Prepare. Prevent. Protect.

emergent biosolutions®

2017 ANNUAL REPORT

Emergent BioSolutions Inc. is a global life sciences company seeking to protect and enhance life by focusing on providing specialty products for civilian and military populations that address accidental, intentional, and naturally occurring public health threats. Through our work, we envision protecting and enhancing 50 million lives with our products by 2025.

Maintaining High Ethical Standards in Everything We Do

Environment

As part of our mission to protect and enhance life, we are committed to conducting our business operations in a safe and sustainable manner and working in our communities to improve the environment for all.

Governance

Emergent is strongly committed to the highest standards of ethical conduct and corporate governance. These standards are consistent with our corporate culture. We understand that adhering to sound principles of corporate governance is critical to earning and maintaining the trust of our customers, employees, and shareholders. Our corporate governance principles and practices are built on a foundation of openness, integrity, and accountability. These are the principles that guide Emergent every day.

Compliance

At Emergent, we have an unwavering commitment to ethics and integrity. Ensuring that our company remains in compliance with our Code of Conduct is an essential component of that commitment. We are dedicated to developing and providing effective compliance training for all our employees, not only on the elements of the Compliance Plan, but also on the pertinent federal and state standards. All Emergent employees are required to complete compliance training every year.

OPERATIONS

HEADQUARTERS: Gaithersburg, MD
MANUFACTURING FACILITIES: United States, Canada
PRODUCT DEVELOPMENT SITES: United States, Canada
SERVICES: Contract development and manufacturing

PRODUCT PORTFOLIO: Vaccines, broad-spectrum anti-infectives, and antibody therapeutics focused on infectious diseases, as well as medical devices for chemical threats

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, 2017

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**

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

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

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

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

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

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

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

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

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐
(Do not check if a smaller reporting company)

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying

with any new or revised financial accounting standards provided pursuant to section 13(a) of the Exchange Act. ☐

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, 2017 was approximately $1.1 billion 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 16, 2018, the registrant had 49,494,612 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2018 annual meeting of stockholders scheduled to be held on May 24, 2018, 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, 2017, are incorporated by reference into Part II, Item 5. and 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 2018 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, 2017

INDEX

PART I

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

PART II

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

PART III

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

PART IV

Item 15. Exhibits and Financial Statement Schedules
Signatures
Exhibit Index

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 the future earnings and performance of Emergent BioSolutions Inc. or any of our businesses, 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 "will", "believes," "expects," "anticipates," "intends," "plans," "forecasts," "estimates" and similar expressions in conjunction with, among other things, discussions of financial performance or financial condition, growth strategy, product sales, manufacturing capabilities, product development, regulatory approvals or expenditures. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate. You should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. You are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

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

- appropriations for the procurement of BioThrax® (Anthrax Vaccine Adsorbed) and our other public health threat products;
- our ability to perform under our contracts with the U.S. government related to BioThrax, our NuThrax product candidate, and our other public health threat products, including the timing of and specifications relating to deliveries;
- our ability to obtain Emergency Use Authorization pre-approval for NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant) from the U.S. Food and Drug Administration;
- the availability of funding for our U.S. government grants and contracts;
- our ability to secure follow-on procurement contracts for our public health threat products that are under current procurement contracts that will be expiring;
- our ability to successfully integrate and develop the products or product candidates, programs, operations and personnel of any entities, businesses or products that we acquire, including our recently completed acquisitions of the ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) and Raxibacumab and the timing and receipt of required FDA approvals for actions contemplated in connection with our integration of these products;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- our ability to successfully identify and respond to new development contracts with the U.S. government, as well as successfully maintain, through achievement of development milestones, current development contracts with the U.S. government;
- our ability and the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices and other regulatory obligations;
- the results of regulatory inspections;
- the operating and financial restrictions placed on us and our subsidiaries under our senior secured credit facility;
- the outcome of the purported class action lawsuit;
- our ability to obtain and maintain regulatory approvals for our product candidates and the timing of any such approvals;
- the procurement of products by U.S. government entities under regulatory exemptions prior to approval by the FDA and corresponding procurement by government entities outside of the United States under regulatory exemptions prior to approval by the corresponding regulatory authorities in the applicable country;
- 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 Securities and Exchange Commission when evaluating our forward-looking statements.

PART I

ITEM 1. BUSINESS

OVERVIEW

Emergent BioSolutions Inc. is a global life sciences company focused on providing specialty products for civilian and military populations that address accidental, intentional and naturally occurring public 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, Suite 400, Gaithersburg, Maryland 20879. Our telephone number is (240) 631-3200, and our website address is www.emergentbiosolutions.com.

Within the category of our specialty products, we are focused on developing, manufacturing and commercializing medical countermeasures, or MCMs, that address public health and national security threats, which we collectively refer to as PHTs. The PHTs that we address fall into two categories: Chemical, Biological, Radiological, Nuclear and Explosives, or CBRNE; and emerging infectious diseases, or EID. We have a portfolio of eight products through which we generate most of our revenue, a fully-integrated portfolio of contract development and manufacturing services and a research and development pipeline of various investigational-stage product candidates. The U.S. government is the primary purchaser of our products and provides us with substantial funding for the development of many of our product candidates. Our development pipeline consists of a diversified mix of both pre-clinical and clinical-stage candidates.

Our business is organized into four business units:

- Vaccines and Anti-Infectives;
- Antibody Therapeutics;
- Devices; and
- Contract Development and Manufacturing.

Vaccines and Anti-Infectives

Our Vaccines and Anti-Infectives business unit consists of the following products and product candidates:

Products

Our Vaccines and Anti-Infectives business unit includes the following products:

- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or FDA, for the general use prophylaxis and post-exposure prophylaxis of anthrax disease; and
- ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), the only vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.

Product Candidates

Our Vaccines and Anti-Infectives business unit also has a pipeline of investigational stage product candidates. These candidates leverage our expertise in process development, manufacturing, clinical, non-clinical, regulatory and quality as well as proprietary platforms (*e.g.,* broad-spectrum antiviral and broad-spectrum antibiotic, among others), as we pursue development of MCMs, including potential dual-market MCMs, that address current and emerging PHTs. Our pipeline includes the following product candidates:

- NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), our next generation anthrax vaccine;
- VLA1601, a highly purified inactivated vaccine candidate being developed against the Zika virus;
- UNI-FLU, a universal influenza vaccine;
- EBX-205, an oral therapeutic to treat acute bacterial skin and skin structure infection, including those caused by methicillin-resistant *Staphylococcus aureus*, or MRSA, as well as to treat other serious bacterial infections caused by biothreat pathogens;
- GC-072, the lead compound in the EV-035 series of broad-spectrum antibiotics, being developed as an oral and intravenous treatment for *Burkholderia pseudomallei* infection; and
- EBI-001, a pan respiratory antiviral from our iminosugar-based discovery program.

Antibody Therapeutics

Our Antibody Therapeutics business unit consists of the following products and product candidates:

Products

Our Antibody Therapeutics business unit includes the following products:

- Raxibacumab (Anthrax Monoclonal), the first fully-human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax;
- Anthrasil® [Anthrax Immune Globulin Intravenous (Human)], the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of inhalational anthrax;
- BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)], the only heptavalent antibody therapeutic licensed by the FDA and Health Canada for the treatment of botulism; and
- VIGIV [Vaccinia Immune Globulin Intravenous (Human)], the only antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination.

Product Candidates

Our Antibody Therapeutics business unit also has a pipeline of investigational stage product candidates. These candidates leverage our expertise in process development, manufacturing, clinical, non-clinical, regulatory and quality as well as our proprietary hyperimmune platform technology, as we pursue development of MCMs, including dual-market MCMs, that address current and emerging PHTs. Our pipeline includes the following product candidates:

- FLU-IGIV (NP025), a human polyclonal antibody therapeutic being developed for the treatment of serious influenza A infection in hospitalized patients;
- ZIKV-IG (NP024), a human polyclonal antibody therapeutic being developed as a prophylaxis for Zika infections in at risk populations; and
- FILOV (NP026), an equine polyclonal antibody therapeutic being developed to treat hemorrhagic fever caused by Filoviruses (Ebola, Marburg and Sudan).

Devices

Our Devices business unit consists of the following products and investigational-stage product candidates:

Products

Our Devices business unit includes the following products:

- RSDL® (Reactive Skin Decontamination Lotion Kit), the only medical device cleared by the FDA to remove or neutralize the following chemical warfare agents from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin; and
- Trobigard™ (atropine sulfate, obidoxime chloride), an auto-injector device designed for intramuscular self-injection of atropine sulfate and obidoxime chloride, as a nerve agent countermeasure. This product is not currently approved or cleared by the FDA or any similar regulatory body, and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

Product Candidates

Our Devices business unit includes the following investigational-stage product candidates:

- D4, a multi-drug delivery device being developed for nerve agent antidote delivery (atropine and pralidoxime chloride in combination); and
- SIAN (stabilized isoamyl nitrite), a stabilized form of isoamyl nitrite in an intra-nasal spray device being developed as a treatment for known or suspected acute cyanide poisoning.

Contract Development and Manufacturing

Our Contract Development and Manufacturing business unit consists of contract development and manufacturing services, which are performed at our facilities located at sites in Maryland, Massachusetts, Michigan and Winnipeg, Manitoba, Canada, and include pharmaceutical process development, manufacturing, and filling services for injectable and other sterile products, inclusive of process design, technical transfer, validations, and analytical development support, as well as manufacturing of vial and pre-filled syringe formats, bulk drug product and finished units of clinical and commercial drugs. We provide these services for a wide variety of drug products – small molecule, biologics and blood products – in all stages of development and commercialization, including over 20 licensed products which are currently sold in approximately 50 countries. Our customers range from small biopharmaceutical companies to major multinational pharmaceutical companies.

For information regarding revenue, profit and loss, total assets and other information concerning our results of operations for our reporting segment 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

Our growth strategy is centered on our core business focus on MCMs addressing PHTs. This growth strategy contemplates that we:

- continue to leverage and expand our leadership position in the PHT market;
- grow through the acquisition of products and businesses, particularly those that are revenue-generating and accretive;
- develop and manufacture innovative products, particularly with funding from governments and non-governmental organizations to defray research and development costs;
- expand our portfolio of best-in-class/only-in-class MCMs and services;
- focus on globalization and related international marketing and sales capabilities;
- diversify our product mix to include products that have both government and non-government market potential, which we refer to as "dual-market."

In executing on our growth strategy, we are leveraging our core competencies. These competencies are:

- government relations and contracting;
- MCM development and commercialization;
- quality manufacturing using multiple platform technologies;
- company, business and product acquisitions; and
- financial discipline.

GROWTH THROUGH ACQUISITIONS AND COLLABORATIONS

We have a track record of growth through the acquisition of revenue-generating and accretive products and businesses. Our goal is to continue our expansion through targeted acquisitions of (1) government-procured MCMs; (2) dual-market product opportunities, which are products that address CBRNE threats but have potential application to commercial customers (*e.g.,* hospitals, clinics and other non-government customers); and (3) products that are purely commercial in nature but would leverage our core competencies in a unique way. Below is a summary of our significant acquisitions and collaborations over the past five years.

ACAM2000

In October 2017, we completed the acquisition of the ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) business of Sanofi Pasteur Biologics, LLC. This acquisition included ACAM2000, the only smallpox vaccine licensed by the FDA, a licensed, live-viral manufacturing facility and office and warehouse space, both in Canton, Massachusetts (for which we received FDA manufacturing approval for the transfer of the upstream portion of the manufacturing process of ACAM2000 in November 2017), and a live-viral fill/finish facility in Rockville, Maryland. With this acquisition, we also acquired an existing 10-year contract with the Centers for Disease Control and Prevention, or CDC, which will expire in March 2018. This contract was originally valued at up to $425 million, and upon acquisition had a remaining value at acquisition of up to approximately $160 million, including delivery of ACAM2000 to the U.S. Strategic National Stockpile, or SNS.

Total consideration for this acquisition was $125 million. At closing, we paid $117.5 million in cash. The agreement also included an additional cash milestone payment of $7.5 million based upon FDA approval of the Canton facility for the manufacturing of ACAM2000. This regulatory milestone was achieved based on such approval in November 2017 and paid in cash in the fourth quarter of 2017.

Raxibacumab

In October 2017, we completed the acquisition from Human Genome Sciences, Inc. and GlaxoSmithKline LLC, collectively GSK, of Raxibacumab, the first fully-human monoclonal antibody product licensed by the FDA for the treatment and prophylaxis of inhalational anthrax. Total consideration for this acquisition was up to $96 million. At closing, we paid $76 million in cash. The agreement also included up to $20 million in future cash payments tied to product sales and manufacturing-related milestones. As of December 31, 2017, the milestones had not yet been achieved. With the acquisition, we assumed responsibility for a multi-year contract with the Biomedical Advanced Research and Development Authority, or BARDA, with a remaining value at acquisition of up to approximately $130 million, to supply Raxibacumab to the SNS through November 2019. We are currently in the process of pursuing FDA licensure for the transfer of manufacturing of Raxibacumab to our Bayview facility, and under the terms of the acquisition agreements we will purchase product from GSK to enable completion of deliveries to the SNS under the current BARDA procurement contract.

Southwest Research Institute

In July 2017, we entered into an agreement with Southwest Research Institute, an independent, nonprofit applied research and development organization headquartered in San Antonio, Texas, under which we are developing SIAN (stabilized isoamyl nitrite) in an intra-nasal spray device for the treatment of known or suspected acute cyanide poisoning. In September 2017, we were awarded a five-year contract by BARDA valued at approximately $63 million to advance the development of SIAN towards licensure. Under this BARDA contract, we will complete regulatory activities required to submit an Investigational New Drug, or IND, application to the FDA to enable first-in-human studies, conduct initial clinical studies, and advance non-clinical and manufacturing development activities.

Valneva SE

In July 2017, we entered into a licensing agreement with Valneva SE, or Valneva, for global exclusive rights to Valneva's Zika vaccine technology, ZIKV. We are co-developing VLA1601, a highly purified inactivated vaccine candidate against the Zika virus.

Unither Virology LLC

In December 2015, we acquired Unither Virology LLC, a glycobiology-focused drug discovery subsidiary of United Therapeutics Corporation. The primary asset of this acquisition was the UVX series of glyco-biologic molecules, a broad family of iminosugar small molecules that have activity against a variety of enveloped viruses, of which the leading product candidate is EBI-001.

Pharma Consult

In August 2015, we entered into an exclusive worldwide license agreement with Pharma Consult Ges.m.b.H of Austria to acquire rights to an auto-injector device intended for military use, which is the device platform upon which our Trobigard™ product is based. This platform was designed for needle penetration and injection through several layers of clothing and intramuscular self-injection of emergency treatment for exposure to certain nerve agents. Trobigard is not currently approved or cleared by the FDA or any similar regulatory body, and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

Evolva Holding SA

In December 2014, we acquired the EV-035 series of molecules from Evolva Holding SA. EV-035 is a series of 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* under a four-year, $15 million contract with the Defense Threat Reduction Agency, or DTRA, of the U.S. Department of Defense, or DoD. A second antibiotic candidate, EBX-205, has been selected from the series and is currently being developed as an oral therapeutic to treat acute bacterial skin and skin structure infection, including those caused by MRSA as well as to treat other serious bacterial infections caused by biothreat pathogens such as *B. anthracis, F. tularensis, Yersinia pestis, Burkholderia mallei* and *Burkholderia pseudomallei*.

Cangene Corporation

In February 2014, we acquired Cangene Corporation, which included the following products: BAT® for the treatment of botulism; Anthrasil for the treatment of anthrax infection; and VIGIV for the treatment of adverse reactions to vaccinia virus vaccinations and hyperimmune technology platform. BAT, Anthrasil and VIGIV are all manufactured in Winnipeg, Manitoba, Canada in our facilities acquired from Cangene. We also acquired Cangene's fill/finish contract manufacturing services business in Baltimore, Maryland (our Camden facility), including agreements with customers to fill/finish a number of commercial and clinical-stage products worldwide.

Healthcare Protective Products Division of Bracco Diagnostics Inc.

In August 2013, we acquired the Healthcare Protective Products Division of Bracco Diagnostics Inc. The assets acquired in this transaction included the RSDL Kit, a medical device countermeasure for the removal and neutralization of chemical warfare agents and T-2 toxin from the skin, a multi-year manufacturing agreement, and the lease for our manufacturing facility in Hattiesburg, Mississippi. With this acquisition, we diversified into another pillar within the CBRNE threat countermeasure market by acquiring an MCM focused on chemical threats, specifically chemical warfare agents. The acquisition also broadened our technical expertise beyond vaccines and therapeutics into medical devices and, at the same time, expanded our CBRNE-related sales and marketing capabilities with respect to ex-U.S. customers, specifically NATO, among others.

SPIN-OFF OF BIOSCIENCES BUSINESS

In August 2016, we completed a tax-free spin-off of our former biosciences business into a separate, stand-alone publicly-traded company, Aptevo Therapeutics Inc. As part of the spin-off transaction, the assets that were a part of our former biosciences business segment were transferred to Aptevo. These assets included our former biosciences commercial products IXINITY [coagulation factor IX (recombinant)], WinRho® SDF [(Rh_o(D) Immune Globulin Intravenous (Human)], HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)] and VARIZIG® [Varicella Zoster Immune Globulin (Human)] as well as our former oncology and hematology therapeutics development assets and platforms.

PRODUCT PORTFOLIO

The chart below summarizes our portfolio of revenue-generating products:

BIOLOGICAL THREATS		
VACCINES AND ANTI-INFECTIVES UNIT		
Product	**Indication(s)**	**Regulatory Approvals**
BioThrax® (Anthrax Vaccine Adsorbed)	GUP - General use prophylaxis of anthrax disease; and PEP - Post-exposure prophylaxis of anthrax disease in combination with appropriate antibacterial drugs.	United States – GUP and PEP Germany - GUP Singapore – GUP
ACAM2000® (Smallpox (Vaccinia) Vaccine, Live)	Vaccination for active immunization against smallpox disease for persons determined to be at high risk for smallpox.	United States Australia Singapore
ANTIBODY THERAPEUTICS UNIT		
Product	**Indication(s)**	**Regulatory Approvals**
Raxibacumab	Treatment and prophylaxis of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate.	United States
Anthrasil® [Anthrax Immune Globulin Intravenous (Human)]	Treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs.	United States Canada
BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)]	Treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients.	United States Canada
VIGIV [Vaccinia Immune Globulin Intravenous (Human)]	Treatment of complications due to vaccinia vaccination, including: • Eczema vaccinatum; • Progressive vaccinia; • Severe generalized vaccinia; and • Aberrant infections induced by vaccinia virus (except in cases of isolated keratitis).	United States Canada
CHEMICAL THREATS		
DEVICES UNIT		
Product	**Indication(s)**	**Regulatory Approvals**
RSDL® (Reactive Skin Decontamination Lotion Kit)	Removal or neutralization of chemical warfare agents and T-2 toxin from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin.	- U.S. Food and Drug Administration (510k) - Health Canada - Australian Therapeutics Goods Administration - European Union: RSDL Kit is CE-marked - Israel Ministry of Health
Trobigard™ (atropine sulfate, obidoxime chloride)	Auto-injector device designed for intramuscular self-injection of atropine sulfate and obidoxime chloride as a nerve agent countermeasure.	Trobigard is not currently approved or cleared by the FDA or any similar regulatory body, and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

OUR BUSINESS UNITS

We are organized into four business units: Vaccines and Anti-Infectives; Antibody Therapeutics; Devices; and Contract Development and Manufacturing.

Vaccines and Anti-Infectives

Our Vaccines and Anti-Infectives business unit contains a portfolio of specialty vaccines and unique anti-infectives that address existing and emerging PHTs.

Products

BioThrax® (Anthrax Vaccine Adsorbed). BioThrax is the only vaccine licensed by the FDA for the general use prophylaxis, or GUP, of anthrax disease. In April 2014, the FDA granted orphan drug designation to BioThrax for the post-exposure prophylaxis, or PEP, indication, (please see "Regulation – Marketing Approval – Biologics, Drugs and Vaccines– Organ Drugs"), giving it market exclusivity in the United States until November 2022. In November 2015, the FDA approved our supplemental Biologics License Application, or BLA, to expand the BioThrax label to include the PEP indication for BioThrax administered in combination with antimicrobial therapy. 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 in a GUP setting 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 one each at 12 and 18 months, with booster doses annually thereafter. BioThrax is administered in a PEP setting in conjunction with recommended antibacterial drugs following suspected or confirmed *Bacillus anthracis* exposure. The vaccination schedule for PEP consists of three doses of BioThrax administered subcutaneously at 0, 2 and 4 weeks post-exposure combined with antimicrobial therapy. In December 2016, we signed a follow-on contract with the CDC, an agency within the U.S. Department of Health and Human Services, or HHS, for the supply of up to approximately 29.4 million doses of BioThrax for delivery into the SNS, over a five-year period ending in September 2021. The potential value of this contract is approximately $911 million, if all procurement options are exercised. In March 2017, we entered into an additional contract with BARDA, originally valued at $100 million, for the delivery of BioThrax to the SNS, over a two-year period of performance. We completed deliveries under this contract in 2017.

In August 2016, the FDA licensed Building 55, our large-scale manufacturing facility in Lansing, Michigan, for the manufacture of BioThrax. This facility has the potential to manufacture up to 20 to 25 million doses of BioThrax annually.

ACAM2000® (Smallpox (Vaccinia) Vaccine, Live). ACAM2000 is the only smallpox vaccine licensed by the FDA and is the primary smallpox vaccine designated for use in a bioterrorism emergency, with more than 230 million doses having been supplied to the SNS. ACAM2000 is also licensed in Australia and Singapore and is currently stockpiled both in the United States and internationally. Smallpox is a highly contagious disease caused by the variola virus, a member of the orthopox virus family. According to the CDC, it is one of the most devastating diseases with a mortality rate as high as 30%. ACAM2000 is administered by percutaneous route in one dose with a bifurcated needle using the multiple puncture method. The vaccine stimulates a person's immune system to develop antibodies and cells in the blood and elsewhere that can then help the body fight off a smallpox infection if exposure to smallpox occurs. Upon the closing of the ACAM2000 acquisition, we acquired an existing 10-year CDC contract, which will expire in March 2018. The original contract, valued at up to $425 million, called for the delivery of ACAM2000 to the SNS and establishing U.S.-based manufacturing of ACAM2000, specifically the transfer of the upstream portion of the ACAM2000 production process from Austria to a U.S.-based manufacturing facility. This technology transfer was completed and approved by the FDA in November 2017. We expect to fulfill the remaining product deliveries to the SNS valued at the time of acquisition of up to approximately $160 million, subject to availability of government funding.

Product Candidates

The chart below highlights our Vaccines and Anti-infectives product candidates:

Product Candidate	Partner	Platform	Threat Type
NuThrax™ *Next generation anthrax vaccine*	**HHS - BARDA**	**Vaccine**	**Biological**
VLA1601 *Zika vaccine*	**Valneva**	**Vaccine**	**EID**
UNI-FLU *Universal flu vaccine*	**--**	**Vaccine**	**EID**
EBX-205 *Broad spectrum antibiotic*	**--**	**Antibacterial**	**EID**
GC-072 (EV-035 Series) *Burkholderia antibiotic*	**DoD – DTRA**	**Antibacterial**	**Biological**
EBI-001 Pan-respiratory *iminosugar antiviral*	**--**	**Antiviral**	**EID**

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. We are developing NuThrax, in part with funding from the National Institute of Allergy and Infectious Diseases, or NIAID, and BARDA, to potentially elicit a more rapid onset of immune response using fewer doses than BioThrax while still providing protective immunity in patients. Using funds from our 2010 development contract with NIAID, 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 requiring a fewer two-dose regimen than the BioThrax three-dose regimen and may shorten the recommended antibiotic (60-day) regimen for anthrax post-exposure prophylaxis. In September 2014, we also obtained additional funding 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 IND 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. In March 2015, we signed a contract with BARDA valued at $31 million to develop NuThrax for post-exposure prophylaxis of anthrax disease. In September 2016, we signed a contract with BARDA for up to approximately $1.5 billion, including a five-year base period of performance valued initially at approximately $200 million to develop NuThrax for post-exposure prophylaxis of anthrax disease and to deliver to the SNS an initial two million doses, subsequently modified to three million doses in March 2017, following Emergency Use Authorization, or EUA, pre-approval by the FDA. Although there can be no assurances, we currently anticipate that the FDA could grant EUA designation to NuThrax as early as 2019, upon the submission of our application for EUA pre-approval, triggering the initial three million dose delivery of NuThrax into the SNS in 2019. The contract also includes procurement options for the delivery of an additional 7.5 million to 50 million doses of NuThrax into the SNS, valued from approximately $255 million to up to $1.3 billion, respectively, and options for an additional clinical study and post-marketing commitments valued at $48 million, which if both were to be exercised in full, could increase the total contract value to approximately $1.5 billion. See "*Management's Discussion and Analysis of Financial Conditions and Results of Operations – Overview – Highlights and Business Accomplishments for 2017"* for additional details.

