Globulin Intravenous (Human)]	ITP – immune thrombocytopenic purpura HDN – hemolytic disease of the newborn Preventing Rh_o(D) immunization in Rh_o(D)(-) women [1] Treating Rh_o(D)(-) patients after transfusions with incompatible Rh_o(D)(+) blood or erythrocyte products [2]	Canada – ITP, HDN United States – ITP, HDN Portugal – [1] and [2]
HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)]	Post-exposure prophylaxis for hepatitis B Prevention of hepatitis B recurrence following liver transplantation in patients who are positive for hepatitis B surface antigen	United States Canada Israel Kuwait Turkey
VARIZIG® [Varicella Zoster Immune Globulin (Human)]	Post-exposure prophylaxis for varicella (chickenpox) in high-risk patient groups, including immunocompromised children, newborns and pregnant women [1]	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 hemagluttin (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., Tetraphase 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 Rh_o(D)(+) red blood cells. As antibodies that are directed to the Rh_o(D) antigen on these red blood cells, WinRho SDF can generally be referred to as an anti-D product. WinRho SDF is approved in the 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;
Anthrasil 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:

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

The FDA also has the authority to require repair, replacement or refund of the cost of any medical device. The FDA also administers certain controls over the export of medical devices from the 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

			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.

	Year Ended December 31,				
(in thousands, except share and per share data)	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

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*;
- §

- 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 [Rh_o(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*; and
- 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.

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		