Within our Vaccines and Anti-Infectives business unit, we are also leveraging our proprietary, potential broad-spectrum anti-viral and broad-spectrum antibiotic platforms to advance the development of potential dual-market molecules to address current and emerging PHTs, including the following additional investigational-stage product candidates:

VLA1601. We are co-developing with Valneva VLA1601, a highly purified inactivated vaccine candidate against the Zika virus, from pre-clinical development through the completion of a Phase 1 safety and immunogenicity clinical trial. VLA1601, which has been shown to elicit functional antibody responses, is based on Valneva's established inactivated, whole virus manufacturing platform on which its licensed Japanese Encephalitis vaccine was developed and produced. A Phase 1 clinical trial is expected to commence in early 2018.

UNI-FLU. We are developing a universal influenza vaccine candidate intended to protect broadly against seasonal and pandemic influenza infections and without the requirement for changes to vaccine composition on an annual basis. This candidate is a nanoparticle vaccine that self-assembles during production and that displays a cross-reactive antigen for each broad influenza group.

EBX-205. We are developing EBX-205, a 2-pyridone antibacterial drug, as an oral therapeutic to treat acute bacterial skin and skin structure infection, including those caused by MRSA.

GC-072. We are developing GC-072, a member of the EV-035 family of bacterial type II topoisomerase inhibitors, belonging to the chemical class of 4-oxoquinolizine as a potential oral treatment for *Burkholderia pseudomallei*. This work is being conducted under a contract with DTRA that was awarded in 2014 and runs through the end of March 2018. GC-072 has demonstrated protection *in vivo* from lethal, aerosol *B. pseudomallei* infection when administered orally, and it shows activity not only on drug-sensitive strains, but also on clinical isolates resistant to marketed antibiotics (including quinolones).

EBI-001. We are developing EBI-001, a next generation pan-respiratory antiviral as part of our iminosugar-based discovery program. Iminosugars are any analog of a sugar where a nitrogen atom has replaced one of the carbon or oxygen atoms and a class of compounds that includes licensed products for treatment of other non-viral diseases. Advantages of this class of host-based therapeutics include activity against a variety of viruses and limited risk for development of drug-induced viral resistance.

Antibody Therapeutics

Our Antibody Therapeutics business unit contains a broad portfolio of specialty antibody-based therapeutics and prophylactics that address a broad range of existing and emerging PHTs.

Products

Raxibacumab. Raxibacumab is the first fully-human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax due to *bacillus anthracis*. It was licensed by the FDA in December 2012 and has orphan drug designation in the United States, giving it market exclusivity in the United States until December 2019. Raxibacumab is indicated for the treatment of adult and pediatric patients with inhalational anthrax in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when

alternative therapies are not available or not appropriate. Raxibacumab has been supplied to the SNS since 2009 under contracts with BARDA. Upon the closing of our acquisition of Raxibacumab from GSK, we assumed responsibility for a multi-year contract with BARDA, valued at up to approximately $130 million at acquisition to supply the product to the SNS through November 2019. We intend to pursue negotiation of a follow-on contract with the U.S. government to ensure the uninterrupted supply of this MCM to the SNS. Under the terms of our acquisition agreements, we will purchase product from GSK to enable completion of deliveries to the SNS under the existing BARDA procurement contract. We have initiated the process of the transfer of Raxibacumab manufacturing from GSK to our Bayview facility.

Anthrasil® [Anthrax Immune Globulin Intravenous (Human)]. Anthrasil is the only polyclonal antibody therapeutic licensed by the FDA for the treatment of inhalational anthrax. Anthrasil is comprised of purified human polyclonal immune globulin G, or IgG, containing polyclonal antibodies directed to the anthrax toxins of *Bacillus anthracis*, the bacteria that causes anthrax disease, and is prepared using plasma collected from healthy, screened donors who have been immunized with our BioThrax vaccine. Anthrasil was licensed by the FDA in March 2015 for the treatment of suspected or documented inhalational anthrax in combination with appropriate antibacterial drugs. Simultaneous with FDA approval in 2015, Anthrasil also received orphan drug designation, resulting in market exclusivity in the United States until March 2022. To date, the principal customer for Anthrasil has been the U.S. government, specifically HHS. Anthrasil is procured by BARDA for delivery into the SNS. We have two current contracts with BARDA: a development and procurement contract with BARDA that expires in April 2021 and a multiple award, indefinite delivery/indefinite quantity contract with BARDA for the collection of anti-anthrax plasma, as well as the manufacture of such plasma into bulk drug substance and finished drug product and delivery of finished product into the SNS over a five-year period through September 2018. BARDA issued one task order under this second contract for the collection of anti-anthrax plasma, which was completed in 2015. In addition to domestic government sales, Anthrasil has been sold to several foreign governments. In December 2017, we were awarded a contract by the Canadian Department of National Defence valued at approximately $8 million to deliver Anthrasil to the Canadian government. This contract award follows the December 2017 approval of Anthrasil by Health Canada under the Extraordinary Use New Drug, or EUND Regulations, which provide a regulatory pathway in Canada for products for which collecting clinical information for its intended use in humans is logistically or ethically not possible.

BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)]. BAT is the only heptavalent antibody therapeutic licensed by the FDA and Health Canada for the treatment of botulism. BAT is comprised of purified polyclonal equine immune globulins (antibodies) directed to the seven toxins (A through G) produced by *Clostridium botulinum*. BAT was licensed by the FDA 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. It was also licensed in Canada in December of 2016 pursuant to Health Canada's EUND regulations. Simultaneous with FDA licensure in 2013, BAT also received orphan drug designation, resulting in market exclusivity in the United States until March 2020. BAT is the only heptavalent botulism antitoxin available in the United States or Canada for treating naturally occurring botulism in adults or pediatric patients. 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 bioterrorism agent 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. We are currently operating under a procurement contract with BARDA in support of the program including stability testing, post marketing commitments, and manufacturing. We signed a modification to our contract with BARDA to manufacture and store bulk drug substance for BAT in March 2017, valued at approximately $53 million with a five-year period of performance. This modification to the contract is intended to enable future filling and deliveries of final drug product to the SNS. In addition to domestic government sales, BAT has been sold to foreign governments. For example, we have a 10-year contract, executed in 2012, to supply BAT to the Canadian Department of National Defense as well as the Public Health Agency of Canada and individual provincial health authorities.

VIGIV [Vaccinia Immune Globulin Intravenous (Human)]. VIGIV is the only polyclonal antibody therapeutic licensed by the FDA to address certain complications from smallpox vaccination. VIGIV is comprised of purified polyclonal human immune globulins (antibodies) directed to the vaccinia virus, the virus that is used in replicating virus vaccinations, such as ACAM2000, a product that is currently being procured and delivered into the SNS. VIGIV is prepared using plasma collected from healthy, screened donors who have been immunized with our ACAM2000 vaccine or previously immunized with the DryVax 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 ACAM2000 or other similar replicating virus vaccines, and these patients may benefit from treatment with VIGIV. VIGIV was licensed by the FDA in May 2005 and by Health Canada in May 2007 for counteracting certain complications that can be associated with smallpox vaccination. Although VIGIV has been sold to foreign governments, to date, the principal customer for VIGIV has been the U.S. government, specifically HHS. We anticipate negotiating a follow-on contract for the continued supply of VIGIV into the SNS.

Product Candidates

The chart below highlights our Antibody Therapeutics product candidates:

Product Candidate	Target Indication
FLU-IGIV *Seasonal influenza therapeutic*	Treatment of serious Influenza A infection in hospitalized patients.
ZIKV-IG *Zika therapeutic*	Prophylaxis for Zika infections in at risk populations.
FILOV *Pan-Ebola therapeutic*	Prevention or treatment of Ebola or Sudan virus infection.

FLU-IGIV (NP025). We are utilizing our hyperimmune platform to develop NP025, a human polyclonal antibody therapeutic enriched with influenza antibodies for the treatment of serious illness caused by influenza A infection in hospitalized patients. Pre-clinical studies are ongoing and we commenced a Phase 2 clinical trial, with the first patient dosed in January 2018.

ZIKV-IG (NP024). We are utilizing our hyperimmune platform to develop NP024, a human polyclonal antibody therapeutic enriched with Zika antibodies, as a prophylaxis for Zika infections in at risk populations. Pre-clinical studies are currently ongoing and we are targeting commencement of a Phase 1 clinical trial in the first quarter of 2018. The FDA has also granted fast-track designation for this program.

FILOV (NP026). In 2016, we signed an exclusive license agreement with Integrated BioTherapeutics, Inc. to use IBT's proprietary vaccine antigens and know how in the development of equine-based antibody therapeutics for the treatment of hemorrhagic fever caused by Filoviruses (*i.e.,* Ebola Zaire, Ebola Sudan and Marburg). Pre-clinical studies are currently ongoing.

Devices

Our Devices business unit contains a broad portfolio of devices that incorporate convergent, or dual-market, technologies for governments and patients to address PHTs and challenging life-threatening conditions:

Products

RSDL® (Reactive Skin Decontamination Lotion Kit). RSDL is the only medical device cleared by the FDA that is intended to remove or neutralize chemical warfare agents from the skin, including tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin. RSDL has been cleared as a medical device by the FDA and Health Canada, has a current European Conformity, or CE mark under European Directives, and is licensed by the Israel Ministry of Health and by Australia's Therapeutics Goods Administration. To date, the principal customers for RSDL have been agencies of the U.S. government, including the DoD and the National Guard. Our current contract with the DoD is a five-year follow-on contract valued at up to approximately $171 million to supply RSDL for use by all branches of the U.S. military, which was awarded in September 2017 after the expiration of our initial DoD contract. In addition to the DoD and other U.S. government agencies, beginning in 2017, we made RSDL available for the first time for purchase by civilians in the United States on Amazon.com. We have also sold RSDL to 35 foreign countries outside the United States since the device was cleared in 2003. We intend to continue our sales to U.S. government agencies and the DoD and to identify new markets where RSDL can be promoted and sold under its current FDA clearance.

Trobigard™ (Atropine Sulfate/Obidoxime Chloride auto-injector). Trobigard auto-injector is designed to deliver atropine sulfate and obidoxime chloride for emergency treatment of organophosphate nerve agent or insecticide poisoning. In October 2017, we were awarded a contract valued at up to approximately $25 million by the U.S. Department of State, or DoS, to deliver our Trobigard product and training auto-injectors for emergency use outside of the United States. The contract consists of a one-year base period of performance with a six-month option period. Trobigard is not currently approved or cleared by the FDA or any similar regulatory body, and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

Product Candidates

Within our Devices business unit, we are leveraging our proprietary auto-injector platform to develop several investigational stage product candidates, including:

SIAN (stabilized isoamyl nitrite). In September 2017, we were awarded a contract by BARDA valued at approximately $63 million to develop an antidote intra-nasal spray device for the treatment of known or suspected acute cyanide poisoning. The single-use intranasal spray device is being developed to deliver a stabilized form of isoamyl nitrite, or SIAN, and is intended to be developed for use by first responders and medical personnel following a cyanide incident.

D4. In July 2017, we were awarded a contract by DoD valued at up to approximately $23 million to develop a multi-drug auto-injector for nerve agent antidote delivery (atropine and pralidoxime chloride), which we refer to as D4.

In addition, we are continuing to look at opportunities to expand our auto-injector product line.

Contract Development and Manufacturing

Our Contract Development and Manufacturing business unit, which is based on our established manufacturing infrastructure and expertise, consists of a broad range of contract development and manufacturing services to third-party customers with specific and unique needs. These services include pharmaceutical product process development, manufacturing and filling services for injectable and other sterile products, inclusive of process design, technical transfer, manufacturing validations, laboratory analytical development support, aseptic filling, lyophilization, final packaging and accelerated and ongoing stability studies. We manufacture both vial and pre-filled syringe formats and we produce bulk drug product and finished units of clinical and commercial drugs. We provide these services for a wide variety of drug products – small molecule, biologics, and blood products – in all stages of development. We perform work for this business unit at facilities located at the following sites:

- *Camden (Baltimore, Maryland).* Primarily supporting our Contract Development and Manufacturing business unit, our Camden facility has provided manufacturing services to more than 50 domestic and international customers and has manufactured over 20 commercial products distributed in approximately 50 countries. This fill/finish manufacturing site offers customers a broad portfolio of capabilities essential to their product development and commercialization efforts.
- *Bayview (Baltimore, Maryland).* Our Bayview facility was designated by the HHS as a Center for Innovation in Advanced Development and Manufacturing, or CIADM, through a contract with BARDA in June 2012. Through this contract, we have responded to four Task Order Requests issued by BARDA for the development and manufacture of product candidates primarily addressing EID threats of high priority to the U.S. government, including Zika and viral hemorrhagic fevers such as Ebola. In support of our Contract Development and Manufacturing business unit, our Bayview facility also provides manufacturing services to non-U.S. Government partners and customers.
- *Rockville, Maryland*. Our cGMP live viral fill/finish facility in Rockville, Maryland is primarily responsible for the processing of formulated bulk ACAM2000 into final packaged vaccine vials, but also provides us with important viral fill/finish capacity for third party customers. It is a BLS2 fill/finish facility utilizing Grade A Isolation Technologies to fill, freeze dry, inspect, label, package and store viral vaccine product. Presently, the facility is a single product-facility but we intend to expand the facility into a multi-product viral fill/finish contract manufacturing facility.
- *Canton, Massachusetts*. Our Canton, Massachusetts facility is equipped with large-scale bioreactors for cell culture propagation and viral infection as well as downstream processing equipment for the production of live viral vaccine products, including ACAM2000. This site also operates as a contract manufacturing operations, or CMO, facility and we intend to expand on this capability.
- *Lansing, Michigan.* Our Lansing campus is our primary manufacturing location servicing our Vaccines and Anti-Infectives business unit for the production of BioThrax and NuThrax. Our Lansing facilities also provide our Contract Development and Manufacturing business unit with capability for both small- and large- scale biologics bulk product manufacturing. We conduct CMO activities in our small-scale facility, Building 12, and we seek to market our available capacity in Lansing to enhance overall facility utilization.
- *Winnipeg, Manitoba, Canada.* Our facilities in Winnipeg contain the primary location for product development and manufacturing in support of our Antibody Therapeutics business unit. These facilities also support our Contract Development and Manufacturing business unit through product development and manufacturing support to a number of customers.

Research and Development

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 (or label expansions of existing products). To offset these expenditures, we actively seek, and historically have been successful in obtaining, contract and grant awards for development funding from U.S. government agencies within both HHS and DoD. Gross research and development expenses and net research and development expense (income) are as follows:

	December 31,		
in millions	**2017**	**2016**	**2015**
Research and development expense	$ 97.4	$ 108.3	$ 119.2
less: Contracts and grants revenue	(70.4)	(143.4)	(117.4)
Net research and development expense (revenue)	$ 27.0	$ (35.1)	$ 1.8

Marketing and Sales

For our Vaccines and Anti-Infectives, Antibody Therapeutics and Devices business units, we sell our products primarily to the U.S. government and domestic non-government organizations. All three business units share a team of dedicated marketing and sales personnel. We intend to use a similar approach to the marketing and sales of other product candidates that we either successfully develop or acquire. In addition to domestic sales, we sell our products to allied foreign governments as well as non-governmental organizations in foreign jurisdictions. For our non-U.S. sales, we use a combination of our employees as well as third-

party marketing distributors and representatives 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 countermeasures addressing PHTs increases outside the United States.

Our Contract Development and Manufacturing business unit is supported by a dedicated group of business development professionals qualified to represent the full spectrum of contract product development and manufacturing services that we offer.

Competition

Our products and product candidates intended for the treatment or prevention of CBRNE and EID threats face significant competition. Our products and any product or product candidate that we acquire or successfully develop and commercialize are likely to compete with current products and product candidates that are in development for the same indications. Specifically, the competition for our products and product candidates includes the following:

- ***BioThrax and NuThrax***. BioThrax is the only vaccine licensed by the FDA for the prevention of anthrax disease. However, we face potential future competition for the supply of anthrax vaccines to the U.S. government if such products are approved. Altimmune, Inc., Pfenex Inc., Soligenix, Inc., Immunovaccine Inc. and NanoBio Corporation are each currently developing anthrax vaccine product candidates.

- ***ACAM2000***. ACAM2000 is the only FDA-licensed smallpox vaccine in the United States. Investigational stage competitor vaccine Imvamune® of Bavarian Nordic may be used in a smallpox emergency under the appropriate regulatory mechanism (*i.e.,* IND or EUA). Imvamune is approved in Canada and in the European Union and is marketed under the trade name Imvanex®. It is indicated for use in immunocompromised patients, including HIV-infected individuals and those undergoing immunosuppressive therapy. Phase 3 registration trials are ongoing in the United States.

- ***Raxibacumab and Anthrasil***. Raxibacumab is the first FDA licensed fully human anthrax monoclonal antibody therapeutic and Anthrasil is the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of toxemia resulting from inhalational anthrax. However, Elusys Therapeutics, Inc. has obtained FDA licensure for Anthim® (obiltoxaximab) injection, indicated for the treatment and prophylaxis of inhalational anthrax.

- ***BAT***. Our botulinum antitoxin immune globulin product is the only heptavalent therapeutic licensed by the FDA and Health Canada for the treatment of botulism and has orphan drug designation. Other companies may be developing therapies aimed at treating or preventing botulism infections, however, direct competition is currently limited.

- ***VIGIV***. Our VIGIV product is the only therapeutic licensed by the FDA and Health Canada to address adverse events from smallpox vaccination with ACAM2000. Other companies may be developing therapies aimed at treating or preventing vaccinia infections; however, direct competition is currently limited. SIGA Technologies, Inc. is developing Tecovirimat (Arestvyr™, ST-26), an oral therapy that targets orthopox viruses such as vaccinia and potentially smallpox. Chimerix is also developing brincidofovir, a nucleotide analog lipid conjugate for treatment of smallpox.

- ***RSDL***. In the United States, the RSDL Kit is the only medical device cleared by the FDA to remove or neutralize chemical warfare agents and T-2 toxin from the skin. Internationally, various Ministries of Defense have procured Fullers Earth, Dutch Powder and French Powder as a preparedness countermeasure for the decontamination of liquid chemical weapons from the skin.

- ***Trobigard***. Trobigard auto-injector delivers obidoxime chloride and atropine sulfate for emergency treatment of organophosphate nerve agent or insecticide poisoning. Meridian Medical Technologies, a subsidiary of Pfizer, is currently the sole owner of FDA-approved nerve agent antidote auto-injector devices to the U.S. government and many international allied governments. Internationally, the remaining market is fragmented and served by regional or national-based defense product manufacturers.

- ***Contract Development and Manufacturing Services Business***. We compete for contract manufacturing service business with a number of biopharmaceutical product development organizations, contract manufacturers of biopharmaceutical products and university research laboratories, including, among others: Lonza Group Ltd., 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. We also compete with in-house research, development and support service departments of other biopharmaceutical companies.

Customer and Geographical Reliance

For the years ended December 31, 2017, 2016 and 2015, our revenues from customers both inside and outside of the United States were as follows:

(in millions)	2017		2016		2015	
	United States	**Ex-U.S.**	**United States**	**Ex-U.S.**	**United States**	**Ex-U.S.**
Total revenues	$ 496.9	$ 64.0	$ 460.6	$ 28.2	$ 467.7	$ 21.6
% of total revenues	89%	11%	94%	6%	96%	4%

For the years ended December 31, 2017, 2016 and 2015, our revenues from the U.S government and other non-U.S. government customers were as follows:

(in millions)	2017		2016		2015	
	U.S. Government Customer	**Non-U.S. Government Customer**	**U.S. Government Customer**	**Non-U.S. Government Customer**	**U.S. Government Customer**	**Non-U.S. Government Customer**
Total revenues	$ 439.8	$ 121.1	$ 421.2	$ 67.6	$ 430.6	$ 58.7
% of total revenues	78%	22%	86%	14%	88%	12%

For the years ended December 31, 2017, 2016 and 2015, our product sales revenue from U.S. and non-U.S. customers as a percentage of total revenues were as follows:

(in millions)	2017		2016		2015	
	United States	**Ex-U.S.**	**United States**	**Ex-U.S.**	**United States**	**Ex-U.S.**
Product sales revenue	$ 377.0	$ 44.5	$ 285.8	$ 10.5	$ 320.0	$ 9.0
% of total revenues	67%	8%	58%	2%	65%	2%

MANUFACTURING

Our Lansing, Michigan site is a vertically integrated manufacturing facility and the location of our BioThrax manufacturing and NuThrax development operations. Located within the Lansing site is Building 55, our large-scale manufacturing facility, which was licensed by the FDA in August 2016 for the manufacture of BioThrax. This facility has the potential to manufacture up to 20 to 25 million doses of BioThrax annually on a single manufacturing train and has the capacity to add additional manufacturing trains, if needed. The manufacturing capabilities of Building 55 are central to our Vaccines and Anti-Infectives business unit. Our Lansing site also comprises biologics bulk product manufacturing capability (large- and small-scale), which we market to CDMO customers.

Our manufacturing facilities located at our Winnipeg, Manitoba, Canada, site are actively engaged in plasma-derived hyperimmune therapeutics manufacturing, chromatography-based plasma fractionation, downstream processing, aseptic filling, packaging and warehousing, quality assurance and control, and include development laboratories and office space. At these facilities, we manufacture and fill our hyperimmune specialty plasma products, including Anthrasil, BAT and VIGIV, and we conduct bulk manufacture of RSDL lotion. Also at these facilities, we manufacture other hyperimmune products for contract manufacturing customers. The facilities at this site will play a key role in executing both product development and manufacturing activities in support of our Antibody Therapeutics and Contract Development and Manufacturing business units.

Our primary contract fill/finish services manufacturing site is located in Baltimore, Maryland, and is referred to as our "Camden Site." The Camden 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 support. This facility is an approved manufacturing facility under the regulatory regimes in the United States, Canada, Japan, Brazil, the Middle East as well as various other countries. The facility includes warehousing space used for cold-storage and freezer capacity to support contract manufacturing customers. Additionally, we intend for this facility to provide fill/finish services to many of our business units for our development and commercial-stage products and product candidates.

Our manufacturing facility focused on disposable manufacturing for viral and non-viral products is located in Baltimore, Maryland, and is referred to as our "Bayview Site." This facility is designed to take advantage of single-use bioreactor technology and to be capable of manufacturing several different products, including products derived from cell culture or microbial systems.

In June 2012, we entered into a contract with BARDA, which established our Bayview Site as a CIADM. In May 2017 we completed work to expand this facility to double its original size to meet the needs of our customers. The new suite within the expanded facility is expected to come online with cGMP production capabilities in late 2018. The facility is one of three centers designated by HHS to provide advanced development and manufacturing of MCMs to support the U.S. government's national security and public health emergency needs. This facility has also been and will continue to be marketed to non-U.S. government clients in need of bulk manufacturing services. We are currently in the process of pursuing FDA licensure for the transfer of manufacturing of Raxibacumab to our Bayview facility.

We also currently lease a packaging facility in Hattiesburg, Mississippi, at the University of Southern Mississippi's Accelerator, a technology innovation and commercialization center. This facility is equipped to package RSDL. RSDL bulk lotion that is manufactured in Winnipeg is shipped to Hattiesburg, Mississippi, for combination with RSDL sponges, which are further manufactured, packaged and then released for sale. All RSDL packets are packaged at this facility.

In October 2017, in connection with our acquisition of the ACAM2000 business from Sanofi, we acquired a live viral manufacturing facility and a leased office and warehouse space, both in Canton, Massachusetts, and a leased cGMP live viral fill/finish facility in Rockville, Maryland. Our Rockville facility is an FDA-licensed manufacturing facility under the regulatory regimes of the United States, Australia and Singapore. In November 2017, we received FDA approval of our supplemental BLA for the transfer of the upstream portion of the manufacturing process of ACAM2000 to our live viral manufacturing facility in Canton, Massachusetts.

Supplies and Raw Materials

We currently rely on contract manufacturers and other third parties to manufacture some of the supplies we require for pre-clinical studies and clinical trials, as well as supplies and raw materials used in the production of our products. Typically, we acquire these supplies and raw materials on a purchase order basis and, when possible, in quantities we believe adequate to meet our needs. We obtain Alhydrogel® adjuvant 2%, 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 single-source suppliers for other raw materials in our manufacturing process.

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 practicable, we pursue 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 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. 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 practicable, we also pursue registered trademarks for our products and product candidates. 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 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, and agency-specific regulations supplemental to FAR, which comprehensively regulate the award, formation, administration and performance of government contracts;
- the Defense Federal Acquisition Regulations, or DFARs, and agency-specific regulations supplemental to DFARs, which comprehensively regulate the award, formation, administration and performance of DoD government contracts;
- the Department of State Acquisition Regulation, or DOSAR, which regulates the relationship between a Department of State organization and a contractor or potential contractor;

- 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, including but not limited to ITAR (International Traffic in Arms 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. 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 rapidly 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.

First Responders Act. The First Responder Anthrax Preparedness Act of 2016 directs the Secretary of Homeland Security, in consultation with the Secretary of HHS, to establish a pilot program to provide short-dated vaccines from the SNS to emergency response providers on a voluntary basis.

Public Readiness and Emergency Preparedness Act. The Public Readiness and Emergency Preparedness Act, or PREP Act, was signed into law in December 2005. The PREP Act creates liability protection for manufacturers of biodefense countermeasures when the Secretary of HHS issues a declaration for their manufacture, administration or use. A PREP Act declaration is intended to provide liability protection from claims under federal or state law for loss arising out of the administration or use of a covered countermeasure under a government contract. The Secretary of HHS has issued PREP Act declarations identifying BioThrax, ACAM2000, Raxibacumab, Anthrasil, BAT and VIGIV, as covered countermeasures. These declarations expire in 2022. Manufacturers are not entitled to protection under the PREP Act in cases of willful misconduct and, accordingly, the PREP Act may not provide adequate protection from all claims made against us.

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

Product Development for Therapeutics and Vaccines

Pre-Clinical Testing. Before beginning testing of compounds in human subjects in the United States, stringent government requirements for pre-clinical data must be satisfied. Pre-clinical testing generally 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 generally perform pre-clinical safety and efficacy testing on our product candidates before we initiate clinical trials.

Animal Rule. For product candidates that are intended to treat or prevent infection from rare life-threatening diseases, conducting controlled clinical trials with human patients 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.

Investigational New Drug Application. Before clinical testing may begin, the results of pre-clinical 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, or IND, application. 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 period.

Clinical Trials. Clinical trials generally involve the administration of the product candidate to healthy human volunteers or to patients under the supervision of a qualified physician (also called an investigator) pursuant to an FDA-reviewed protocol. In certain cases, described below, animal studies may be used in place of human studies. 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 number of patients with the target disease or disorder and seek to assess the efficacy of the drug for specific 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, larger-scale studies of patients with the target disease or disorder to obtain definitive statistical evidence of the efficacy and safety of the proposed product candidate using a specific 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 patient population. As part of a product approval, the FDA may require that certain Phase 4 studies, which are sometimes called post-marketing commitment studies, be conducted post-approval.

Good Clinical Practice. All 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.

Marketing Approval – Biologics, Drugs and Vaccines

Biologics License Application/New Drug Application. For large molecule products, including products such as vaccines, products derived from blood and blood components, and antibodies and other recombinant proteins, all data obtained from a development program, including research and product development, manufacturing, pre-clinical and clinical trials, labeling and related information are submitted in a biologics licensing 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 Prescription Drug User Fee Act, or PDUFA, requires the FDA to review the application within 10 months of its 60-day filing date, although in practice, longer review times may 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 drug designation has been granted.

In reviewing a BLA or NDA, the FDA may grant approval, request more information or data, or deny the application if it determines the application does not provide an adequate basis for approval. 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 of the product candidate as 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. This 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 product.

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 granted fast track status to NuThrax in June 2011 and to ZIKV-IG in December 2017.

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. A manufacturer must request orphan drug designation prior to 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 in the United States include the following:

- BioThrax for post-exposure prophylaxis of disease following suspected or confirmed *B. anthracis* exposure, when administered in conjunction with recommended antibacterial drugs, with exclusivity though November 2022;
- Raxibacumab for the treatment of adult and pediatric patients with inhalational anthrax in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not available or not appropriate, with exclusivity through December 2019;
- Anthrasil for the treatment of toxemia associated with inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs, with exclusivity through March 2022; and
- BAT for the treatment of suspected or documented exposure to botulinum neurotoxin A, B, C, D, E, F or G, with exclusivity through March 2020.

Post-Approval Requirements. Any drug, biologic 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, cGMPs 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 facility 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 Anthrasil and VIGIV in the United States.

Vaccine and Therapeutic Product Lot Release and FDA Review. Because the manufacturing process for biological products is 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. All of our vaccines and immune globulin products are subject to lot release protocols by the FDA and other regulatory agencies. 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. The length of the 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 regulatory agency testing, if applicable.

Priority Review Vouchers. In 2007, the Food and Drug Administration Amendments Act added Section 524 to the Food, Drug, and Cosmetic Act and established the Neglected Tropical Disease Priority Review Voucher, or PRV, program. This PRV program was expanded in 2012 by the Food and Drug Administration Safety and Innovation Act to include rare pediatric diseases. In December 2016, the 21st Century Cures Act established a PRV program within the FDA for MCMs for chemical, biological,

radiological or nuclear threats, and those vaccines, therapeutics and MCMs, that prevent or treat material threat agents as identified in the Public Health Service Act. Under the PRV program, companies receive a special voucher which allows them to have a drug reviewed under FDA's priority review system, with the anticipation that it will accelerate the regulatory review to get the product to market more rapidly. Recipients of a PRV may transfer that voucher to another party for consideration.

Several of our investigational stage product candidates may be eligible for PRV under multiple PRV programs upon the product approval. We believe that ZIKV-IG (NP024), a human polyclonal antibody therapeutic being developed as a prophylaxis and treatment for Zika infections in at risk populations; and VLA1601, a vaccine being developed against Zika infection, may each have the potential for a PRV under the Neglected Tropical Disease PRV program. We believe that GC-072, the lead compound in the EV-035 series of broad-spectrum antibiotics being developed as an oral and intravenous treatment for *Burkholderia pseudomallei* infection; UNI-FLU, a universal influenza vaccine candidate for prevention of pandemic influenza infections; EBX-205, an oral therapeutic to treat acute bacterial skin and skin structure infection caused by biothreat pathogens, such as *B. anthrasis*, *F. tularensis*, *Yersinia pestis*, *Burkholderia mallei* and *Burkholderia pseudomallei*; and EBI-001, a pan-respiratory iminosugar antiviral intended for treatment of pandemic influenza, may each have the potential for a PRV under the MCM PRV program. We believe that FILOV (NP026), an equine polyclonal antibody therapeutic being developed to treat hemorrhagic fever caused by Filoviruses (Ebola, Marburg and Sudan), may have potential for a PRV under either the Neglected Tropical Disease PRV program or the MCM PRV program.

Marketing Approval – Devices

Devices may fall within the definition of a Medical Device or may be a Combination Product including both a device for delivery of a drug product and the drug product itself. 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 effectiveness. The RSDL Kit is regulated as a non-restricted Class II medical device. Our Trobigard auto-injector product is not currently approved or cleared by the FDA or any similar regulatory body and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

- Class I devices are those for which safety and effectiveness 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 effectiveness of the device. Review and clearance by the FDA for these devices is typically accomplished through the 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-cleared 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 effectiveness, 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 cleared prior to May 28, 1976, the proposed device is cleared based on a pre-amendment and is cleared 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. 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.

Combination Products, of the type described above, are subject to the BLA/NDA regulatory regime. Our Trobigard auto-injector is a combination product and is not currently approved or cleared by the FDA or any similar regulatory body and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

Foreign Regulation

Currently, we maintain a commercial presence in the United States and Canada as well as select foreign countries. We intend to 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). Additionally, each foreign country subjects medical devices to its own regulatory requirements. In the European Union, a harmonized medical device directive legislates approval requirements. Within this framework, the CE Mark, an attestation of conformity with the essential health, safety and environmental requirements and compliance with relevant European Union legislation, allows for the legal marketing of the product in all European Economic Area member states. Additionally, to the extent that a product is marketed outside of the United States, a facility may also be registered with applicable ex-U.S. regulatory authorities, who may also require inspections for compliance with local marketing regulations.

Anti-Corruption Laws

As part of the Affordable Care Act, the federal government 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.

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 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 Industry 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 the use of data, 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 16, 2018, we had 1,256 full-time employees. None of our employees is represented by a labor union or covered by collective bargaining agreements. We believe that our relations with our employees are good.

AVAILABLE INFORMATION

We maintain a website at www.emergentbiosolutions.com. We make available, free of charge on our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or

furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, or the Exchange Act, as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the Securities and Exchange Commission, or SEC.

We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. In addition, we intend to make available on our website all disclosures that are required to be posted by applicable law, the rules of the SEC or the New York Stock Exchange listing standards regarding any amendment to, or waiver of, our code of business conduct and ethics. We have included our website address as an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of, or incorporated by reference into, this Annual Report on Form 10-K.

ITEM 1A. RISK FACTORS

You should carefully consider 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 flows. 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 flows. 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 flows. The discussion of these factors is incorporated by reference into and considered an integral part of Part II, Item 7, "Management's Discussion and Analysis of Financial Conditions and Results of Operations."

GOVERNMENT CONTRACTING RISKS

We currently derive a substantial portion of our revenue from sales of BioThrax to our principal customer, the U.S. government. If the U.S. government's demand for and/or funding for procurement of BioThrax is substantially reduced, our business, financial condition, operating results and cash flow would be materially harmed.

We have derived, and expect for the foreseeable future to derive, a substantial portion of our revenue from sales of BioThrax, our anthrax vaccine licensed by the FDA to the U.S. government. In December 2016, we signed a follow-on procurement contract with the CDC for the delivery of approximately 29.4 million doses of BioThrax for placement into the SNS over a five-year period ending in September 2021. The potential value of this contract is approximately $911 million if all procurement options are exercised.

The procurement of doses of BioThrax by the CDC is subject to the availability of funding. We have no certainty that funding will be made available for the procurement of doses under the CDC contract. 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 submission of NuThrax for EUA pre-approval and eventual FDA licensure may not be approved by the FDA in a timely manner or at all. Delays in our ability to achieve such pre-approval and licensure could prevent us from realizing the full potential value of our BARDA contract for the advanced development and delivery of NuThrax.

In September 2016, we entered into a contract with HHS through BARDA for the advanced development and delivery of NuThrax, our next generation anthrax vaccine candidate. The contract, as modified in March 2017, is valued at up to approximately $1.5 billion.

We intend to submit an application with the FDA for EUA pre-approval of NuThrax this year, and although there can be no assurances, we currently anticipate that the FDA could authorize NuThrax for emergency use as early as 2019, triggering deliveries of NuThrax to the SNS for use in an emergency situation as early as 2019. However, the FDA does not have review deadlines with respect to such submissions and, therefore, the timing of any approval of an EUA pre-approval submission is uncertain. We cannot guarantee that the FDA will review our data in a timely manner, or that the FDA will accept the data when reviewed. The FDA may decide that our data are insufficient for EUA pre-approval and require additional pre-clinical, clinical or other studies and refuse to approve our application. If we are unsuccessful in obtaining EUA pre-approval for NuThrax and eventual FDA licensure in a timely manner or at all, we may not be able to realize the full potential value of the contract, which could have a material adverse effect on our future business, financial condition, operating results and cash flows.

In addition, if priorities for the SNS change, funding to procure any future doses of NuThrax may be limited or not available, and our future business, financial condition and operating results could be materially harmed.

Our U.S. government procurement and development contracts require ongoing funding decisions by the U.S. government. Reduced or discontinued funding of these contracts could cause our business, financial condition, operating results and cash flows to suffer materially.

The U.S. government is the principal customer for our PHT-focused MCMs and is the primary source of funds for the development of our product candidates in our development pipeline, most notably our NuThrax product candidate. We anticipate that the U.S. government will also be a principal customer for those MCMs that we successfully develop within our existing product development pipeline, as well as those we acquire in the future. Additionally, a significant portion of our revenue comes from U.S. government development contracts and grants. Over its lifetime, a U.S. government procurement or development program may be implemented through the award of many different individual contracts and subcontracts. The funding for such government programs is subject to Congressional appropriations, generally made on a fiscal year basis, even for programs designed to continue for several years. For example, sales of BioThrax to be supplied under our procurement contract with the CDC are subject to the availability of funding, mostly from annual appropriations. These appropriations can be subject to political considerations and stringent budgetary constraints.

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 September 2016 contract award from BARDA for the development and delivery to the SNS of NuThrax for post-exposure prophylaxis of anthrax disease consists of a five-year base period of performance valued at approximately $200 million. The contract award also includes options for the delivery of additional doses of NuThrax to the SNS and options for an additional clinical study and post-marketing commitments which if both were to be exercised in full, would increase the total contract value to up to $1.5 billion. If levels of government expenditures and authorizations for public health countermeasure preparedness 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 existing contracts, our business, revenues, operating results and cash flows would suffer.

There can be no assurance that we will be able to secure follow-on procurement contracts with the U.S. government upon the expiration of any of our current product procurement contracts.

Our revenue is substantially dependent upon product procurement contracts with the U.S. government and foreign governments for our PHT products. Upon the expiration of a procurement contract, we may not be able to negotiate a follow-on procurement contract for the particular product for a similar product volume, period of performance, pricing or other terms, or at all. The inability to secure a similar or increased procurement contract could materially affect our business, revenues, operating results and cash flows. For example, the CDC procurement contract for ACAM2000 that we recently acquired in our acquisition of the ACAM2000 business from Sanofi will be up for renewal or extension in March 2018. The BARDA procurement contract for Raxibacumab that we recently assumed responsibility for in our acquisition of Raxibacumab from GSK expires in 2019. Our CDC procurement contract for BioThrax expires in 2021. We intend to negotiate follow-on procurement contracts for each of our PHT products upon the expiration of a related procurement contract, but there can be no assurance that we will be successful in doing so. Even if we are successful in negotiating a follow-on procurement contract, it may be for a lower product volume, over a shorter period of performance or be on less favorable pricing or other terms. An inability to secure follow-on procurement contracts for our products could materially and adversely affect our revenues, operating results, cash flows and business prospects.

The government contracting process is typically a competitive bidding process and involves unique risks and requirements.

Our business involves government contracts and grants, which may be awarded through competitive bidding. Competitive bidding for government contracts presents a number of risks and requirements, including:

- the possibility that we may be ineligible to respond to a request for proposal issued by the government;
- 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 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 could 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 either the development of our new product candidates or for the procurement of our existing products addressing PHTs, and may instead award such contracts to our competitors. If we are unable to secure particular contracts, we may not be able to operate in the market for products that are provided under those

contracts. 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 we will be required to secure and, if applicable, perform under 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 reputation and relationship with the U.S. government, which could have a material adverse effect on our business, financial condition and operating results.

As a manufacturer and supplier of MCMs to the U.S. government addressing PHTs, we must comply with numerous laws and regulations relating to the procurement, formation, administration and performance of government contracts. These laws and regulations govern how we transact business with our government clients and, in some instances, impose additional costs and related obligations on our business operations. Among the most significant government contracting regulations that affect our business are:

- the FAR and agency-specific regulations supplemental to FAR, which comprehensively regulate the award, formation, administration and performance of government contracts;
- the DFARs and agency-specific regulations supplemental to DFARs, which comprehensively regulate the award, formation, administration and performance of the DoD government contracts;
- the DOSAR, which regulates the relationship between a Department of State organization and a contractor or potential contractor;
- 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, including but not limited to International Traffic in Arms 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. Even though we take significant precautions to identify, prevent and deter fraud, misconduct and non-compliance, we face the risk that our personnel or outside partners may engage in misconduct, fraud or improper activities. 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 suffer significant reputational harm. Loss of our status as an eligible government contractor would have a material adverse effect on our business.

The amount we are paid under our fixed price government procurement contracts is based on estimates we have made of the time, resources and expenses required for us to perform under 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.

Our current procurement contracts with HHS and the DoD are fixed price contracts. We expect that future procurement contracts we successfully secure with the U.S. government would also 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 business, 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 procurement contract or to fund additional development under a development contract;
- decline to renew a procurement 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 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. All of our contracts, both development and procurement, with the U.S. government, are terminable at the U.S. government's convenience with these potential consequences.

In addition, 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.

REGULATORY AND COMPLIANCE RISKS

Our long-term success depends, in part, upon our ability to develop, receive regulatory approval for and commercialize product candidates we develop or acquire and, if we are not successful, our business, financial condition 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.

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 BLA to the FDA. Ordinarily, the FDA requires a company to support a BLA with substantial evidence of the product candidate's safety and efficacy in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted.

However, NuThrax and many of our MCM product candidates, for example, are subject to a different regulatory approval pathway under the FDA's "Animal Rule". The Animal Rule provides a regulatory pathway for drug and biologic products targeting indications for which human efficacy studies are not feasible or would be unethical. Instead, efficacy must be demonstrated, in part, by utilizing animal models rather than testing in humans. We cannot guarantee that the FDA will permit us to proceed with licensure of NuThrax or any of our PHT MCM 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 product candidate's clinical benefit and to assess its safety when used as indicated. We cannot guarantee that we will be able to meet this regulatory requirement even if one or more of our product candidates are approved under the Animal Rule.

The process of obtaining these regulatory approvals is expensive, often takes many years if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidate involved. Changes in the regulatory approval process during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review process 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.

We intend to transfer the manufacturing of Raxibacumab, which we recently acquired from GSK, to our facilities in Baltimore, Maryland, and this transfer of manufacturing operations requires FDA approval.

Under our arrangements with GSK for our acquisition of the Raxibacumab product, we will continue to purchase product from GSK to satisfy deliveries to the SNS under the current BARDA contract, which expires in 2019. We intend to seek FDA

approval to transfer the manufacturing of Raxibacumab to our Baltimore, Maryland manufacturing facilities and currently anticipate FDA approval of this technology transfer in 2020. Approval of this technology transfer may involve complications or may not be secured on a timely basis or at all. Any delay in the approval of this anticipated technology transfer would delay our expected benefits and synergies from this product acquisition and could materially harm our business, revenues, operating results and cash flows. Until approval of this technology transfer, we must rely on GSK to supply product to us to satisfy deliveries to the SNS under the BARDA contract, and GSK may fail to meet delivery obligations, which could result in our inability to satisfy requirements under the BARDA contract.

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

Any vaccine, therapeutic product or medical device for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies. Our approved products are subject to these requirements and ongoing review. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, cGMP, requirements relating to potency and stability, 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.

Our regulators enforce 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. Health Canada may conduct similar inspections of our facilities where Canadian marketed products are produced, or related formulation and filling operations are conducted. The FDA, Health Canada, and other foreign regulatory agencies conduct periodic inspections of our facilities. For example, our Lansing Building 55 facility was inspected most recently by the FDA in June 2016, our Lansing Building 12 facility was inspected most recently by the FDA in April 2016, our Winnipeg manufacturing facility was inspected most recently by the FDA in May 2017 and Health Canada in November 2016, our Canton, Massachusetts manufacturing facility was inspected most recently by the FDA in December 2017, our Rockville facility was inspected most recently by the FDA in March 2017, and our Baltimore (Camden) facility was most recently inspected by the Health Products Regulatory Authority of Ireland in February 2017, FDA in January 2017 and Health Canada in October 2016. Following several of these inspections, regulatory authorities issued inspectional observations, some of which were significant, but all of which are being, or have been, addressed through corrective actions. If, in connection with any future inspection, regulatory authorities find that we are not in substantial compliance with all applicable requirements, or if they are not satisfied with the corrective actions we take, our regulators 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 should we fail to comply with regulatory requirements, or later discover previously unknown problems with our products or manufacturing processes. For instance, our products are tested regularly to determine if they satisfy potency and stability requirements for their required shelf lives. 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.

Additionally, companies may not promote drugs for "off-label" uses (*i.e.,* uses that are not described in the product's labeling and that differ from those approved by the applicable regulatory agencies). A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies (such as entering into corporate integrity agreements with the U.S. government), as well as criminal sanctions. If our employees or agents engage in "off-label" marketing of any of our products, we could be subject to civil or criminal investigations, monetary and injunctive penalties, which could adversely impact our ability to conduct business in certain markets, negatively affect our financial condition and results of operations, and damage our reputation.

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 intend to sell certain of 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 beyond that required by the FDA. 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 successfully commercialize our products internationally. We have limited experience in preparing, filing and prosecuting the applications necessary to gain foreign regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process.

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 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 are found to be in violation of the FCPA or similar foreign laws despite our training and compliance efforts, 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

Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture BioThrax or our other products, which would harm our business, financial condition and operating results.

An interruption in our manufacturing operations in Lansing, Michigan, could result in our inability to produce BioThrax for delivery to satisfy the product demands of our customers in a timely manner, which would reduce our revenues and materially harm our business, financial condition, operating results and cash flows. 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;
- injunctions;
- damage to or destruction of the facility; and
- product contamination or tampering.

Providers of PHT countermeasures could be subject to an increased risk of terrorist activities. The U.S. government has designated both our Lansing, Michigan and our Bayview bulk manufacturing facility in Baltimore, Maryland 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 facilities in Winnipeg, Manitoba, Canada; other Baltimore, Maryland facilities; and Canton, Massachusetts; Rockville, Maryland; and Hattiesburg, Mississippi facilities. Any such disruption, damage, or destruction of these facilities could impede our ability to manufacture our products, our product candidates and our ability to produce products for external customers, 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.

We may not be able to utilize the full manufacturing capacity of our manufacturing facilities, which could impact our future revenues and materially harm our business, financial condition, operating results and cash flows.

Despite our ongoing efforts to optimize the utilization of our manufacturing infrastructure (including bulk, fill/finish, support, aseptic filling, lyophilization, final packaging), we may not be able to realize full utilization, which could adversely affect our future revenues, financial condition, operating results and cash flows.

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

BioThrax, Raxibacumab, ACAM2000, Anthrasil, BAT, VIGIV, and many of our current product candidates, including NuThrax, 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 during manufacturing may arise 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 including from particulates among other things, filtration, filling, labeling, packaging, storage and shipping, potency and stability issues and other 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, including warning letters and other restrictions on the marketing or manufacturing of a product, 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.

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 and adversely impact our revenues.

Manufacturing 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 required to obtain FDA approval prior to the release of each lot of BioThrax, which may not be obtained on a timely basis or at all.

FDA approval is required for the release of each lot of BioThrax. A "lot" is approximately 181,000 doses. We are not 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 reference lot and periodically produce and qualify a new reference lot to replace the existing reference lot. If we are not able to produce and qualify a new reference 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 materially harm our business, financial condition, operating results and cash flows.

If we are unable to obtain supplies for the manufacture of our products and product candidates in sufficient quantities, at an acceptable cost and in acceptable quality, our ability to manufacture or to develop and commercialize our products and product candidates could be impaired, which could materially harm our revenues, lead to a termination of one or more of our contracts, lead to delays in clinical trials or otherwise materially 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, and currently rely on a single-source supplier to manufacture Raxibacumab. We also rely on single-source suppliers for the sponge applicator device and the active ingredient used to make RSDL as well as the specialty plasma in our hyperimmune specialty plasma products and certain ingredients for ACAM2000. A disruption in the availability of such materials or services from these suppliers or in the quality of the material provided by such 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 materially harm our business, financial condition and operating results.

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 and viruses, 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, financial condition and results of operations. 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.

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, structuring, 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 biopharmaceutical field. These companies may have a competitive advantage over us due to their size, cash resources, cost of capital, effective tax rate 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 company or product, 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, our recently completed acquisition of the ACAM2000 business required initial payments of $117.5 million and an additional milestone payment of $7.5 million on the achievement of a regulatory event. In addition, our recently completed acquisition of Raxibacumab required a $76 million upfront payment and may require up to $20 million in additional future milestone payments.

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, and we could be compelled to record significant impairment charges to write-down the carrying value of our acquired intangible assets, which could materially harm our financial condition and operating results.

Our failure to successfully integrate acquired assets into our operations could adversely affect our ability to realize the benefits of such acquisitions and, therefore, to grow our business.

We may not be able to integrate any acquired business successfully 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 or products 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;
- successfully executing technology transfers and obtaining required regulatory approvals;
- 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 pending and 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 and our financial condition and operating results.

COMPETITIVE AND POLITICAL 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 and medical technology products is highly competitive and subject to rapid technological advances. We may face future competition from other companies and governments, universities and other non-profit research organizations in 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. 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 have greater resources to devote to marketing or selling their products, adapt more quickly to new technologies, scientific advances or patient preferences and needs, 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 products or product candidates addressing PHT preparedness that are competing with us for both U.S. government procurement and development resources. Many of our competitors have greater financial, technical and marketing resources than we do. Our competitors may receive patent protection that dominates, blocks or adversely affects our products or product candidates.

Any reduction in demand for our products or reduction or loss of development funding for our products or product candidates in favor of a competing product could lead to a loss of market share for our products and cause reduced revenues, margins and levels of profitability for us, which could adversely affect our business, financial condition and operating results.

Our Biologic Products may face risks of competition from biosimilar manufacturers.

Competition for BioThrax, Raxibacumab, ACAM2000, Anthrasil, BAT and VIGIV, otherwise referred to as 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. The specific regulatory framework for this biosimilar approval path 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. 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, financial condition 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 counter the potential impact of PHTs, whether CBRNE or EID, are subject to changing political and social environments. The political responses and social awareness of the risks of these threats on military personnel or civilians may vary over time. If the threat of terrorism were to decline, then the public perception of the risk on public health and safety may be reduced. This perception, as well as political or social pressures, could delay or cause resistance to bringing our products in development to market or limit pricing or purchases of our products, any of which could negatively affect our revenues and our financial condition and operating results.

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 PHT countermeasures and thereby limit the demand for our products, which would adversely affect our business, financial condition and operating results.

PRODUCT DEVELOPMENT AND COMMERCIALIZATION RISKS

Our growth 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 effort and financial resources in the development of our vaccines, therapeutics and medical device 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 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 manufacturing that meets FDA or other foreign regulatory requirements;
- successful program partnering;
- 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;
- 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 and other customers.

Under certain circumstances, we might sell unapproved MCMs to governmental entities. While this is permissible in some cases, the extent to which we may be able to lawfully market and sell unapproved products in many jurisdictions may be unclear or ambiguous. Such sales could subject us to regulatory enforcement action, product liability and reputational risk.

Under certain circumstances, MCMs may be procured by government entities prior to approval by FDA or other regulatory authorities. In the United States, the Project BioShield Act of 2004, or Project BioShield, permits the Secretary of HHS to contract to purchase MCMs for the SNS prior to FDA approval of the countermeasure in specified circumstances. Project BioShield and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 also allow the FDA Commissioner to authorize the emergency use of medical products that have not yet been approved by the FDA under an EUA pre-approval. Absent an applicable exception, our MCM product candidates generally will have to be approved by FDA or other regulatory authorities through traditional pathways before we can sell those products to governments. Additionally, the laws in certain jurisdictions regarding the ability of government entities to purchase unapproved product candidates are ambiguous, and the permissibility of exporting unapproved products from the United States and importing them to foreign countries may be unclear. Nevertheless, governmental bodies, such as U.S. federal entities other than HHS, state and local governments within the United States, and foreign governments, may seek to procure our MCM product candidates that are not yet approved. If so, we would expect to assess the permissibility and liability implications of marketing our product candidates to such entities on a case-by-case basis, which presents certain challenges, both in the case of U.S. and foreign governments, and particularly under emergency conditions. In addition, agencies or branches of one country's government may take different positions regarding the permissibility of such sales than another country's government or even other agencies or branches of the same government. If we determine that we believe such activities are permissible, local enforcement authorities could disagree with our conclusion and take enforcement action against us.

In addition, the sale of unapproved products also could give rise to product liability claims for which we may not be able to obtain indemnification or insurance coverage. For example, liability protections applicable to claims arising under U.S. law and resulting from the use of certain unlicensed products, such as a declaration issued under the Public Readiness and Emergency Preparedness Act, or the PREP Act, may not cover claims arising under non-U.S. law.

Regardless of the permissibility and liability risks, in the event a user of one or more of our products suffers an adverse event, we may be subject to additional reputational risk if the product has not been approved by the FDA or the corresponding regulatory authority of another country particularly because we will not have approved labeling regarding the safety or efficacy of those products. In addition, legislatures and other governmental bodies that have oversight responsibility for procuring agencies may raise concerns after the fact even if procurement was permissible at the time, which could result in negative publicity, reputational risk and harm to our business prospects.

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. Failure to obtain regulatory approval for product candidates, particularly in the United States, could materially and adversely affect our financial resources, results of operations and cash flows.

Before obtaining regulatory approval for the marketing of our product candidates, we and our collaborative partners, where applicable, must conduct 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 product candidates addressing CBRNE threats, 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 Project BioShield, the Secretary of HHS can contract to purchase MCMs 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. If our product candidates are not selected under this Project BioShield authority, they generally will have to be approved by the FDA through traditional regulatory mechanisms for distribution in the United States.

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;
- drug immunogenicity;
- lack of efficacy of product candidates during the trials;
- government or regulatory restrictions or delays; and
- greater than anticipated costs of trials.

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, financial condition, results of operations and cash flows 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, which may not be approved.

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 product development 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. We may change or refocus our existing product development, commercialization and manufacturing activities based on government funding decisions. 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 or choose candidates for which government development funds are not available. 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, financial condition, results of operations and cash flows could be materially harmed.

Our success, especially with respect to our small molecule product candidates, 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 biopharmaceutical field 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 patent applications related to patent families in the ordinary course of business. In the future we may 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. In addition, some countries do not grant patent claims directed to methods of treating humans, and, in these countries, patent protection may not be available at all to protect our products or product candidates.

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, are unenforceable, or must be interpreted narrowly and that we do not have the right to stop another 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, operating results and cash flows 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 intellectual property rights in which we have an interest and, although we may have the right to assume the maintenance and defense of such intellectual property rights if these third parties do not do so, our ability to maintain and defend such 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 NuThrax anthrax vaccine product candidate.

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, operating results, and cash flows 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 and adversely affect our business, financial condition, operating results and cash flows.

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 for 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, these could materially harm our business, financial condition, operating results and cash flows.

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 subject us to damages, which may be material.

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.

We also rely upon unpatented proprietary technology, processes and know-how, particularly as to our proprietary manufacturing processes. Because we do not have patent protection for all of our current products, our only other intellectual property protection for 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 confidential information and 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 materially and adversely impact our business.

FINANCIAL RISKS

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.

We recently entered into a five-year $200 million syndicated senior secured revolving credit facility that replaced our prior $100 million facility, which was scheduled to expire in December 2018. The senior secured credit facility also includes a $100 million accordion feature in revolver or incremental term loans, at our option, which could expand total commitments to up to $300 million subject to certain conditions and requirements under the credit agreement. We may also 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 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, and our results of operations and financial condition.

We may require significant additional funding to grow our business, including efforts 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, 2017, we had approximately $178.3 million of cash and cash equivalents. 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 and integrate companies, businesses, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs;
- the extent to which we repurchase additional common stock under a new share repurchase program; 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. In May 2015, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer" under SEC rules, this shelf registration statement, effective until May 2018, allows us to issue an unrestricted amount of equity, debt and certain other types of securities through one or more future primary or secondary offerings. If we do not file a new shelf registration statement prior to May 2018, the existing shelf registration statement will expire and we will not be able to publicly raise capital or issue debt until a new registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatically effective shelf registration statement at a future date when we may need to raise funds publicly.

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 2.875% Convertible Senior Notes due 2021, or 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. However, our senior secured credit facility restricts our ability to incur additional indebtedness, including secured indebtedness.

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 second quarter of 2016 and in each of the first quarters of 2015, 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. We may not be able to achieve consistent profitability on a quarterly basis or sustain or increase profitability on an annual basis.

THE SPIN-OFF OF OUR BIOSCIENCES BUSINESS

If the spin-off distribution on August 1, 2016 of all of the outstanding shares of Aptevo Therapeutics Inc. common stock to our stockholders does not qualify as a tax-free transaction for U.S. federal income tax purposes, we and our stockholders could be subject to significant tax liabilities.

It was our intention that our distribution on August 1, 2016 of all of the outstanding shares of Aptevo common stock to our stockholders, or the Distribution, together with certain related transactions, qualify as a tax-free transaction described under

Sections 355 and 368(a)(1)(D) of the Internal Revenue Code of 1986, as amended, or the Code. In anticipation of the Distribution, we received a favorable private letter ruling from the Internal Revenue Service, or the IRS, regarding certain U.S. federal income tax matters relating to the Distribution and certain related transactions and an opinion of counsel substantially to the effect that, for U.S. federal income tax purposes, the Distribution, together with certain related transactions, will qualify as a transaction described under Sections 355 and 368(a)(1)(D) of the Code. A "private letter ruling," is a written statement issued to a taxpayer by an Associate Chief Counsel Office of the Office of Chief Counsel that interprets and applies the tax laws to a specific set of facts. Our private letter ruling is based on certain facts and representations submitted by us to the IRS and the opinion of counsel was based upon and relied on, among other things, the IRS private letter ruling and certain facts and assumptions, as well as certain representations and covenants of us and Aptevo contained in a tax matters agreement and certain representations contained in representation letters provided by us, Aptevo and certain stockholders to such counsel, including representations and covenants relating to the past and future conduct of us, Aptevo and such stockholders. If any of these facts, assumptions, representations, or covenants are, or become, inaccurate or incomplete, the IRS private letter ruling and/or the opinion of counsel may be invalid and the conclusions reached therein could be jeopardized and, as a result, the Distribution, together with certain related transactions, could fail to qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code for U.S. federal income tax purposes.

In addition, the IRS private letter ruling only addresses certain limited matters relevant to determining whether the Distribution, together with certain related transactions, qualifies as a transaction described under Sections 355 and 368(a)(1)(D) of the Code, and the opinion of counsel only represents the judgment of such counsel, which is not binding on the IRS or any court. Accordingly, notwithstanding the IRS private letter ruling and the opinion of counsel, there can be no assurance that the IRS will not assert that the Distribution, together with certain related transactions, should be treated as a taxable transaction for U.S. federal income tax purposes or that a court would not sustain such a challenge.

If the Distribution, together with certain related transactions, fails to qualify as a tax-free transaction described under Sections 355 and 368(a)(1)(D) of the Code, for U.S. federal income tax purposes, in general, (i) we would recognize taxable gain on the Distribution equal to the amount by which the fair market value of the Aptevo shares distributed to our shareholders exceeded our tax basis in the Aptevo shares and (ii) each of our shareholders who received Aptevo shares in the Distribution would be treated as receiving a taxable distribution equal to the fair market value of the Aptevo shares received by such shareholder.

Under the tax matters agreement that we entered into with Aptevo in connection with the spin-off, Aptevo may be required to indemnify us against any tax liabilities and related expenses resulting from the failure of the Distribution, together with certain related transactions, to qualify as a transaction described under Sections 355 and 368(a)(1)(D) of the Code to the extent that the failure to so qualify is attributable to actions, events or transactions relating to Aptevo's stock, assets or business, or a breach of the relevant representations or covenants made by Aptevo in the tax matters agreement or the IRS private letter ruling or in the representation letters provided to our counsel for purposes of their opinion. Any such indemnity obligations could be material, and there can be no assurance that Aptevo will be able to pay any such indemnification.

To preserve the tax-free treatment of the Distribution, together with certain related transactions, and in addition to Aptevo's indemnity obligation, the tax matters agreement restricts Aptevo from taking any action that prevents such transactions from being tax-free for U.S. federal income tax purposes. In particular, for the two-year period following the Distribution, Aptevo is restricted from taking certain actions (including restrictions on share issuances, business combinations, sales of assets, amendments to organizational documents and similar transactions) that could cause the Distribution, together with certain related transactions, to fail to qualify as a tax-free transaction for U.S. federal income tax purposes. There can be no assurance that Aptevo will comply with these restrictions. Failure of Aptevo to satisfy its obligations could have a substantial impact on our tax obligations, consolidated financial condition and cash flows.

In connection with Aptevo's separation from us, Aptevo agreed to indemnify us for certain matters. This indemnity may not be sufficient to hold us harmless from the full amount of losses that we may incur in connection with these matters, and Aptevo may not be able to satisfy its indemnification obligations to us.

Pursuant to the agreements that we entered into with Aptevo at the time of Aptevo's separation from us, Aptevo agreed to indemnify us for certain matters, including liabilities related to Aptevo's business or for which Aptevo otherwise agreed to be responsible in the separation. This indemnity from Aptevo may not be sufficient to protect us against the full amount of losses that we may incur in connection with these matters, including if third parties assert claims against us for liabilities that were allocated to Aptevo in the separation. Moreover, Aptevo may dispute its indemnification obligation to us or have insufficient resources to satisfy its indemnification obligations to us. Even if we ultimately succeed in recovering from Aptevo the amount of any losses that we incur in connection with these matters, the recovery could take a substantial amount of time and we may be required to bear these losses ourselves while we seek recovery. Each of these risks could negatively affect our business, results of operations and financial condition.

OTHER BUSINESS RISKS

Pending litigation and legal proceedings and the impact of any finding of liability or damages could adversely impact our business, financial condition and results of operations.

From time to time, we may be named as a defendant in various legal actions or other proceedings. Certain of these actions include and future actual or threatened legal actions may include, claims for substantial and indeterminate amounts of damages, or may result in other action adverse to us.

For example, a purported class action lawsuit was filed against us and several of our senior officers and directors in the United States District Court for the District of Maryland seeking unspecified damages on behalf of a putative class of persons who purchased or otherwise acquired our common stock between January 11, 2016 and June 21, 2016. The complaint, as amended on December 27, 2016, alleges, among other things, that we made materially false and misleading statements about the government's demand for BioThrax and expectations that our five-year exclusive procurement contract with HHS would be renewed and omitted certain material facts.

The results of this lawsuit and possible other future legal proceedings cannot be predicted with certainty. Accordingly, we cannot determine whether our insurance coverage would be sufficient to cover the costs or potential losses, if any. Regardless of merit, litigation may be both time-consuming and disruptive to our operations and cause significant expense and diversion of management attention. If we do not prevail in the purported class action lawsuit or in other future legal proceedings, we may be faced with significant monetary damages or injunctive relief against us that may adversely affect our business, financial condition and results of operations.

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 liability protection 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 liability protection from all claims under federal or state law for loss arising out of the administration or use of a covered countermeasure under a government contract. The Secretary of HHS has issued PREP Act declarations identifying certain of our products, namely BioThrax, ACAM2000, Raxibacumab, Anthrasil, BAT and VIGIV, as covered countermeasures. These declarations expire in 2022. 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, certain of our products, namely 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, Raxibacumab, ACAM2000, Anthrasil, BAT 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.

The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. If we identify a material weakness in our internal control over financial reporting, it could have an adverse effect on our business and financial results and our ability to meet our reporting obligations could be negatively affected, each of which could negatively affect the trading price of our common stock.

Internal control over financial reporting can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements and may not prevent or detect misstatements. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Failure to maintain effective internal control over financial reporting, or lapses in disclosure controls and procedures, could impact our financial information and disclosures, require significant resources to remediate, and expose us to legal or regulatory proceedings.

We regularly review and update our internal controls and disclosure controls and procedures. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Our system of internal controls, however well-designed, can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial reporting, and the trading price of our common stock could be negatively affected.

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 materially and 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 to 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 16, 2018, Mr. El-Hibri was the beneficial owner of approximately 11% of our outstanding common stock. As a result, Mr. El-Hibri could exercise substantial influence over all corporate actions requiring board or stockholder approval, including a change of control, or 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;
- 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, we are subject to Section 203 of the Delaware General Corporation Law, or Section 203. In general and subject to certain exceptions, Section 203 prohibits a publicly-held 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 Board of Directors may implement a new stockholder rights plan without stockholder approval, which 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.

Our Board of Directors may implement a stockholder rights plan without stockholder approval. We previously implemented a stockholder rights plan, which expired on November 14, 2016. Under our prior stockholder rights plan, we issued to each of our stockholders one preferred stock purchase right for each outstanding share of our common stock. Each right, when exercisable, would have entitled 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 was 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.

Our Board of Directors may implement a new stockholder rights plan, which may have anti-takeover effects, potentially preventing a change in control of us in instances in which some stockholders may believe a change in control is in their best interests. This could 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 16, 2018, our common stock has traded as high as $51.25 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 has 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:

- contracts, decisions and procurement policies by the U.S. government affecting BioThrax and our other products and product candidates;
- the success of competitive products or technologies;
- results of clinical and non-clinical trials of our product candidates;
- announcements of acquisitions, financings or other transactions by us;
- litigation or legal proceedings;

- 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 limits 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 16, 2018, have the right to require us to register these shares of common stock under specified circumstances. In May 2015, we filed an automatic shelf registration statement, which immediately became effective under SEC rules. For so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer" under SEC rules, this shelf registration statement, effective until May 2018, would provide for a secondary offering of these shares from time to time.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

The following table sets forth the location and general character of our materially important physical properties and whether they are owned or leased:

Location	Use	Approximate square feet Owned/leased	Owned/leased
Lansing, Michigan	Manufacturing operations facilities, office space and laboratory space	336,000	Owned
Winnipeg, Manitoba, Canada	Manufacturing operations facilities, office space and laboratory space	315,000	Owned
Gaithersburg, Maryland	Office space and rental real estate	130,000	Owned
Baltimore, Maryland (Camden)	Manufacturing facilities and office and laboratory space	78,000	Owned
Rockville, Maryland	Fill/finish facility	59,000	Lease expires 2023
Canton, Massachusetts	Manufacturing facilities and office and warehouse space	57,000	Owned
Baltimore, Maryland (Bayview)	Manufacturing facilities and office and laboratory space	56,000	Owned
Gaithersburg, Maryland	Office and laboratory space	48,000	Owned
Baltimore, Maryland (Camden)	Office and warehouse space	41,000	Lease expires 2027
Canton, Massachusetts	Office and warehouse space	27,000	Lease expires 2023
Hattiesburg, Mississippi	Manufacturing facilities	9,000	Lease expires 2026

Lansing, Michigan. We own a multi-building campus on approximately 12.5 acres in Lansing, Michigan that includes 336,000 square feet of facilities for BioThrax manufacturing and NuThrax development operations, including fermentation, filtration and formulation, as well as for raw material storage and in-process and final product warehousing.

Winnipeg, Manitoba, Canada. We own 315,000 square feet of facilities in Winnipeg, Manitoba, Canada including a manufacturing facility focused primarily on plasma-derived hyperimmune therapeutics and a manufacturing facility focused primarily on bacterial fermentation, with a total size of 336,000 square feet.

Gaithersburg, Maryland. We own a 130,000 square foot building in Gaithersburg, Maryland, a portion of which we utilize as our corporate headquarters, and we rent out a portion of the remainder of the space.

Baltimore, Maryland (Camden). We own a 78,000 square foot manufacturing facility 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.

Rockville, Maryland. We lease a 59,000 square foot fill/finish facility in Rockville, Maryland. We are using this facility for the processing of formulated bulk ACAM2000 into final packaged vaccine vials, but it also provides us with additional viral fill/finish capacity for third party customers. This facility is currently a single product-facility but we intend to expand the facility into a multi-product viral fill/finish contract manufacturing facility.

Canton, Massachusetts. We own a 57,000 square foot manufacturing facility in Canton, Massachusetts. This facility is equipped with large-scale bioreactors for cell culture propagation and viral infection, as well as downstream processing equipment for the production of live viral vaccine products, including ACAM2000.

Baltimore, Maryland (Bayview). 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. The future use of this facility will be dependent on the progress of our existing development programs, the success of our contract manufacturing business and the outcome of our efforts to acquire new product candidates.

Gaithersburg, Maryland. We own an additional facility in Gaithersburg, Maryland that is approximately 48,000 square feet and contains a combination of laboratory and office space.

Baltimore, Maryland (Camden). We lease office and warehouse space in Baltimore that is approximately 41,000 square feet, which primarily supports our contract manufacturing business.

Canton, Massachusetts. We lease additional space that is approximately 27,000 square feet in Canton Massachusetts. This leased facility contains a combination of office space and excess warehouse capacity.

Hattiesburg, Mississippi. We lease a 900 square foot 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 in Hattiesburg, Mississippi.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in various legal proceedings and claims that arise in or outside the ordinary course of our business. We believe that the outcome of these pending legal proceedings in the aggregate is unlikely to have a material adverse effect on our business, financial condition or results of operations.

Purported Shareholder Class Action Lawsuit Filed July 19, 2016

On July 19, 2016, Plaintiff William Sponn, or Sponn, filed a putative class action complaint in the United States District Court for the District of Maryland on behalf of purchasers of the Company's common stock between January 11, 2016 and June 21, 2016, inclusive, or the Class Period, seeking to pursue remedies under the Securities Exchange Act of 1934 against the Company and certain of its senior officers and directors, collectively, the Defendants. The complaint alleges, among other things, that the Company made materially false and misleading statements about the government's demand for BioThrax and expectations that the Company's five-year exclusive procurement contract with HHS would be renewed and omitted certain material facts. Sponn is seeking unspecified damages, including legal costs. On October 25, 2016, the Court added City of Cape Coral Municipal Firefighters' Retirement Plan and City of Sunrise Police Officers' Retirement Plan as plaintiffs and appointed them Lead Plaintiffs and Robins Geller Rudman & Dowd LLP as Lead Counsel. On December 27, 2016, the Plaintiffs filed an amended complaint that cites the same class period, names the same defendants and makes similar allegations to the original complaint. The Company filed a Motion to Dismiss on February 27, 2017. The Plaintiffs filed an opposition brief on April 28, 2017. The Company's Motion to Dismiss was heard and denied on July 6, 2017. The Company filed its answer on July 28, 2017. The parties are currently in the process of exchanging discovery. The Plaintiffs' filed an amended motion for class certification and appointment of Sponn and Geoffrey L. Flagstad as lead plaintiffs on December 20, 2017. A hearing on that motion is set for May 2, 2018. The Defendants believe that the allegations in the complaint are without merit and intend to defend themselves vigorously against those claims.

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, 2017 and December 31, 2016:

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year Ended December 31, 2017				
High	$ 35.00	$ 34.90	$ 40.60	$ 47.90
Low	$ 28.06	$ 27.94	$ 32.48	$ 36.38
Year Ended December 31, 2016				
High	$ 39.29	$ 44.38	$ 34.10	$ 36.64
Low	$ 31.26	$ 27.01	$ 26.12	$ 24.47

As of February 16, 2018, the closing price per share of our common stock on the New York Stock Exchange was $49.96 and we had 25 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 have no plans to pay dividends.

Recent Sales of Unregistered Securities

On November 14, 2017, or the Announcement Date, we announced the termination of the conversion rights on our outstanding Senior Convertible Notes, effective as of December 29, 2017, or Conversion Rights Termination Date. In response to such announcement, 8,508,056 shares of common stock were issued to holders of the Senior Convertible Notes who sought to convert their Senior Convertible Notes during the period between the Announcement Date and the Conversion Rights Termination Date. The issuances of common stock upon the conversions described above were exempt from registration under the Securities Act of 1933, as amended, pursuant to Section 3(a)(9).

Use of Proceeds

Not applicable.

Purchases of Equity Securities

The table below presents information regarding shares of our common stock that we repurchased during the year ended December 31, 2017.

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
First quarter of 2017 (1)	2,719	$ 30.63	-	$ -
Fourth quarter of 2017 (2)	788,894	41.84	788,894	16,992,675
Total	791,613	$ 41.81	788,894	$16,992,675

(1) In February 2017, 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 officer in which we acquired 2,719 shares of common stock as payment for the exercise price of 3,662 stock options.

(2) On July 14, 2016, our board of directors authorized management to repurchase, from time to time, up to an aggregate of $50 million of our common stock under a board-approved share repurchase program. The term of the board authorization of the repurchase program was until December 31, 2017. Repurchased shares will be available for use in connection with our stock plans and for other corporate purposes.

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, 2017, 2016, and 2015 and the consolidated balance sheet data as of December 31, 2017, and 2016 from our audited consolidated financial statements, which are included in this annual report on Form 10-K. All results and data in the tables below reflect continuing operations, unless otherwise noted. As a result, the data presented below will not necessarily agree to previously issued financial statements. See Note 3, "Discontinued operations" in the Notes to consolidated financial statements in Item 8 of this Form 10-K for additional information on discontinued operations. 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)	**2017**	**2016**	**2015**	**2014**	**2013**
Statements of operations data:					
Revenues:					
Product sales	$ 421,516	$ 296,278	$ 328,969	$ 281,845	$ 257,922
Contract manufacturing	68,935	49,138	42,968	30,944	-
Contracts and grants	70,422	143,366	117,394	91,677	54,823
Total revenues	560,873	488,782	489,331	404,466	312,745
Operating expenses:					
Cost of product sales and contract manufacturing	195,707	131,284	107,486	101,963	62,127
Research and development	97,384	108,290	119,186	104,721	81,759
Selling, general & administrative	143,497	143,686	121,145	108,594	86,844
Total operating expenses	436,588	383,260	347,817	315,278	230,730
Income from operations	124,285	105,522	141,514	89,188	82,015
Other income (expense):					
Interest income	1,753	1,053	572	320	139
Interest expense	(6,590)	(7,617)	(6,523)	(8,240)	-
Other income (expense), net	(815)	263	153	2,926	409
Total other income (expense)	(5,652)	(6,301)	(5,798)	(4,994)	548
Income from continuing operations before provision for income taxes	118,633	99,221	135,716	84,194	82,563
Provision for income taxes	36,039	36,697	44,300	29,928	12,270
Net income from continuing operations	82,594	62,524	91,416	54,266	70,293
Net loss attributable to noncontrolling interest	-	-	-	-	876
Net income attributable to Emergent BioSolutions Inc. from continuing operations	82,594	62,524	91,416	54,266	71,169
Net loss from discontinued operations	-	(10,748)	(28,546)	(17,525)	(40,034)
Net income	$ 82,594	$ 51,776	$ 62,870	$ 36,741	$ 31,135
Net income per share from continuing operations-basic	$ 1.98	$ 1.56	$ 2.37	$ 1.45	$ 1.97
Net loss per share from discontinued operations-basic	-	(0.27)	(0.74)	(0.47)	(1.11)
Net income per share-basic	$ 1.98	$ 1.29	$ 1.63	$ 0.98	$ 0.86
Net income per share from continuing operations-diluted	$ 1.71	$ 1.35	$ 2.02	$ 1.26	$ 1.94
Net loss per share from discontinued operations-diluted	-	(0.22)	(0.61)	(0.38)	(1.09)
Net income per share-diluted (1)	$ 1.71	$ 1.13	$ 1.41	$ 0.88	$ 0.85
Weighted average number of shares — basic	41,816,431	40,184,159	38,595,435	37,344,891	36,201,283
Weighted average number of shares — diluted	50,327,937	49,335,112	47,255,842	45,802,807	36,747,556

(in thousands)	As of December 31, 2017	2016	2015	2014	2013
Balance Sheet Data:					
Cash and cash equivalents	$ 178,292	$ 271,513	$ 308,304	$ 276,786	$ 179,338
Working capital	385,321	404,362	425,865	312,767	284,652
Total assets	1,070,206	970,111	931,836	815,611	521,898
Total long-term liabilities	57,793	268,050	274,622	281,472	83,853
Total stockholders' equity	912,345	596,205	574,951	454,495	482,395

(1) See "Earnings per share" footnote for details on calculation.

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 carefully review the "Cautionary 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

We are a global life sciences company focused on providing specialty products for civilian and military populations that address accidental, intentional and naturally occurring public health threats, or PHTs. Within the category of our specialty products, we are focused on developing, manufacturing and commercializing medical countermeasures, or MCMs, that address PHTs. The PHTs that we address fall into two categories: Chemical, Biological, Radiological, Nuclear and Explosives or CBRNE; and emerging infectious diseases, or EID. We have a portfolio of eight products through which we generate most of our revenue, a research and development pipeline of various investigational stage product candidates and a fully-integrated portfolio of contract manufacturing services. The U.S. government is the primary purchaser of our products and provides us with substantial funding for the development of many of our product candidates. Our development pipeline consists of a diversified mix of both pre-clinical- and clinical-stage candidates.

Our MCM products are:

- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration, or FDA, for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), the only smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection (acquired from Sanofi Pasteur Biologics, LLC in October 2017);
- Raxibacumab (Anthrax Monoclonal), the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax (acquired from GlaxoSmithKline LLC in October 2017);
- Anthrasil® [Anthrax Immune Globulin Intravenous (Human)], the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of inhalational anthrax;
- BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)], the only heptavalent antibody therapeutic licensed by the FDA and Health Canada for the treatment of botulism;
- VIGIV [Vaccinia Immune Globulin Intravenous (Human)], the only antibody therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination;
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only medical device cleared by the FDA to remove or neutralize the following chemical warfare agents from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin; and
- Trobigard™ (atropine sulfate, obidoxime chloride), an auto-injector device designed for intramuscular self-injection of atropine sulfate and obidoxime chloride, as a nerve agent countermeasure. This product is not currently approved or cleared by the FDA or any similar regulatory body, and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

Our lead investigational stage MCM candidates, many of which are under an active development contract with significant funding from the U.S. government, are:

- NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), a next generation anthrax vaccine;
- FLU-IGIV (NP025), a human polyclonal antibody therapeutic being developed for the treatment of serious influenza A infection in hospitalized patients;

- ZIKA-IG (NP024), a human polyclonal antibody therapeutic being developed as a prophylaxis for Zika infections in at risk populations;
- FILOV (NP026), an equine polyclonal antibody therapeutic being developed to treat hemorrhagic fever caused by Filoviruses (Ebola, Marburg and Sudan);
- VLA1601, a highly purified inactivated vaccine against the Zika virus;
- UNI-FLU, a universal influenza vaccine;
- EBX-205, an oral therapeutic to treat acute bacterial skin and skin structure infection, including those caused by methicillin-resistant *Staphylococcus aureus*, or MRSA, as well as to treat other serious bacterial infections caused by biothreat pathogens;
- EBI-001, a pan respiratory antiviral from our iminosugar-based discovery program;
- GC-072, an oral and intravenous treatment for *Burkholderia pseudomallei* infection (GC-072 is the lead compound in the EV-035 series of broad-spectrum antibiotics);
- D4, a multi-drug auto-injector device being developed for nerve agent antidote delivery (Atropine and Pralidoxime Chloride in combination); and
- SIAN (stabilized isoamyl nitrite), a stabilized form of isoamyl nitrite in an intra-nasal spray device being developed as a treatment for known or suspected acute cyanide poisoning.

Highlights and Business Accomplishments for 2017

On December 12, 2017, we were awarded a contract by the Canadian Department of National Defence, or DND, valued at approximately $8 million to deliver Anthrasil® (Anthrax Immune Globulin Intravenous [human]) to the Canadian government. This contract award follows the recent approval of Anthrasil by Health Canada under the Extraordinary Use New Drug, or EUND, Regulations, which provide a regulatory pathway for products for which collecting clinical information for its intended use in humans is logistically or ethically not possible. Anthrasil is indicated for the treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs.

On November 14, 2017, we issued a Notice of Termination of Conversion Rights for all of our outstanding 2.875% Convertible Senior Notes due 2021, or Notes, and elected to exercise our right to terminate all conversion rights of the Notes on December 29, 2017. The indenture dated January 29, 2014 between us and Wells Fargo Bank, National Association, as trustee, governing the Notes permitted us to terminate the holders' rights to convert all the Notes at any time on or after January 20, 2017 if the last reported sale price of the common stock has been at least 130% of the conversion price for at least 20 trading days during any 30-consecutive trading-day period, which equals $40.14 per share. The $40.14 per share threshold was achieved in early November 2017. As a result of this termination, Notes representing approximately $239 million of our $250 million of outstanding Convertible Senior Notes were converted into approximately 8.5 million shares of our common stock.

On October 6, 2017, we completed the acquisition of the ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) business of Sanofi Pasteur Biologics, LLC, or Sanofi, for total consideration of $125 million. At closing, we paid $97.5 million in cash in an upfront payment and $20 million in milestone payments tied to the achievement of certain regulatory and manufacturing-related milestones. The agreement also includes a potential additional milestone payment of up to $7.5 million tied to the achievement of a regulatory milestone event, which was achieved and paid in full in cash during the fourth quarter of 2017. This acquisition includes ACAM2000, the only smallpox vaccine approved by the FDA, a current good manufacturing practices, or cGMP, live viral manufacturing facility and office and warehouse space, both in Canton, Massachusetts, and a cGMP viral fill/finish facility in Rockville, Maryland. With this acquisition, we also acquired an existing 10-year contract with the Centers for Disease Control and Prevention, or CDC, originally valued at up to $425 million and with a remaining value at acquisition of up to approximately $160 million, for the delivery of ACAM2000 to the U.S. Strategic National Stockpile, or SNS, and establishing U.S.-based manufacturing of ACAM2000. In November 2017, the FDA approved our supplemental Biologics License Application, or sBLA, for the manufacture of ACAM2000 in our newly-acquired cGMP live viral manufacturing facility in Canton, Massachusetts.

On October 4, 2017, we were awarded a contract valued at up to approximately $25 million by the U.S. Department of State to supply our Trobigard auto-injector, a drug-device combination product for emergency use in the event of nerve agent or organophosphate poisoning. Trobigard is designed for intramuscular self- or buddy-administration of atropine sulfate and obidoxime chloride for pre-hospital intervention.

On October 2, 2017, we completed the acquisition of Raxibacumab, the first fully human monoclonal antibody approved by the FDA for the treatment and prophylaxis of inhalational anthrax, from Human Genome Sciences, Inc. and GlaxoSmithKline LLC, collectively, GSK. With the acquisition, we assumed responsibility for a multi-year contract with BARDA, with a remaining value at acquisition of up to approximately $130 million, to supply the product to the SNS through November 2019. The all-cash transaction consisted of a $76 million upfront payment and up to $20 million in product sale and manufacturing-related milestone payments. As of December 31, 2017, none of the milestones have been achieved.

On September 29, 2017, we completed a new five-year, $200 million syndicated senior secured credit facility, with a $100 million accordion feature, which could expand total commitments to up to $300 million, subject to certain conditions and requirements set forth in the senior secured credit agreement. The new facility enhances our financial flexibility, providing increased capacity for strategic acquisitions and working capital, as needed.

On September 25, 2017, we were awarded a five-year follow-on contract valued at up to approximately $171 million by the U.S. Department of Defense, or DoD, to supply RSDL for use by all branches of the U.S. military.

On September 18, 2017, we were awarded a contract valued at approximately $63 million by BARDA to develop an antidote spray device for the treatment of known or suspected acute cyanide poisoning. The single-use intranasal spray device will deliver a stabilized form of isoamyl nitrite, or SIAN, and is intended for use by first responders and medical personnel following a cyanide incident.

On July 31, 2017, we were awarded a contract valued at up to approximately $23 million to develop a novel multi-drug auto-injector for nerve agent antidote delivery from the DoD. Our device is being designed for intramuscular self- or buddy-administration of antidotes for use in military environments and for civilian emergencies.

On July 26, 2017, we announced a licensing agreement with Valneva SE, or Valneva, for global exclusive rights to Valneva's Zika vaccine technology, ZIKV. We will co-develop VLA1601, a highly purified inactivated vaccine candidate against the Zika virus, from preclinical development through completion of a Phase 1 safety and immunogenicity clinical trial. VLA1601, which has been shown to elicit functional antibody responses, is based on Valneva's established inactivated, whole virus manufacturing platform on which its licensed Japanese Encephalitis vaccine was developed and produced. A Phase 1 clinical trial is expected to commence in early 2018.

On March 31, 2017, we signed a modification to our contract with BARDA to manufacture and store bulk drug substance for our botulism antitoxin, BAT, valued at approximately $53 million with a five-year period of performance. This modification to the contract is intended to enable future filling and deliveries of final drug product to the SNS. BAT is indicated for the treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients.

On March 16, 2017, we entered into a contract with BARDA, valued at $100 million, for the delivery of BioThrax to the SNS over a two-year period of performance. In conjunction with the signing of the $100 million contract for delivery of BioThrax with BARDA, or the BARDA BioThrax Contract, we entered into a modification to our previously disclosed multi-year contract with BARDA for the advanced development and delivery of the leading next generation anthrax vaccine candidate NuThrax, or the BARDA NuThrax Contract. The modification increases the number of doses of NuThrax to be delivered under the base period from two million to three million doses with a commensurate reduction in dose price for the initial deliveries. The modification also reduces the purchase price for doses to be procured during the option period by $100 million thereby reducing the total contract value to be up to $1.5 billion.

On February 13, 2017, we received a task order from BARDA valued at up to $30.5 million to develop monoclonal antibody therapeutics for viral hemorrhagic fever. This task order will utilize our CIADM facility located in Baltimore, Maryland. Using monoclonal antibodies from Mapp Biopharmaceutical Inc., we will conduct technology transfer of process materials and information, perform process and analytical method development, execute small-scale production runs, and perform cGMP and cell banking leading to cGMP manufacture of bulk drug substance. The task order consists of a three-year period of performance with a base task order valued at $7.4 million and options that, if executed, will bring the total task order value over three years to up to $30.5 million.

On January 27, 2017, we received from the Paul-Ehrlich-Institut the regulatory agency under the German Federal Ministry of Health, approval for our large-scale manufacturing facility, Building 55, located in Lansing, Michigan. This approval allows us to market in Germany BioThrax manufactured in Building 55.

Manufacturing Infrastructure

Our Lansing, Michigan, manufacturing location is a vertically-integrated manufacturing facility and the location of our BioThrax manufacturing operations. Building 55 is our large-scale manufacturing facility, which was licensed by the FDA in August 2016 for the manufacture of BioThrax. This facility has the potential to manufacture up to 20 to 25 million doses of BioThrax annually on a single manufacturing train.

Our manufacturing facilities in Winnipeg, Manitoba, Canada are actively engaged in plasma-derived hyperimmune therapeutics manufacturing, chromatography-based plasma fractionation, bacterial fermentation, downstream processing, aseptic filling, packaging and warehousing, quality assurance and control, and include development laboratories and office space. Bulk manufacture of RSDL lotion also occurs in Winnipeg. At these facilities, we manufacture our hyperimmune specialty plasma products, including BAT, VIGIV and Anthrasil. We also manufacture other products for contract manufacturing customers at these facilities.

Our contract fill/finish services facility is located in Baltimore, Maryland, and is referred to as our "Camden Site." The Camden 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 support. This facility is an approved or inspected manufacturing facility under the regulatory regimes in the United States, Canada, Japan, Brazil, the Middle East and several other countries. The facility includes warehousing space used for cold-storage and freezer capacity to support contract manufacturing customers.

Our manufacturing facility focused on disposable manufacturing for viral and non-viral products is located in Baltimore, Maryland, and is referred to as our "Bayview Site." This facility was designed to take advantage of single-use bioreactor technology and is capable of manufacturing several different products, including products derived from cell culture or microbial systems. In June 2012, we entered into a contract with BARDA, which established our Bayview Site as a Center for Innovation in Advanced Development and Manufacturing, or CIADM. We envision this facility supporting future CIADM development and manufacturing activities for chemical, biological, radiological, and nuclear threat countermeasures, as well as our current and future non-CIADM product development and manufacturing needs.

In October 2017, in connection with our acquisition of the ACAM2000 business from Sanofi, we acquired a live viral manufacturing facility and office and warehouse space, both in Canton, Massachusetts, and a cGMP live viral fill/finish facility in Rockville, Maryland. In November 2017, we received FDA approval of our supplemental Biologics License Application for the transfer of the upstream portion of the manufacturing process of ACAM2000 to our live viral manufacturing facility in Canton, Massachusetts.

Aptevo Spin-off

On August 1, 2016, we completed the spin-off of Aptevo Therapeutics Inc., or Aptevo. As a result of the spin-off, the operating results of Aptevo have been reflected as discontinued operations for the years ended December 31, 2016 and 2015. See Note 3. "Discontinued operations" for further details regarding the spin-off. Unless otherwise stated, financial results herein for the years ended December 31, 2016 and 2015 reflect such results on a continuing operations basis.

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 and contract manufacturing 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
- collectability is reasonably assured.

We have generated BioThrax sales revenues under U.S. government contracts with U.S. Department of Health and Human Services, or HHS and the Centers for Disease Control and Prevention, or the CDC. Under our current contract with the CDC, we invoice the CDC and recognize the related revenues upon acceptance by the government. The title to the product passes to the CDC at the delivery site.

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 analyze our multiple element revenue-generating arrangements to determine whether the elements should be separated and accounted for individually as separate units of accounting. An item should 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 should 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.

In May 2014, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2014-09, *Summary and Amendments That Create Revenue from Contracts with Customers (Topic 606) and Other Assets and Deferred Costs—Contracts with Customers (Subtopic 340-40) (*"ASU No. 2014-09"). ASU No. 2014-09 supersedes the revenue recognition requirements in Topic 605, Revenue Recognition, as well as most industry-specific guidance, and significantly enhances comparability of revenue recognition practices across entities and industries by providing a principles-based, comprehensive framework for addressing revenue recognition issues. In order for a provider of promised goods or services to recognize as revenue the consideration that it expects to receive in exchange for the promised goods or services, the provider should apply the following five steps: (1) identify the contract with a customer(s); (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. ASU No. 2014-09 also specifies the accounting for some costs to obtain or fulfill a contract with a customer and provides enhanced disclosure requirements. The standard will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period.

Mergers and Acquisitions

In determining whether an acquisition is a business combination versus an asset acquisition, the accounting guidance requires an entity to first evaluate whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If that threshold is met, the set of assets and activities is not a business and therefore treated as an asset acquisition. If it's not met, the entity evaluates whether the set meets the definition of a business. If an acquired asset or asset group does not meet the definition of a business, the transaction is accounted for as an asset acquisition. Otherwise, the acquisition is treated as a business combination.

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 our results of operations.

The fair values of identifiable intangible assets related to current 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 take into consideration the following factors: 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 our 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 Consideration

We record contingent consideration associated with both (a) sales based royalties and (b) development and regulatory milestones at fair value. 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 and achievement of the milestones. The inputs we use for determining the fair value of the contingent consideration associated with sales based royalties and development and regulatory milestones 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 consideration associated with sales based royalties along with development and regulatory milestones are based on an increased likelihood that the underlying net sales or milestones will be achieved.

The associated payment or payments which will therefore become due and payable for sales based royalties associated with products will result in a charge to cost of product sales and contract manufacturing in the period in which the increase is determined. Similarly, any future decrease in the fair value of contingent consideration associated with sales based royalties will result in a reduction in cost of product sales and contract manufacturing. The changes in fair value for potential future sales based royalties associated with product candidates in development will result in a charge to selling, general and administrative expense in the period in which the increase is determined. Similarly, any future decrease in the fair value of contingent consideration associated with potential future sales based royalties for products candidates will result in a reduction in selling, general and administrative expense.

The associated payment or payments which will therefore become due and payable for development and regulatory milestones 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 for development and regulatory milestones will result in a reduction in research and development expense.

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 benefit of credit carryforwards, the anticipated future benefit of net operating losses and other timing differences between the financial reporting and tax basis of assets and liabilities.

On December 22, 2017, the President of the United States signed into law the Tax Reform Act. The legislation significantly changes U.S. tax law by, among other things, lowering corporate income tax rates, implementing a territorial tax system and imposing a repatriation tax on deemed repatriated earnings of foreign subsidiaries. The Tax Reform Act permanently reduces the U.S. corporate income tax rate from a maximum of 35% to a flat 21% rate, effective January 1, 2018. The SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Reform Act. The Company has recognized the provisional tax impacts related to deemed repatriated earnings and the revaluation of deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. The ultimate impact may differ from these provisional amounts, possibly materially, due to, among other things, additional analysis, changes in interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of the Tax Reform Act. The accounting is expected to be complete when the 2017 U.S. corporate income tax return is filed in 2018.

Management believes that the assumptions and estimates related to the provision for income taxes are critical to the Company's results of operations. For the year ended December 31, 2017, income tax expense totaled $36.1 million. For every 1% change in the 2017 effective rate, income tax expense would have changed by approximately $1.2 million.

We have historically incurred net operating losses for income tax purposes in some states and foreign jurisdictions. 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, 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 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.

Financial Operations Overview

Revenues

We have derived a majority of our historical product sales revenues from BioThrax sales to the U.S. government. We are a party to a contract with the CDC, an operating division of HHS, valued at up to $911 million, to supply approximately 29.4 million doses of BioThrax to the SNS through September 2021. In addition, during 2017 we completed delivery on the BARDA BioThrax Contract of 3.4 million doses to the SNS. We are focused on increasing the sales of our marketed MCMs to U.S. government customers, as well as expanding the market for our MCM product portfolio to other customers domestically and internationally.

For at least the next two to three years, we expect to continue to derive a substantial portion of our product sales revenues from sales of BioThrax to the U.S. government.

We have received contract and grant funding from BARDA, DoD, CDC, the Defense Threat Reduction Agency, or DTRA, and the National Institute of Allergy and Infectious Diseases, or NIAID, for the following development programs:

Development Programs	Funding Source	Award Date	Performance Period
Anthrasil	BARDA	9/2005	9/2005 — 4/2021
	BARDA	9/2013	9/2013 — 9/2018
Auto-injector platform	DoD	7/2017	7/2017 — 6/2022
BAT	BARDA	5/2006	5/2006 — 12/2027
CIADM	BARDA	6/2012	6/2012 — 6/2037
GC-072	DTRA	8/2014	8/2014 — 3/2018
Large-scale manufacturing for BioThrax	BARDA	7/2010	7/2010 — 7/2017
NuThrax	NIAID	8/2014	8/2014 — 1/2019
	BARDA	3/2015	3/2015 — 12/2017
	BARDA	9/2016	9/2016 — 9/2021
SIAN	BARDA	9/2017	9/2017 — 9/2022
UV-4B	NIAID	9/2011	9/2011 — 9/2018
VIGIV	CDC	8/2012	8/2012 — 8/2017

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

Cost of Product Sales and Contract Manufacturing

The primary expenses that we incur to deliver our Vaccines and Anti-Infectives products and Antibody Therapeutics products to our customers and to perform contract manufacturing services for our customers are manufacturing costs consisting of fixed and variable costs. Variable manufacturing costs consist primarily of costs for materials and personnel-related expenses for direct and indirect manufacturing support staff, contract manufacturing operations, sales-based royalties, shipping and logistics. Fixed manufacturing costs include facilities, utilities and amortization of intangible assets. We determine the cost of product sales for products sold during a reporting period based on the average manufacturing cost per unit in the period those units were

manufactured. In addition to the fixed and variable manufacturing costs described above, the cost of product sales depends on utilization of available manufacturing capacity.

The primary expenses that we incur to deliver our Devices to our customers are the cost per unit of production from our third-party contract manufacturers, costs for materials and personnel-related expenses for direct and indirect manufacturing support staff along with facilities and utilities costs. Other associated expenses include sales-based royalties (which includes fair value adjustments associated with contingent consideration), amortization of intangible assets, shipping, and logistics.

Research and Development Expenses

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

- personnel-related expenses;
- fees to professional service providers for, among other things, analytical testing, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies;
- costs of contract manufacturing services for clinical trial material; and
- costs of materials used in clinical trials and research and development.

In many cases, we plan to seek funding for development activities from external sources and third parties, such as governments and non-governmental organizations, or through collaborative partnerships. We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development spending, the number of product candidates under development, the size, structure and duration of any clinical programs that we may initiate, the costs associated with manufacturing our product candidates on a large-scale basis for later stage clinical trials, and our ability to use or rely on data generated by government agencies, such as studies involving BioThrax conducted by the CDC.

Selling, General and Administrative Expenses

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

Results of Operations

Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

Revenue

(in thousands)	Year ended December 31, 2017	2016	$ Change	% Change
Product sales:				
BioThrax	$ 286,651	$ 237,030	$ 49,621	21%
Other	134,865	59,248	75,617	128%
Total product sales	421,516	296,278	125,238	42%
Contract manufacturing	68,935	49,138	19,797	40%
Contracts and grants	70,422	143,366	(72,944)	(51%)
Total revenues	$ 560,873	$ 488,782	$ 72,091	15%

Product sales:

The increase in BioThrax sales was primarily due to the timing of BioThrax deliveries to the SNS. BioThrax product sales revenues during the year ended December 31, 2017 consisted of sales to the U.S. Government of $282.6 million and aggregate international and other sales of $4.0 million. BioThrax product sales revenues during the year ended December 31, 2016 consisted of sales to the U.S. Government of $235.8 million and aggregate international and other sales of $1.2 million.

The increase in other product sales relates primarily to:

- the timing of BAT deliveries to the SNS;
- international sales for VIGIV and Trobigard; and
- sales of ACAM2000 and Raxibacumab, both acquired in October 2017.

Contract manufacturing:

The increase in Contract manufacturing is primarily due to:

- manufacturing services for Aptevo;
- fill/finish services provided to third parties; and
- manufacturing services performed for third party development stage product candidates.

Contracts and grants:

The decrease in Contracts and grants revenues primarily reflects a reduction in revenue associated with the successful completion of multiple U.S. Government contracts, as well as reduced R&D activities related to certain ongoing funded development programs, including:

- decreased development funding of $37.7 million related to our CIADM program. This decrease includes a reduction of $20.5 million related to the timing of facility construction activities and $17.1 million related to CIADM task orders (primarily the successful completion of manufacturing development for Ebola monoclonal antibodies);
- decreased development funding of $34.1 million for VIGIV related to the timing of plasma collection; and
- decreased development funding of $6.8 million for large scale manufacturing of BioThrax primarily due to the successful completion of the Building 55 development program in 2016 that did not recur in 2017.

These decreases were partially offset by an increase in development funding for NuThrax of $6.7 million, primarily related to non-clinical animal studies and manufacturing activities.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $64.4 million, or 49%, to $195.7 million for 2017 from $131.3 million for 2016. The increase was primarily attributable to:

- the increase in RSDL deliveries to the DoD along with the timing of non-cash fair value adjustments to the contingent consideration liability;
- timing of BAT sales to the SNS;
- timing of international sales for VIGIV and Trobigard;
- sales of the newly acquired ACAM2000 and Raxibacumab products (both acquired October 2017); and
- increased costs associated with the expansion of our contract manufacturing business.

These increases were partially offset by the increase in the 2016 BioThrax cost per dose sold associated with lower production yield in the period in which the doses sold were produced.

Research and Development Expense

Research and development expenses decreased by $10.9 million, or 10%, to $97.4 million for 2017 from $108.3 million for 2016. This decrease primarily reflects lower contract development services costs. Net of contracts and grants revenues, we incurred net research and development expenses of $27.0 million during 2017. Net of contracts and grants revenues, our research and development expenses were fully funded during 2016, resulting in a net contribution from funded development programs of $35.1 million.

Our principal research and development expenses for 2017 and 2016 are shown in the following table:

(in thousands)	Year ended December 31, 2017	2016	$ Change	% Change
NuThrax	$ 30,000	$ 22,478	$ 7,522	33%
UV-4B	6,331	5,588	743	13%
Auto-injector program	5,245	9,000	(3,755)	(42%)
FLU-IGIV (NP025)	5,334	-	5,334	N/A
EV-035 series of molecules	4,123	326	3,797	1,165%
VLA1601	3,509	-	3,509	N/A
BAT	2,709	3,904	(1,195)	(31%)
ZIKV-IG	3,246	836	2,410	288%
CIADM task orders	2,321	13,955	(11,634)	(83%)
Raxibacumab	2,142	-	2,142	N/A
VIGIV	1,223	12,019	(10,796)	(90%)
BioThrax related programs	1,474	3,069	(1,595)	(52%)
Anthrasil	612	1,279	(667)	(52%)
Large-scale manufacturing for BioThrax	756	6,104	(5,348)	(88%)
Other	28,359	29,732	(1,373)	(5%)
Total	$ 97,384	$ 108,290	$ (10,906)	(10%)

The decrease in research and development expense was primarily attributable to:

- the timing of device and cartridge supply development work related to our Auto-injector program;
- the timing of stability testing related to our BAT program;
- the successful completion of manufacturing development for Ebola monoclonal antibodies and Zika under current CIADM-related task order awards;
- the timing of plasma collection related to our VIGIV program;
- the timing of clinical studies to support applications for label expansion for BioThrax under the auspices of our BioThrax related development programs;
- the timing of non-clinical activities related to our Anthrasil program;
- the completion of development work and the licensure of Building 55, our large-scale manufacturing facility, in August 2016; and
- increased expenses related to our funded pre-clinical product candidates and manufacturing development activities within our other development activities.

These decreases were partially offset by increased research and development activity primarily attributable to the timing of:

- manufacturing development activities related to our NuThrax product candidate;
- clinical trial activity to evaluate safety and tolerability related to our UV-4B product candidate; we anticipate a reduction in funding by the U.S. government for this product candidate and as a result we will cease further development work on UV-4B and expect the spending to be minimal in the future;
- preparation activities and initiation of Phase 2 clinical study related to our FLU-IGIV (NP025) program;
- formulation development activities, along with screening of molecules within the series, related to our EV-035 series of molecules;
- payment of license fees to Valneva in association with our VLA1601 program;
- preparation activities for Phase 1 clinical study for our ZIKV-IG product candidate; and
- manufacturing development activities related to Raxibacumab (acquired in October 2017).

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $0.2 million to $143.5 million for 2017 from $143.7 million for 2016. The decrease was primarily attributable to a decrease in costs associated with the restructuring activities at our Lansing, Michigan site during 2016, partially offset by an increase in professional services to support our strategic growth initiatives, along with an increase in compensation related costs.

Total Other Expense

Total net other expense decreased by $0.6 million, or 10%, to $5.7 million for 2017 from $6.3 million for 2016. The decrease was primarily attributable to a decrease in interest expense due in part to the conversion of the vast majority of the outstanding convertible debt to equity in the fourth quarter.

Income Taxes

Provision for income taxes decreased by $0.7 million, or 2%, to $36.0 million for 2017 from $36.7 million for 2016. The provision for income taxes for 2017 resulted primarily from our income before provision for income taxes of $118.6 million and an effective annual tax rate of approximately 30%. Due to the impact of the Tax Reform Act enacted on December 22, 2017, the Company recognized a $13.4 million tax benefit as a result of revaluing the U.S. ending net deferred tax liabilities from 35% to the newly enacted U.S. corporate income tax rate of 21%. The tax benefit was fully offset by tax expense of $13.6 million for the transition tax on the deemed mandatory repatriation of undistributed earnings. The provision for income taxes for 2016 resulted primarily from our income before provision for income taxes of $99.2 million and an effective annual tax rate of approximately 37%.

Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

Revenues

(in thousands)	Year ended December 31, 2016	2015	$ Change	% Change
Product sales:				
BioThrax	$ 237,030	$ 293,921	$ (56,891)	(19%)
Other	59,248	35,048	24,200	69%
Total product sales	296,278	328,969	(32,691)	(10%)
Contract manufacturing	49,138	42,968	6,170	14%
Contracts and grants	143,366	117,394	25,972	22%
Total revenues	$ 488,782	$ 489,331	$ (549)	0%

Product sales:

The decrease in BioThrax sales was primarily due to the timing of deliveries under our contracts with the CDC, principally due to reduced deliveries in the fourth quarter of 2016 related to the timing of signing our new contract with CDC in December 2016. BioThrax product sales revenues during the year ended December 31, 2016 consisted of sales to the CDC of $235.8 million and aggregate international and other sales of $1.2 million. BioThrax product sales revenues during the year ended December 31, 2015 consisted primarily of BioThrax sales to the CDC of $292.8 million and aggregate international and other sales of $1.1 million.

The increase in other product sales was primarily due to the timing of BAT and VIGIV sales to the SNS, as well as RSDL sales to the Department of Defense, or DoD.

Contract manufacturing:

The increase in Contract manufacturing revenues was primarily due to the increase of fill/finish services from our facility in Baltimore and our plasma based manufacturing facility in Winnipeg, partially offset by a decrease in contract manufacturing revenue related to the production of an MVA Ebola vaccine candidate in 2015.

Contracts and grants:

The increase in Contracts and grants revenues was primarily due to the following:

- increased development funding of $39.1 million related to our CIADM program, including $17.1 million from new CIADM task orders;
- increased development funding of $29.9 million for VIGIV related to plasma collection; and
- increased development funding of $9.4 million for NuThrax related to preparation for a Phase III clinical trial.

These increases were partially offset by decreases in development funding for:

- the Anthrasil program of approximately $37.6 million related to the timing of plasma collection;
- PreviThrax of approximately $8.9 million due to reduced interest by the U.S. government for this product candidate; and
- Large-scale manufacturing of BioThrax of approximately $6.1 million due to completion of the program and FDA licensure of building 55 in August 2016.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $23.8 million, or 22%, to $131.3 million for 2016 from $107.5 million for 2015. The increase was attributable to an increase in the BioThrax cost per dose sold associated with lower

production yield in the period in which the doses sold were produced along with increased costs associated with the increase in Other product sales, partially offset by a decrease in BioThrax sales to the SNS.

Research and Development Expense

Research and development expenses decreased by $10.9 million, or 9%, to $108.3 million for 2016 from $119.2 million for 2015. This decrease primarily reflects lower contract service costs. Net of contracts and grants revenues, our research and development expenses were fully funded during 2016, resulting in a net contribution from funded development programs of $35.1 million. Net of contracts and grants revenues, we incurred net research and development expenses of $1.8 million during 2015.

Our principal research and development expenses for 2016 and 2015 are shown in the following table:

	Year ended December 31,			
(in thousands)	**2016**	**2015**	**$ Change**	**% Change**
NuThrax	$ 22,478	$ 12,560	$ 9,918	79%
UV-4B	5,588	-	5,588	N/A
Auto-injector program	9,000	4,643	4,357	94%
EV-035 series of molecules	326	6,801	(6,475)	(95%)
BAT	3,904	4,867	(963)	(20%)
ZIKV-IG	836	-	836	N/A
CIADM task orders	13,955	2,957	10,998	372%
VIGIV	12,019	3,060	8,959	293%
BioThrax related programs	3,069	3,511	(442)	(13%)
Anthrasil	1,279	25,986	(24,707)	(95%)
Large-scale manufacturing for BioThrax	6,104	9,911	(3,807)	(38%)
Other	29,732	44,890	(15,158)	(34%)
Total	$ 108,290	$ 119,186	$ (10,896)	(9%)

The decrease in research and development expense was primarily attributable to:

- pharmacologic and formulation activities and a third quarter 2015 non-cash impairment charge of $9.8 million due to toxicity related issues, partially offset by a net decrease of $3.3 million (2016 vs. 2015) for the contingent consideration associated with the estimated timing and probability of achievement for certain development and regulatory milestones related to our EV-035 series of molecules program;
- stability testing and plasma collection related to our BAT program;
- timing of plasma collection services related to our Anthrasil program;
- clinical studies to support applications for label expansion for BioThrax related to BioThrax related programs;
- timing of manufacturing development activities and due to the successful licensure of the large-scale manufacturing facility in August 2016 related to our Large-scale manufacturing of BioThrax program; and
- decreased expenses related to our manufacturing development activities within our other development activities.

These decreases were partially offset by increased research and development activity primarily attributable to the timing of:

- non-clinical animal studies and manufacturing development activities related to our NuThrax product candidate;
- clinical trial activity to evaluate safety and tolerability related to our UV-4B product candidate;
- Auto-injector program, primarily for device and cartridge supply development;
- preparation for a clinical trial related to our ZIKV-IG program;
- manufacturing development of Ebola monoclonal antibodies related to our CIADM task orders; and
- plasma collection related to our VIGIV program.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $22.6 million, or 19%, to $143.7 million for 2016 from $121.1 million for 2015. The increase includes costs associated with the restructuring activities at our Lansing, Michigan site, increased professional services to support our strategic growth initiatives, and increased information technology investments.

Total Other Expense

Total net other expense increased by $0.5 million, or 9%, to $6.3 million for 2016 from $5.8 million for 2015. The increase was primarily attributable to a $0.5 million payment to the Internal Revenue Service for interest related to the audit of 2009 and 2010 federal income tax returns.

Income Taxes

Provision for income taxes decreased by $7.6 million, or 17%, to $36.7 million for 2016 from $44.3 million for 2015. The provision for income taxes for 2016 resulted primarily from our income before provision for income taxes of $99.2 million and an effective annual tax rate of approximately 37%. The provision for income taxes for 2015 resulted primarily from our income before provision for income taxes of $135.7 million and an effective annual tax rate of approximately 33%. The provision for income taxes for 2016 and 2015 reflects net tax credits associated with research and developments activities of $1.6 million and $4.8 million, respectively. The increase in the effective annual tax rate is primarily related to tax on the sale, within our consolidated group, of assets from Canadian subsidiaries to U.S. subsidiaries in preparation of the spin-off of Aptevo, and a valuation allowance charge recorded in its continuing operations related to Aptevo deferred tax assets prior to the distribution. We determined that upon spin-off, the deferred tax assets of Aptevo would be unrealizable. The increase in the effective annual tax rate as a result of the above was partially offset by a release of valuation allowances associated with Canadian Scientific Research and Experimental Development tax credits.

Liquidity and Capital Resources

Sources of Liquidity

From inception through 2017, we have funded our cash requirements principally with a combination of cash from our operations, debt financing, development funding, the net proceeds from our initial public offering and the sale of our common stock upon exercise of stock options. We have operated profitably for each of the last five years ended December 31, 2017. As of December 31, 2017, we had cash and cash equivalents of $178.3 million. The closing of the acquisitions of ACAM2000 and Raxibacumab in early October of 2017 resulted in combined cash outflows of $193.5 million.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2017, 2016 and 2015.

	Year ended December 31,		
(in thousands)	**2017**	**2016**	**2015**
Net cash provided by (used in):			
Operating activities(1)	$ 208,112	$ 54,752	$ 42,367
Investing activities	(249,932)	(76,257)	(45,462)
Financing activities	(51,401)	(19,777)	35,391
Net (decrease) increase in cash and cash equivalents	$ (93,221)	$ (41,282)	$ 32,296

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

Operating Activities:

Net cash provided by operating activities of $208.1 million in 2017 was primarily due to our net income excluding non-cash items of $154.4 million and changes in working capital which resulted in a net cash inflow of $53.7 million. Cash inflows include activity the timing of accounts payable associated with ADM, an increase in deferred revenue and an increase in income taxes payable (primarily due to the transition tax on the deemed mandatory repatriation of undistributed earnings).

Net cash provided by operating activities of $54.8 million in 2016 was primarily due to our net income excluding non-cash items of $98.9 million and changes in working capital which resulted in a net cash outflow of $44.3 million. Cash outflow includes the timing of collection of accounts receivables related to amounts billed (primarily to the CDC), unpaid balances in accounts payable associated with ADM and increase in inventories related to BioThrax.

Net cash provided by operating activities of $42.4 million in 2015 was primarily due to our net income excluding non-cash items of $110.4 million and changes in working capital which resulted in a net cash outflow of $67.8 million. Cash outflow includes the timing of collection of accounts receivables related to amounts billed (primarily to the CDC) and an increase in inventory due to raw material purchases for RSDL.

Investing Activities:

Net cash used in investing activities of $249.9 million in 2017 was primarily due to our acquisitions of ACAM2000 and Raxibacumab, along with software, infrastructure and equipment investments.

Net cash used in investing activities of $76.3 million in 2016 was primarily due to our expansion at Bayview CIADM site, along with software, infrastructure and equipment investments.

Net cash used in investing activities of $45.5 million in 2015 was primarily due to software, infrastructure and equipment investments.

Financing Activities:

Net cash used by financing activities of $51.4 million in 2017 was primarily due to $33.1 million utilized to purchase treasury stock, the payment of a $20.0 million note payable to Aptevo in conjunction with the spin-off, $4.3 million associated with the taxes paid on behalf of employees for equity activity and $10.9 million in contingent obligation payments, partially offset by $19.3 million in proceeds from the issuance of common stock pursuant to our employee equity awards plan.

Net cash used by financing activities of $19.8 million in 2016 was primarily due to $45.0 million in cash provided to Aptevo on date of distribution, August 1, 2016 that is partially offset by $17.1 million in proceeds from the issuance of common stock pursuant to employee equity plans and $10.6 million in excess tax benefits from exercise of stock options.

Net cash provided by financing activities of $35.4 million in 2015 was primarily due to $26.0 million in proceeds from the issuance of common stock pursuant to employee equity plans, $11.3 million in excess tax benefits from the exercise of stock options and $2.0 million in proceeds from long-term indebtedness, partially offset by $5.7 million in contingent obligation payments.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2017:

	Payments due by period				
(in thousands)	**Total**	**Less than 1 year**	**1 to 3 Years**	**3 to 5 Years**	**More than 5 years**
Contractual obligations:					
Long-term indebtedness	$ 14,529	$ 305	$ 610	$ 13,614	$ -
Operating lease obligations	10,730	1,626	2,730	2,689	3,685
Deemed mandatory repatriation tax (1)	13,584	1,087	3,260	5,841	3,396
Purchase commitments	7,015	3,095	3,920	-	-
Total contractual obligations	$ 45,858	$ 6,113	$ 10,520	$ 22,144	$ 7,081

(1) U.S. federal income tax on deemed mandatory repatriation is payable over 8 years pursuant to the Tax Reform Act.

Debt Financing

On January 29, 2014, the Company issued $250.0 million aggregate principal amount of 2.875% Convertible Senior Notes due 2021 (the "Notes"). The Notes mature on January 15, 2021, unless earlier purchased by the Company or converted. The original conversion rate was equal to 30.8821 shares of common stock per $1,000 principal amount of notes (which is equivalent to a conversion price of approximately $32.38 per share of common stock). The conversion rate was subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest. As of August 1, 2016, certain conversion features were triggered due to the completion of the Aptevo spin-off. The conversion rate under the Notes was adjusted in accordance with the terms of the indenture. Effective August 12, 2016, the conversion rate was adjusted to 32.3860 shares of common stock per $1,000 principal amount of notes (which is equivalent to a conversion price of approximately $30.88 per share of common stock).

On November 14, 2017, we issued a notice of termination of conversion rights for the Notes, of which $250.0 million was outstanding as of the notice date. In connection with the notice of termination, bondholders were given the option to convert their notes into our common stock at a rate of 32.386 per $1,000 of principal outstanding, plus a make-whole of an additional 3.1556 shares per $1,000 principal outstanding, in accordance with the terms of the indenture. We were not obligated to pay accrued or unpaid interest on converted notes, and bondholders who did not convert by the deadline of December 28, 2017 retained their bonds but lost the conversion rights associated with the Notes and therefore will be paid interest of 2.875% until the earlier of maturity of the Notes in 2021 or the bonds being called and repaid in full by us. Between November 14, 2017 and December 28, 2017 (the "conversion period"), approximately $239.4 million of bonds were converted into 8.5 million shares of the Company's common stock, inclusive of shares issued as part of the make-whole provision. After giving effect to the converted bonds, the outstanding principal balance of the Notes was $10.6 million as of December 31, 2017.

On September 29, 2017, the Company entered into a senior secured credit agreement (the "2017 Credit Agreement") with four lending financial institutions, which replaced the Company's prior senior secured credit agreement (the "2013 Credit Agreement"). The 2017 Credit Agreement provides for a senior secured credit facility of up to $200 million through September 29, 2022. The 2017 Credit Agreement also includes a $100 million accordion feature, which could provide an additional $100 million in revolver or incremental term loans, at the option of the Company, resulting in a potential aggregate commitment of up to $300 million, subject to certain conditions and requirements set forth in the 2017 Credit Agreement. As of December 31, 2017, no amounts were drawn under the 2017 Credit Agreement.

The Company's payment obligations under the 2017 Credit Agreement are secured by a lien on substantially all of the Company's assets, including the stock of all of the Company's domestic subsidiaries, and the assets of the subsidiary guarantors. Borrowings under the 2017 Credit Agreement will bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.50% to 2.50% per annum, depending on the Company's consolidated net leverage ratio or (b) a base rate (which is the highest of the prime rate, the federal funds rate plus 0.50% and a eurocurrency rate for an interest period of one month plus 1%) plus a margin ranging from 0.50% to 1.50%, depending on the Company's consolidated net leverage ratio. The Company is required to make quarterly payments under the 2017 Credit Agreement of accrued and unpaid interest on the outstanding principal balance, based on the above interest rates. In addition, the Company is required to pay commitment fees ranging from 0.25% to 0.40% per annum, depending on the Company's consolidated net leverage ratio, in respect of daily unused commitments under the 2017 Credit Agreement.

The 2017 Credit Agreement contains affirmative and negative covenants customary for financings of this type. Negative covenants in the 2017 Credit Agreement, among other things, limit the Company's ability to incur indebtedness and liens; dispose of assets; make investments including loans, advances, guarantees, or acquisitions (other than permitted acquisitions, subject to compliance with the financial covenants and certain other conditions); and enter into certain mergers or consolidation transactions. The 2017 Credit Agreement also contains financial covenants, tested quarterly and in connection with any triggering events under the 2017 Credit Agreement: (1) a minimum consolidated debt service coverage ratio of 2.50 to 1.00, and (2) a maximum consolidated net leverage ratio of 3.50 to 1.00, which may be adjusted to 4.00 to 1.00 for a four- quarter period in connection with a permitted acquisition, subject to the terms and conditions of the 2017 Credit Agreement. Each of the ratios referred to in the foregoing clauses (1) and (2) is calculated on a consolidated basis for each consecutive four fiscal quarter periods.

Funding Requirements

We expect to continue to fund our anticipated operating expenses, capital expenditures, debt service requirements and any future repurchase of our common stock from the following sources: existing cash and cash equivalents; net proceeds from the sale of our products and contract manufacturing services; development contracts and grants funding; and our senior secured credit facility and any other lines of credit we may establish from time to time. There are numerous risks and uncertainties associated with product sales and with the development and commercialization of our product candidates. We may seek additional external financing to provide additional financial flexibility. Our future capital requirements will depend on many factors, including (but not limited to):

- the level, timing and cost of product sales and contract manufacturing services;
- the extent to which we acquire or invest in and integrate companies, businesses, products or technologies;
- the acquisition of new facilities and capital improvements to new or existing facilities;
- the payment obligations under our indebtedness;
- the scope, progress, results and costs of our development activities;
- our ability to obtain funding from collaborative partners, government entities and non-governmental organizations for our development programs; 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. In May 2015, we filed an automatic shelf registration statement, which immediately became effective under the Securities and Exchange Commission, or SEC, rules. For so long as we continue to satisfy the requirements to be deemed a "well-known seasoned issuer" under SEC rules, this shelf registration statement, effective until May 2018, allows us to issue an unrestricted amount of equity, debt and certain other types of securities through one or more future primary or secondary offerings. If we do not file a new shelf registration statement prior to May 2018, the existing shelf registration statement will expire and we will not be able to publicly raise capital or issue debt until a new registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatically effective shelf registration statement at a future date when we may need to raise funds publicly.

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, which could limit or restrict our ability to take specific actions, such as incurring additional debt, making capital expenditures, pursuing acquisition opportunities, buying back shares 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 remaining senior convertible notes from incurring additional debt, securing existing or future debt, recapitalizing our debt or taking a number of other actions that are not limited by the terms of the indenture governing our notes that could have the effect of diminishing our ability to make payments on our indebtedness. However, our senior secured credit facility restricts our ability to incur additional indebtedness, including secured indebtedness, as discussed in the Notes to the Consolidated Financial Statements included in Item 8.

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.

Share Repurchase Program

On July 14, 2016, our board of directors authorized our management to repurchase from time to time up to an aggregate of up to $50 million of our common stock under a board-approved share repurchase program. The term of the board authorization of the repurchase program was until December 31, 2017. Any repurchased shares will be available for use in connection with our stock plans and for other corporate purposes. During the year ended December 31, 2017, we repurchased 0.8 million shares of common stock for $33.1 million.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Emergent BioSolutions Inc. and subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Emergent BioSolutions Inc. and subsidiaries (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and financial statement schedule listed in the Index at Item 15 (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2017 and 2016, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 22, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2004.

Tysons, Virginia
February 22, 2018

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

	December 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 178,292	$ 271,513
Restricted cash	1,043	-
Accounts receivable, net	143,653	138,478
Inventories	142,812	74,002
Income tax receivable, net	2,432	9,996
Prepaid expenses and other current assets	17,157	16,229
Total current assets	485,389	510,218
Property, plant and equipment, net	407,210	376,448
Intangible assets, net	119,597	33,865
Goodwill	49,130	41,001
Deferred tax assets, net	2,834	6,096
Other assets	6,046	2,483
Total assets	$ 1,070,206	$ 970,111
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 41,751	$ 34,649
Accrued expenses and other current liabilities	4,831	6,368
Accrued compensation	37,882	34,537
Notes payable	-	20,000
Contingent consideration, current portion	2,372	3,266
Deferred revenue, current portion	13,232	7,036
Total current liabilities	100,068	105,856
Contingent consideration, net of current portion	9,902	9,919
Long-term indebtedness	13,457	248,094
Income taxes payable, net of current	12,500	-
Deferred revenue, net of current portion	17,259	8,433
Other liabilities	4,675	1,604
Total liabilities	157,861	373,906
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized, 0 shares issued and outstanding at both December 31, 2017 and December 31, 2016	-	-
Common stock, $0.001 par value; 200,000,000 shares authorized, 50,619,808 shares issued and 49,405,365 shares outstanding at December 31, 2017; 40,996,890 shares issued and 40,574,060 shares outstanding at December 31, 2016	50	41
Treasury stock, at cost, 1,214,443 and 422,830 common shares at December 31, 2017 and December 31, 2016, respectively	(39,497)	(6,420)
Additional paid-in capital	618,416	352,435
Accumulated other comprehensive loss	(3,698)	(4,331)
Retained earnings	337,074	254,480
Total stockholders' equity	912,345	596,205
Total liabilities and stockholders' equity	$ 1,070,206	$ 970,111

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

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

	Year Ended December 31,		
	2017	**2016**	**2015**
Revenues:			
Product sales	$ 421,516	$ 296,278	$ 328,969
Contract manufacturing	68,935	49,138	42,968
Contracts and grants	70,422	143,366	117,394
Total revenues	560,873	488,782	489,331
Operating expenses:			
Cost of product sales and contract manufacturing	195,707	131,284	107,486
Research and development	97,384	108,290	119,186
Selling, general and administrative	143,497	143,686	121,145
Income from operations	124,285	105,522	141,514
Other income (expense):			
Interest income	1,753	1,053	572
Interest expense	(6,590)	(7,617)	(6,523)
Other income (expense), net	(815)	263	153
Total other expense, net	(5,652)	(6,301)	(5,798)
Income from continuing operations before provision for income taxes	118,633	99,221	135,716
Provision for income taxes	36,039	36,697	44,300
Net income from continuing operations	82,594	62,524	91,416
Net loss from discontinued operations	-	(10,748)	(28,546)
Net income	$ 82,594	$ 51,776	$ 62,870
Net income per share from continuing operations-basic	$ 1.98	$ 1.56	$ 2.37
Net loss per share from discontinued operations-basic	-	(0.27)	(0.74)
Net income per share-basic	$ 1.98	$ 1.29	$ 1.63
Net income per share from continuing operations-diluted	$ 1.71	$ 1.35	$ 2.02
Net loss per share from discontinued operations-diluted	-	(0.22)	(0.61)
Net income per share-diluted (1)	$ 1.71	$ 1.13	$ 1.41
Weighted-average number of shares - basic	41,816,431	40,184,159	38,595,435
Weighted-average number of shares - diluted	50,327,937	49,335,112	47,255,842

(1) See “Earnings per share” footnote for details on calculation.

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

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

	December 31,		
	2017	**2016**	**2015**
Net income	$ 82,594	$ 51,776	$ 62,870
Foreign currency translations, net of tax	633	(1,618)	295
Comprehensive income	$ 83,227	$ 50,158	$ 63,165

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

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

	Year Ended December 31,		
	2017	2016	2015
Cash flows from operating activities:			
Net income	$ 82,594	$ 51,776	$ 62,870
Adjustments to reconcile to net cash provided by (used in) operating activities:			
Stock-based compensation expense	15,213	18,477	15,848
Depreciation and amortization	42,572	38,229	35,335
Deferred income taxes	3,259	5,190	3,464
Change in fair value of contingent obligations	7,830	(10,838)	(10,599)
Impairment of intangible assets (including IPR&D)	-	701	9,827
Impairment and abandonment of long-lived assets	1,936	5,569	1,147
Bad debt expense	-	-	3,481
Excess tax benefits from stock-based compensation	-	(10,619)	(11,281)
Other	1,011	452	271
Changes in operating assets and liabilities:			
Accounts receivable	(4,810)	(22,446)	(64,351)
Inventories	6,066	(9,026)	(11,262)
Income taxes	20,067	(3,424)	(5,492)
Prepaid expenses and other assets	(3,730)	(2,089)	2,319
Accounts payable	16,134	(14,791)	4,749
Accrued expenses and other liabilities	1,626	624	45
Accrued compensation	3,349	2,236	2,680
Provision for chargebacks	-	-	(8)
Deferred revenue	15,022	4,602	3,474
Net cash provided by operating activities	208,139	54,623	42,517
Cash flows from investing activities:			
Purchases of property, plant and equipment	(54,828)	(76,257)	(44,812)
Acquisitions	(195,104)	-	(650)
Net cash used in investing activities	(249,932)	(76,257)	(45,462)
Cash flows from financing activities:			
Proceeds from long-term debt obligations	-	-	2,000
Issuance of common stock upon exercise of stock options	19,346	17,125	25,961
Excess tax benefits from stock-based compensation	-	10,619	11,281
Debt issuance costs	(1,426)	-	-
Taxes paid on behalf of employees for equity activity	(4,260)	(1,136)	1,942
Payments of notes payable	(20,000)	-	-
Distribution to Aptevo	-	(45,000)	-
Contingent consideration payments	(10,941)	(1,385)	(5,693)
Restricted cash	(1,043)	-	-
Purchase of treasury stock	(33,077)	-	(100)
Net cash (used in) provided by financing activities	(51,401)	(19,777)	35,391
Effect of exchange rate changes on cash and cash equivalents	(27)	129	(150)
Net (decrease) increase in cash and cash equivalents	(93,221)	(41,282)	32,296
Cash and cash equivalents at beginning of year	271,513	312,795	280,499
Cash and cash equivalents at end of year	$ 178,292	$ 271,513	$ 312,795
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$ 8,416	$ 8,210	$ 7,751
Cash paid during the year for income taxes	$ 11,977	$ 10,081	$ 28,271
Supplemental information on non-cash investing and financing activities:			
Purchases of property, plant and equipment unpaid at year end	$ 4,587	$ 13,459	$ 4,379

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

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

	$0.001 Par Value Common Stock		Additional Paid-In	Treasury Stock		Accumulated Other Comprehensive	Retained	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	Loss	Earnings	Equity
Balance at December 31, 2014	38,129,872	$ 38	$ 274,222	(420,189)	$ (6,320)	$ (3,008)	$ 288,269	$ 553,201
Employee equity plans activity	1,699,536	2	43,749	-	-	-	-	43,751
Treasury stock	-	-	-	(2,641)	(100)	-		(100)
Net income	-	-	-	-	-	-	62,870	62,870
Foreign currency translation, net of tax	-	-	-	-	-	295	-	295
Balance at December 31, 2015	39,829,408	$ 40	$ 317,971	(422,830)	$ (6,420)	$ (2,713)	$ 351,139	$ 660,017
Employee equity plans activity	1,167,482	1	34,464			-	-	34,465
Separation of Aptevo	-	-	-	-	-	-	(148,435)	(148,435)
Treasury stock	-	-	-	-	-	-	-	-
Net income	-	-	-	-	-	-	51,776	51,776
Foreign currency translation, net of tax	-	-	-	-	-	(1,618)	-	(1,618)
Balance at December 31, 2016	40,996,890	$ 41	$ 352,435	(422,830)	$ (6,420)	$ (4,331)	$ 254,480	$ 596,205
Employee equity plans activity	1,114,830	1	27,951	-	-	-	-	27,952
Shares issued to extinguish convertible notes	8,508,088	8	238,030	-	-	-	-	238,038
Treasury stock	-	-	-	(791,613)	(33,077)	-	-	(33,077)
Net income	-	-	-	-	-	-	82,594	82,594
Foreign currency translation, net of tax	-	-	-	-	-	633	-	633
Balance at December 31, 2017	50,619,808	$ 50	$ 618,416	(1,214,443)	$(39,497)	$ (3,698)	$ 337,074	$ 912,345

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

1. Nature of the business and organization

Organization and business

Emergent BioSolutions Inc. (the "Company" or "Emergent") is a global life sciences company focused on providing specialty products for civilian and military populations that address accidental, intentional and naturally occurring public health threats.

Within the category of the Company's specialty products, it is focused on developing, manufacturing and commercializing medical countermeasures ("MCMs"), that address public health and national security threats, which the Company collectively refer to as PHTs. The PHTs that the Company is addressing fall into two categories: Chemical, Biological, Radiological, Nuclear and Explosives ("CBRNE"); and emerging infectious diseases ("EID"). The Company has a portfolio of eight products through which it generates most of its revenue, a fully-integrated portfolio of contract development and manufacturing services and a research and development pipeline of various investigational-stage product candidates.

Our MCM products are:

- BioThrax® (Anthrax Vaccine Adsorbed), the only vaccine licensed by the U.S. Food and Drug Administration ("FDA"), for the general use prophylaxis and post-exposure prophylaxis of anthrax disease;
- ACAM2000® (Smallpox (Vaccinia) Vaccine, Live), the only smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection (acquired from Sanofi Pasteur Biologics, LLC in October 2017);
- Raxibacumab (Anthrax Monoclonal), the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax (acquired from GlaxoSmithKline LLC in October 2017);
- Anthrasil® [Anthrax Immune Globulin Intravenous (Human)], the only polyclonal antibody therapeutic licensed by the FDA and Health Canada for the treatment of inhalational anthrax;
- BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)], the only heptavalent antibody therapeutic licensed by the FDA and Health Canada for the treatment of botulism;
- VIGIV [Vaccinia Immune Globulin Intravenous (Human)], the only therapeutic licensed by the FDA and Health Canada to address certain complications from smallpox vaccination;
- RSDL® (Reactive Skin Decontamination Lotion Kit), the only medical device cleared by the FDA to remove or neutralize the following chemical warfare agents from the skin: tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin; and
- Trobigard™ (atropine sulfate, obidoxime chloride), an auto-injector device designed for intramuscular self-injection of atropine sulfate and obidoxime chloride, as a nerve agent countermeasure. This product is not currently approved or cleared by the FDA or any similar regulatory body, and is only distributed to authorized government buyers for use outside the United States. This product is not distributed in the United States.

Aptevo spin-off

On August 1, 2016, the Company completed the spin-off of Aptevo Therapeutics Inc. ("Aptevo") and has classified the results of operations of Aptevo as discontinued operations for the years ended December 31, 2016 and 2015. The historical financial statements and footnotes have been revised accordingly.

2. Summary of significant accounting policies

Basis of presentation and consolidation

The accompanying consolidated financial statements include the accounts of Emergent and its wholly owned and majority owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

In anticipation of the spin-off, the Company realigned certain components of its biosciences business to the new Aptevo segment to be consistent with how the Company's chief operating decision maker ("CODM") allocates resources and makes decisions about the operations of the Company. Effective January 1, 2016, the Company changed its segment presentation to reflect this new structure, and recast all prior periods presented to conform to the new presentation. On August 1, 2016, the Company completed the spin-off of Aptevo. As of December 31, 2017, the results of operations and financial position of Aptevo are reflected as discontinued operations for all periods presented through the date of the spin-off. The historical financial statements and footnotes have been revised accordingly. See Note 3. "Discontinued operations" for further details regarding the spin-off. For periods following the spin-off, the Company reports financial results under one operating segment which is also a single reportable segment.

Use of estimates

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

Cash and cash equivalents

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

Fair value of measurements

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

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

The carrying amounts of the Company's short-term financial instruments, which include cash and cash equivalents, accounts receivable and accounts payable, approximate their fair values due to their short maturities.

Significant customers and accounts receivable

The Company has derived a majority of its revenue from sales of BioThrax under contracts with the U.S. government. The Company's current Centers for Disease Control ("CDC") contract does not necessarily increase the likelihood that it will secure future comparable contracts with the U.S. government. The Company expects that a significant portion of the business that it will seek in the near future, in particular for BioThrax, will be under government contracts that present a number of risks that are not typically present in the commercial contracting process. U.S. government contracts for BioThrax are subject to unilateral termination or modification by the government. The Company may fail to achieve significant sales of BioThrax to customers in addition to the U.S. government, which would harm its growth opportunities. The Company may not be able to sustain or increase profitability. The Company may not be able to manufacture BioThrax consistently in accordance with FDA specifications.

Accounts receivable are stated at invoice amounts and consist primarily of amounts due from the U.S. government, as well as amounts due under reimbursement contracts with other government entities and non-government organizations. If necessary, the Company records a provision for doubtful receivables to allow for any amounts which may be unrecoverable. This provision is based upon an analysis of the Company's prior collection experience, customer creditworthiness and current economic trends.

Concentrations of credit risk and uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company places its cash and cash equivalents with high quality financial institutions. Management believes that the financial risks associated with its cash and cash equivalents are minimal. Because accounts receivable consists primarily of amounts due from the U.S. government for product sales and from government agencies under government grants and development contracts, management does not deem the credit risk to be significant.

Inventories

Inventories are stated at the lower of cost or net realizable value with cost being determined using a standard cost method, which approximates average cost. Average cost consists primarily of material, labor and manufacturing overhead expenses (including fixed production-overhead costs) and includes the services and products of third party suppliers. The Company analyzes its inventory levels quarterly and writes down, in the applicable period, inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected customer demand. The Company also writes off, in the applicable period, the costs related to expired inventory. Costs of purchased inventories are recorded using weighted-average costing. The Company determines normal capacity for each production facility and allocates fixed production-overhead costs on that basis.

Property, plant and equipment

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

Buildings	31-39 years
Building improvements	10-39 years
Furniture and equipment	3-15 years
Software	3-7 years or product life
Leasehold improvements	Lesser of the asset life or lease term

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

The Company capitalizes internal-use software when both (a) the software is internally developed, acquired, or modified solely to meet the entity's internal needs and (b) during the software's development or modification, no substantive plan either exists or is being developed to market the software externally. Capitalization of qualifying internal-use software costs begins when the preliminary project stage is completed, management with the relevant authority, implicitly or explicitly, authorizes and commits to the funding of the software project, and it is probable that the project will be completed and the software will be used to perform the function intended.

Income taxes

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

Deferred income tax effects of transactions reported in different periods for financial reporting and income tax return purposes are recognized under the asset and liability method of accounting for income taxes. This method gives consideration to the future tax consequences of the deferred income tax items and immediately recognizes changes in income tax laws in the year of enactment. On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act (the "Tax Reform Act"). Further information on the tax impacts of the Tax Reform Act is included in Note 12 of the Company's consolidated financial statements.

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

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

Because tax laws are complex and subject to different interpretations, significant judgment is required. As a result, the Company makes certain estimates and assumptions, in (1) calculating the Company's income tax expense, deferred tax assets and deferred tax liabilities, (2) determining any valuation allowance recorded against deferred tax assets and (3) evaluating the amount of unrecognized tax benefits, as well as the interest and penalties related to such uncertain tax positions. The Company's estimates and assumptions may differ significantly from tax benefits ultimately realized.

Revenue recognition

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

- there is persuasive evidence of an arrangement;
- delivery has occurred or title has passed to the Company's customer;
- the fee is fixed or determinable; and
- collectability is reasonably assured.

Under the Company's contracts with the CDC, the Company invoices the CDC and recognizes the related revenue upon acceptance by the government at delivery site, at which time title to the product passes to the CDC.

Agreements with multiple components ("deliverables" or "items") are evaluated to determine if the deliverables can be divided into more than one unit of accounting. An item can generally be considered a separate unit of accounting if both of the following criteria are met:

(1) the delivered item or items have value to the customer on a standalone basis. The item or items have value on a standalone basis if they are sold separately by any vendor or the customer could resell the delivered item(s) on a standalone basis. In the context of a customer's ability to resell the delivered item(s), this criterion does not require the existence of an observable market for the deliverable(s); and

(2) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in control of the Company. Items that cannot be divided into separate units are combined with other units of accounting, as appropriate. Consideration received is allocated among the separate units based on the relative selling price of each deliverable. The Company deems service to have been rendered if no continuing obligation exists on the part of the Company.

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

The Company's BAT contract with BARDA is a service arrangement that includes multiple elements. The deliverables to BARDA include supplying product to the SNS, performing stability testing for the product, achievement of extended product expiry dating, maintenance of horse populations and plasma extraction. The Company has determined that each of the deliverables above represents a separate unit of accounting as they have standalone value to the U.S. government. The Company allocated the value of the contract to the undelivered elements based on best estimate of selling price ("BESP"). BESP methodology for the deliverables, excluding the product sales, was developed using a cost build-up for internal and external costs, plus a specified mark-up. The allocation of value to the product sales was based on the remaining unallocated value. The Company completed the final delivery of the BAT product in 2017. The Company recognizes revenue for:

- BAT product sales upon delivery to the SNS;
- stability testing based on the required testing schedule of the product;
- extended product expiry based on achievement of the extension;
- horse maintenance based on a per horse basis; and
- plasma collection on a per liter basis.

The Company's contracts for VIGIV with the CDC and for Anthrasil with BARDA are service arrangements that include multiple elements. The deliverables to BARDA include to supply product to the SNS, perform stability testing for the product, achievement of extended product expiry dating and plasma extraction. The Company has determined that each of the deliverables above represents separate units of accounting as they have standalone value to the U.S. government. The Company allocated the value of the contract to the undelivered elements based on BESP. BESP methodology for the deliverables, excluding the product sales, was developed using a cost build-up for internal and external costs, plus a specified mark-up. The allocation of value to the product sales was based on the remaining unallocated value. The Company recognizes revenue for:

- VIGIV and Anthrasil product sales upon delivery to the CDC;
- stability testing based on the required testing schedule of the product;
- extended product expiry based on achievement of the extension; and
- plasma collection on a per liter basis.

The Company's contract for the NuThrax product candidate with BARDA, which was entered into on September 30, 2016 is a service arrangement that includes multiple elements. The deliverables to BARDA are the completion of development for NuThrax and the procurement of product for the SNS. The Company has determined that each of the deliverables above are a separate unit of accounting as they have standalone value to the U.S. government. The Company allocated the value of the contract to the undelivered elements based on best estimate of selling price ("BESP"). BESP methodology for the development deliverable was developed using a cost build-up for internal and external costs, plus a specified mark-up.

The Company has determined that the procurement of NuThrax under the BARDA NuThrax Contract is a contingent deliverable, as it is dependent upon successful completion of development; therefore, the Company has excluded this from the allocation of the contract consideration. The Company has allocated $147.5 million to the development services deliverable and will recognize revenue as the services are provided.

On March 16, 2017, the Company entered into a contract with BARDA, valued at $100 million, for the delivery of BioThrax to the SNS over a two-year period of performance. In conjunction with the signing of this contract, the Company entered into a modification to its BARDA NuThrax Contract that increases the number of doses of NuThrax to be delivered under the base period from two million to three million doses with a commensurate reduction in dose price for the initial deliveries. The modification also provides for a discount on the sales price for doses to be procured during the option period up to $100 million. As a result of the modification of the BARDA NuThrax Contract, in conjunction with execution of the BARDA BioThrax Contract, the Company has determined that the two agreements are linked under the revenue recognition requirements of the Financial Accounting Standards Board ("FASB") Topic 605, Revenue Recognition. The Company analyzed these agreements and determined that the units of accounting under the linked agreements are:

- development services for the NuThrax product candidate under the BARDA NuThrax Contract; and
- procurement of BioThrax under the BARDA BioThrax Contract.

The Company's allocation of contract consideration for the development services was updated based on the services provided prior to March 17, 2017. The allocation of contract consideration for the BioThrax doses to be sold under the BARDA BioThrax Contract was determined based on similar pricing provided to other customers. The Company's determination of the amount of contract consideration to be allocated to the discounts was based on an undiscounted probability adjusted model, which factored in the expected timing of regulatory approval for the NuThrax product candidate, expected levels of procurement of the NuThrax product candidate upon regulatory approval and the market conditions for these types of medical countermeasures. The Company allocated the contract consideration to the two units of accounting as follows:

- $137.1 million was allocated to the development services for the NuThrax product candidate under the BARDA NuThrax Contract; and
- $93.6 million was allocated to the procurement of BioThrax under the BARDA BioThrax Contract.

The Company deferred a portion of the consideration received for doses delivered under the BARDA BioThrax Contract and the development services for the NuThrax product candidate. The Company will recognize the deferred revenue upon the delivery of NuThrax doses under the BARDA NuThrax Contract, or upon the future extinguishment of the Company's obligation to deliver NuThrax doses to which the discount applies.

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

Milestones are considered substantive if all of the following conditions are met: (1) the milestone is non-refundable, (2) achievement of the milestone was not reasonably assured at the inception of the arrangement, (3) substantive effort is involved to achieve the milestone, and (4) the amount of the milestone appears reasonable in relation to the effort expended. Payments received in advance of work performed are recorded as deferred revenue.

The Company generates contracts and grants revenue from cost-plus-fee contracts. Revenues from reimbursable contracts are recognized as costs are incurred, generally based on allowable costs incurred during the period, plus any recognizable earned fee. The Company considers fixed fees under cost-plus-fee contracts to be earned in proportion to the allowable costs incurred in performance of the contract. The Company analyzes costs for contracts and reimbursable grants to ensure reporting of revenues gross versus net is appropriate. For each of the three years in the period ended December 31, 2017, the costs incurred under the contracts and grants approximated the revenue earned.

Acquisitions

In determining whether an acquisition is a business combination versus an asset acquisition, the accounting guidance requires an entity to first evaluate whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If that threshold is met, the set of assets and activities is not a business and therefore treated as an asset acquisition. If it's not met, the entity evaluates whether the set meets the definition of a business. If an acquired asset or asset group does not meet the definition of a business, the transaction is accounted for as an asset acquisition. Otherwise, the acquisition is treated as a business combination.

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the merger or acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are recognized at fair value if fair value can reasonably be estimated. If the acquisition date fair value of an asset acquired or liability assumed that arises from a contingency cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's 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 the Company's consolidated financial statements after the date of the merger or acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded.

The fair values of intangible assets, including acquired in-process research and development ("IPR&D"), are determined utilizing information available at or near the merger or acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, the Company typically obtains assistance from third-party valuation specialists for significant items. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets. Upon successful completion of each project, the Company will make a separate determination as to the remaining 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 current 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. The Company's estimates of market participant net cash flows consider historical and projected pricing, margins and expense levels, the performance of competing products where applicable, relevant industry and therapeutic area growth drivers and factors, current and expected trends in technology and product life cycles, the time and investment that will be required to develop products and technologies, the ability to obtain marketing and regulatory approvals, the ability to manufacture and commercialize the products, the extent and timing of potential new product introductions by the Company's competitors, and the life of each asset's underlying patent, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

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

Intangible assets and long-lived assets

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

The Company assesses the recoverability of its long-lived assets or asset groups for which an indicator of impairment exists by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If the Company concludes that the carrying value will not be recovered, the Company measures the amount of such impairment by comparing the fair value to the carrying value of the assets or asset groups.

Goodwill

The Company assesses the carrying value of goodwill on an annual basis, or whenever events or changes in circumstances indicate the carrying value of goodwill may not be recoverable, to determine whether any impairment in this asset may exist and, if so, the extent of such impairment. The provisions of the relevant accounting guidance require that the Company perform a two-step impairment test. In the first step, the Company compares the fair value of its reporting unit to the carrying value of the reporting unit. If the carrying value of the reporting unit exceeds the fair value of the reporting unit, then the second step of the impairment test is performed in order to determine the implied fair value of the reporting unit's goodwill. If the carrying value of the reporting unit's goodwill exceeds its implied fair value, an impairment loss equal to the difference is recognized. The Company calculates the fair value of the reporting unit utilizing the income approach. The income approach utilizes a discounted cash flow model, using a discount rate based on the Company's estimated weighted average cost of capital. The Company also

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

The determination of the fair value of a reporting unit is judgmental in nature and involves the use of significant estimates and assumptions. The estimates and assumptions used in calculating fair value include identifying future cash flows, which requires that the Company makes a number of critical legal, economic, market and business assumptions that reflect best estimates as of the testing date. The Company's assumptions and estimates may differ significantly from actual results, or circumstances could change that would cause the Company to conclude that an impairment now exists or that it previously understated the extent of impairment. The Company selected October 1 as its annual goodwill impairment test date.

Contingent Consideration

The Company records contingent consideration associated with (a) sales based royalties and (b) development and regulatory milestones at fair value. 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 and achievement of the milestones. The inputs the Company uses for determining the fair value of the contingent consideration associated with sales based royalties and development and regulatory milestones are Level 3 fair value measurements. The Company re-evaluates 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 consideration associated with sales based royalties along with development and regulatory milestones are based on an increased likelihood that the underlying net sales or milestones will be achieved.

The associated payment or payments which will become due and payable for sales based royalties associated with products will result in a charge to cost of product sales and contract manufacturing in the period in which the increase is determined. Similarly, any future decrease in the fair value of contingent consideration associated with sales based royalties will result in a reduction in cost of product sales and contract manufacturing. The changes in fair value for potential future sales based royalties associated with product candidates in development will result in a charge to selling, general and administrative expense in the period in which the increase is determined. Similarly, any future decrease in the fair value of contingent consideration associated with potential future sales based royalties for products candidates will result in a reduction in selling, general and administrative expense.

The associated payment or payments which will become due and payable for development and regulatory milestones 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 for development and regulatory milestones will result in a reduction in research and development expense.

Research and development

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

- personnel-related expenses;
- fees to professional service providers for, among other things, analytical testing, independent monitoring or other administration of our clinical trials and obtaining and evaluating data from our clinical trials and non-clinical studies;
- costs of contract manufacturing services for clinical trial material; and
- costs of materials used in clinical trials and research and development.

In many cases, we plan to seek funding for development activities from external sources and third parties, such as governments and non-governmental organizations, or through collaborative partnerships. We expect our research and development spending will be dependent upon such factors as the results from our clinical trials, the availability of reimbursement of research and development spending, the number of product candidates under development, the size, structure and duration of any clinical programs that we may initiate, the costs associated with manufacturing our product candidates on a large-scale basis for later stage clinical trials, and our ability to use or rely on data generated by government agencies, such as studies involving BioThrax conducted by the CDC.

Comprehensive income

Comprehensive income is comprised of net income and other changes in equity that are excluded from net income. The Company includes translation gains and losses incurred when converting its subsidiaries' financial statements from their functional currency to the U.S. dollar in accumulated other comprehensive income.

Foreign currencies

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

Capitalized interest

The Company capitalizes interest based on the cost of major ongoing capital projects which have not yet been placed in service. For the years ended December 31, 2017, 2016, and 2015, the Company incurred interest of $7.0 million, $8.3 million and $7.8 million, respectively. Of these amounts, the Company capitalized $2.2 million, $2.2 million and $2.9 million, respectively.

Earnings per share

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

For the years ended December 31, 2017, 2016, and 2015, the Company calculated diluted earnings per share using the if-converted method by dividing the adjusted net income by the adjusted weighted average number of shares of common stock outstanding during the period. The adjusted net income is adjusted for interest expense and amortization of debt issuance cost, both net of tax, associated with the Company's 2.875% Convertible Senior Notes due 2021 (the "Notes"). The weighted average number of diluted shares is adjusted for the potential dilutive effect of the exercise of stock options and the vesting of restricted stock units along with the assumption of the conversion of the Notes, each at the beginning of the period. During the fourth quarter of 2017, the Company issued a notice of termination of conversion rights related to the Notes and issued 8.5 million shares of common stock due to conversions that occurred in 2017.

Accounting for stock-based compensation

The Company has one stock-based employee compensation plan, the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan"), which includes both stock options and restricted stock units.

As of December 31, 2017, an aggregate of 18.9 million shares of common stock were authorized for issuance under the 2006 Plan, of which a total of approximately 4.9 million shares of common stock remain available for future awards to be made to plan participants. The exercise price of each option must be not less than 100% of the fair market value of the shares underlying such option on the date of grant. Awards granted under the 2006 Plan have a contractual life of no more than 10 years. The terms and conditions of equity awards (such as price, vesting schedule, term and number of shares) under the 2006 Plan is determined by the compensation committee of the Company's board of directors, which administers the 2006 Plan. Each equity award granted under the 2006 Plan vests as specified in the relevant agreement with the award recipient and no option can be exercised after ten years from the date of grant.

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

	Year Ended December 31,		
	2017	2016	2015
Expected dividend yield	0%	0%	0%
Expected volatility	37-40%	31-33%	34-35%
Risk-free interest rate	1.66-1.88%	0.93-1.22%	1.27-1.61%
Expected average life of options	4.3 years	4.3 years	4.3 years

- Expected dividend yield — the Company does not pay regular dividends on its common stock and does not anticipate paying any dividends in the foreseeable future.
- Expected volatility — a measure of the amount by which a financial variable, such as share price, has fluctuated (historical volatility) or is expected to fluctuate (implied volatility) during a period. The Company analyzed its own historical volatility to estimate expected volatility over the same period as the expected average life of the options.
- Risk-free interest rate — the range of U.S. Treasury rates with a term that most closely resembles the expected life of the option as of the date on which the option is granted.
- Expected average life of options — the period of time that options granted are expected to remain outstanding, based primarily on the Company's expectation of optionee exercise behavior subsequent to vesting of options.

Recently issued accounting standards

ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)*

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU No. 2014-09"). ASU No. 2014-09 supersedes the revenue recognition requirements in *Topic 605, Revenue Recognition*, as well as most industry-specific guidance, and significantly enhances comparability of revenue recognition practices across entities and industries by providing a principles-based, comprehensive framework for addressing revenue recognition issues. In order for a provider of promised goods or services to recognize as revenue the consideration that it expects to receive in exchange for the promised goods or services, the provider should apply the following five steps: (1) identify the contract with a customer(s); (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. ASU No. 2014-09 also specifies the accounting for some costs to obtain or fulfill a contract with a customer and provides enhanced disclosure requirements. The standard will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period. The Company will adopt the requirements of the new standard in the first quarter of 2018 using the modified retrospective method. The modified retrospective method requires companies to recognize the cumulative effect of initially applying the new standard as an adjustment to opening retained earnings.

The Company used a cross functional team to identify and organize its contracts for analysis. The Company has finalized its review of its revenue contract portfolio and made its determination of its revenue streams as well as completed extensive contract specific reviews to determine the impacts of the new standard on its historical and prospective revenue recognition. Because many of the Company's contracts with customers have unique contract terms, the Company reviewed all of its non-standard agreements in order to determine the effect of adoption. As a result, it has determined the BARDA BioThrax Contract and BARDA NuThrax Contract will have a material change in revenue recognition that will likely increase the amount of deferred revenue on the adoption date. The Company is in the process of finalizing its analysis of the CIADM contract but expects that the revenue recognition policy and possibly the cumulative effect could be material. The Company is also finalizing its accounting policy; related income tax effects for these contracts; evaluating costs that may need to be capitalized or expensed; and designing and implementing the necessary changes to processes and controls in order to account for revenue under the new standard. Based on the Company's timeline and planned resources, the Company anticipates completing its implementation in connection with its first quarter 2018 interim financial statements.

ASU 2016-02, *Leases (Topic 842)*

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU No. 2016-02"). ASU No. 2016-02 increases transparency and comparability among organizations by requiring the recognition of lease assets and lease liabilities on the balance sheet and disclosure of key information about leasing arrangements for both lessees and lessors. The standard will be effective January 1, 2019 for the Company, with early adoption permitted. The standard will be applied using a modified retrospective approach to the beginning of the earliest period presented in the financial statements. The Company is currently evaluating the expected impact to its consolidated financial statements and related disclosures.

ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718)*

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718)* ("ASU No. 2016-09"). ASU No. 2016-09 simplifies several aspects of the accounting for share-based payment award transactions, including: (1) the income tax consequences, (2) classification of awards as either equity or liabilities, and (3) classification on the statement of cash flows. As of January 1, 2017, the Company adopted and performed the evaluation required by the standard and did not identify any conditions or events that would have a material impact on the current disclosures in the financial statements. The Company has retrospectively adjusted the operating and financing sections within the statement of cash flows for the classification of employee taxes paid associated with equity award activities for the year ended December 31, 2016. In addition, the Company prospectively adopted the provisions related to the excess tax benefits, and as a result prior periods were not adjusted. If the Company had adopted this provision retrospectively, there would have been approximately 4% change to the estimated effective annual tax rate for the year ended December 31, 2016, but for the year ended December 31, 2016, there would have been a tax benefit associated with stock option activity of $3.3 million recorded in the provision for income taxes on the Company's statement of operations.

ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU No. 2017-01"). ASU No. 2017-01 provides clarification for the definition of a business with the objective of adding guidance and providing a more robust framework to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The new standard will be effective for all annual periods beginning after December 15, 2017. During the fourth quarter of 2017, the Company early adopted ASU 2017-01 and determined the acquisition of Raxibacumab is an asset acquisition. See Note 4. "Acquisitions" for further details regarding this acquisition.

ASU No. 2017-04, *Intangibles - Goodwill and Other (Topic 250): Simplifying the Test for Goodwill Impairment*

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles - Goodwill and Other (Topic 250): Simplifying the Test for Goodwill Impairment (*"ASU No. 2017-04"). The standard eliminates the second step in the goodwill impairment test, which requires an entity to determine the implied fair value of the reporting unit's goodwill. Instead, an entity should recognize an impairment loss if the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, with the impairment loss not to exceed the amount of goodwill allocated to the reporting unit. The standard is effective for annual and interim goodwill impairment tests conducted in fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company does not believe that the new standard will have a material impact on its consolidated financial statements.

ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU No. 2017-09"). ASU No. 2017-09 clarifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The standard is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company has not determined the impact that adoption of this guidance will have on its consolidated financial statements.

There are no other recently issued accounting pronouncements that are expected to have a material effect on the Company's financial position, results of operations or cash flows.

3. Discontinued operations

On August 1, 2016, the Company completed the spin-off of Aptevo through the distribution of 100% of the outstanding shares of common stock of Aptevo to the Company's shareholders (the "Distribution"). The Distribution was made to the Company's shareholders of record as of the close of business on July 22, 2016 (the "Record Date"), who received one share of Aptevo common stock for every two shares of Emergent common stock held as of the Record Date. The Distribution was intended to qualify as a tax-free distribution for federal income tax purposes in the United States. In the aggregate, approximately 20.2 million shares of Aptevo common stock were distributed to the Company's shareholders of record as of the Record Date in the Distribution. After the Distribution, the Company no longer holds shares of Aptevo's common stock. In addition, on August 1, 2016, the Company entered into a non-negotiable, unsecured promissory note with Aptevo to provide an additional $20 million in funding, which the Company paid in January 2017.

The historical statements of operations of Aptevo have been presented as discontinued operations in the consolidated financial statements and the prior period has been restated. Discontinued operations include results of Aptevo's business except for certain allocated corporate overhead costs and certain costs associated with transition services provided by the Company to Aptevo. These allocated costs remain part of continuing operations. Due to differences between the basis of presentation for discontinued operations and the basis of presentation as a stand-alone company, the financial results of Aptevo included within discontinued operations for the Company may not be indicative of actual financial results of Aptevo.

The following table summarizes results from discontinued operations of Aptevo included in the consolidated statements of operations for the year ended December 31, 2016 and 2015:

	Years ended December 31,	
(in thousands)	**2016**	**2015**
Revenues:		
Product sales	$ 21,183	$ 27,947
Collaborations	187	5,511
Total revenues	21,370	33,458
Operating expense:		
Cost of product sales	11,556	16,809
Research and development	18,024	34,811
Selling, general and administrative	23,792	27,313
Loss from operations	(32,002)	(45,475)
Other income (expense), net:	(41)	(472)
Loss from discontinued operations before benefit from income taxes	(32,043)	(45,947)
Benefit from income taxes	(21,295)	(17,401)
Net loss from discontinued operations	$ (10,748)	$ (28,546)

The following table summarizes the cash flows of Aptevo included in the years ended December 31, 2016 and 2015 consolidated statements of cash flows:

	Years ended December 31,	
(in thousands)	**2016**	**2015**
Net cash used in operating activities	$ (10,299)	$ (12,716)
Net cash used in investing activities	(1,926)	(1,518)
Net cash provided by financing activities	7,733	15,012
Net increase (decrease) in cash and cash equivalents	$ (4,492)	$ 778

4. Acquisitions

Acquisition of ACAM2000 business

On October 6, 2017, the Company completed the acquisition of the ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) business of Sanofi Pasteur Biologics, LLC ("Sanofi"). This acquisition includes ACAM2000, the only smallpox vaccine licensed by the FDA, a current good manufacturing practices ("cGMP") live viral manufacturing facility and office and warehouse space, both in Canton, Massachusetts, and a cGMP viral fill/finish facility in Rockville, Maryland. With this acquisition, the Company also acquired an existing 10-year contract with the Centers for Disease Control and Prevention ("CDC"), which will expire and be up for renewal or extension in March 2018. This contract had a stated value up to $425 million, with a remaining contract value of up to approximately $160 million as of the acquisition date, for the delivery of ACAM2000 to the SNS and establishing U.S.-based manufacturing of ACAM2000. This acquisition added to the Company's product portfolio and expanded the Company's manufacturing capabilities.

At the closing, the Company paid $97.5 million in an upfront payment and $20 million in milestone payments earned as of the closing date tied to the achievement of certain regulatory and manufacturing-related milestones, for a total payment in cash of $117.5 million. The agreement includes an additional milestone payment of up to $7.5 million upon achievement of a regulatory milestone, which was achieved in November 2017. The $7.5 million milestone payment was made during the fourth quarter of 2017. This transaction will be accounted for by the Company under the acquisition method of accounting, with the Company as the acquirer. Under the acquisition method of accounting, the assets and liabilities of the ACAM2000 business will be recorded as of October 6, 2017, the acquisition date, at their respective fair values, and combined with those of the Company.

The contingent purchase consideration obligation is based on a regulatory milestone. At October 6, 2017, the contingent purchase consideration obligation related to the regulatory milestone was recorded at a fair value of $2.2 million. The Level 3 fair value of this obligation is based on a present value model of management's assessment of the probability of achievement of the regulatory milestone as of the acquisition date. This assessment is based on inputs that have no observable market.

The total purchase price is summarized below:

(in thousands)	
Amount of cash paid to Sanofi	$ 117,500
Fair value of contingent purchase consideration	2,200
Total purchase price	$ 119,700

The table below summarizes the preliminary allocation of the purchase price based upon estimated fair values of assets acquired and liabilities assumed at October 6, 2017. The allocation is preliminary based upon the finalization of valuation reports.

(in thousands)	
Fair value of tangible assets acquired and liabilities assumed:	
Inventory	$ 74,876
Property, plant and equipment	19,995
Total fair value of tangible assets acquired and liabilities assumed	94,871
Acquired intangible asset	16,700
Goodwill	8,129
Total purchase price	$ 119,700

The Company determined the fair value of the intangible asset using the income approach, which is based on the present value of future cash flows. The fair value measurements are based on significant unobservable inputs that are developed by the

Company using estimates and assumptions of the respective market and market penetration of the Company's products. The Company determined the fair value of the ACAM2000 intangible asset using the income approach with a present value discount rate of 15.5%, based on the estimated weighted-average cost of capital for substantially similar companies. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value these intangible assets. The projected cash flows from ACAM2000 intangible asset were based on key assumptions, including: estimates of revenues and operating profits, the life of the potential commercialized product and associated risks, and risks related to the viability of and potential alternative treatments in any future target markets. The Company has determined the ACAM2000 intangible asset will be amortized over 10 years.

The Company determined the fair value of the inventory using the probability adjusted comparative sales method, which estimates the expected sales price reduced for all costs expected to be incurred to complete/dispose of the inventory with a profit on those costs.

The Company determined the fair value of the property, plant and equipment utilizing either the cost approach or the sales comparison approach. The cost approach is determined by determining replacement cost of the asset and then subtracting any value that has been lost due to economic obsolescence, functional obsolescence, or physical deterioration. The sales comparison approach determines an asset is equal to the market price of an asset of comparable features such as design, location, size, construction, materials, use, capacity, specification, operational characteristics and other features or descriptions.

The Company recorded approximately $8.1 million in goodwill related to the ACAM2000 acquisition, representing the purchase price paid in the acquisition that was in excess of the fair value of the tangible and intangible assets acquired. There is no goodwill for tax purposes.

The Company has incurred transaction costs related to the ACAM2000 acquisition of approximately $2.5 million for the year ended December 31, 2017, which has been recorded in selling, general and administrative expenses.

The Company has determined the historical results for ACAM2000 were not significant to the Company's results of operations, and as such no proforma disclosures have been presented.

Acquisition of Raxibacumab asset

On October 2, 2017, the Company completed the acquisition of Raxibacumab, a fully human monoclonal antibody therapeutic product approved by the U.S. Food and Drug Administration ("FDA") for the treatment and prophylaxis of inhalational anthrax, from Human Genome Sciences, Inc. and GlaxoSmithKline LLC (collectively referred to as "GSK"). The all-cash transaction consists of a $76 million upfront payment and up to $20 million in product sale and manufacturing-related milestone payments. None of the milestones have been achieved as of December 31, 2017.

The Company has determined that substantially all of the value of Raxibacumab is attributed to the Raxibacumab asset and therefore the Raxibacumab acquisition is considered an asset acquisition. In addition, the Company has capitalized $1.6 million of transaction costs associated with the acquisition. The Company has determined the Raxibacumab asset will be amortized over 10 years.

5. Fair value measurements

Contingent consideration are liabilities measured at fair value on a recurring basis. For the year ended December 31, 2017, the contingent consideration for ACAM2000 increased by $5.3 million and the remaining $7.5 million regulatory milestone was paid. For the year ended December 31, 2017 and 2016, the contingent consideration obligation associated with the EV-035 series of molecules and the broad spectrum antiviral platform program decreased by $0.2 million and $5.4 million, respectively. The changes are primarily due to the estimated timing and probability of success for certain development and regulatory milestones of the program, which are inputs that have no observable market (Level 3). These changes are classified in the Company's statement of operations as both selling, general and administrative expense and research and development expense.

For the years ended December 31, 2017 and 2016, the contingent consideration obligations associated with RSDL increased by $2.7 million and decreased by $5.4 million, respectively. The changes in the fair value of the RSDL contingent consideration obligations are primarily due to the expected amount and timing of future net sales, which are inputs that have no observable market (Level 3). These changes are classified in the Company's statement of operations as cost of product sales and contract manufacturing.

The following table is a reconciliation of the beginning and ending balance of the liabilities measured at fair value using significant unobservable inputs (Level 3) during the years ended December 31, 2017 and 2016.

(in thousands)	
Balance at December 31, 2015	$ 25,155
(Income) expense included in earnings	(10,857)
Settlements	(1,113)
Balance at December 31, 2016	$ 13,185
(Income) expense included in earnings	7,830
Settlements	(10,941)
Purchases, sales and issuances	2,200
Balance at December 31, 2017	$ 12,274

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a non-recurring basis. As of December 31, 2017 and 2016, there were no assets or liabilities measured at fair value on a non-recurring basis.

6. Accounts receivable

Accounts receivable consist of the following:

	December 31,	
(in thousands)	**2017**	**2016**
Billed	$ 118,918	$ 90,439
Unbilled	24,735	48,039
Total	$ 143,653	$ 138,478

As of December 31, 2017 and 2016, the Company's accounts receivable balances were comprised of 89% and 83%, respectively, from the U.S. government. The overall increase in the percentage of accounts receivable attributed to U.S. government was due primarily to the timing of shipments of product and payments received for BioThrax product sales under the Company's contract with the CDC. Unbilled accounts receivable relates to various service contracts for which work has been performed, though invoicing has not yet occurred. Unbilled accounts receivable has decreased by $23.3 million due primarily to the timing of billings under our contract with the U.S. government related to the Company's CIADM program.

7. Inventories

Inventories consist of the following:

	December 31,	
(in thousands)	**2017**	**2016**
Raw materials and supplies	$ 36,069	$ 30,687
Work-in-process	76,610	19,821
Finished goods	30,133	23,494
Total inventories	$ 142,812	$ 74,002

The increase in inventories for the year ended December 31, 2017 was primarily due to the acquisition of ACAM2000 in October 2017.

8. Property, plant and equipment

Property, plant and equipment consist of the following:

	December 31,	
(in thousands)	**2017**	**2016**
Land and improvements	$ 21,843	$ 20,340
Buildings, building improvements and leasehold improvements	160,005	147,130
Furniture and equipment	206,819	190,157
Software	50,829	52,564
Construction-in-progress	100,088	77,813
	539,584	488,004
Less: Accumulated depreciation and amortization	(132,374)	(111,556)
Total property, plant and equipment, net	$ 407,210	$ 376,448

For the year ended December 31, 2017 and 2016, construction-in-progress primarily includes costs related to the build out of the Company's CIADM manufacturing facility.

Depreciation and amortization expense was $32.2 million, $28.0 million and $23.7 million for the years ended December 31, 2017, 2016, and 2015, respectively.

9. Intangible assets and goodwill

As of October 1, 2017 and 2016, the Company performed a qualitative assessment of goodwill associated with the Therapeutics and Vaccines reporting unit, Contract Manufacturing reporting unit, and the Devices reporting unit and determined there were no indicators of impairment.

Intangible assets consisted of the following:

(in thousands)	Total
Cost basis	
Balance at December 31, 2016	$ 57,099
Additions	94,304
Balance at December 31, 2017	$ 151,403
Accumulated amortization	
Balance at December 31, 2016	$ (23,234)
Amortization	(8,572)
Balance at December 31, 2017	$ (31,806)
Net book value at December 31, 2017	$ 119,597

For the years ended December 31, 2017, 2016 and 2015, the Company recorded amortization expense of $8.6 million, $6.9 million and $7.4 million, respectively, for intangible assets, which has been recorded in operating expenses, specifically selling, general and administrative and cost of product sales and contract manufacturing. As of December 31, 2017, the weighted average amortization period remaining for intangible assets is 105 months.

Future amortization expense as of December 31, 2017 is as follows:

(in thousands)	
2018	$ 15,647
2019	15,168
2020	15,087
2021	13,596
2022 and beyond	60,099
Total remaining amortization	$ 119,597

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

(in thousands)	Therapeutics and vaccines	Contract manufacturing	Devices	Total
Cost Basis				
Balance at December 31, 2016	$ 24,349	$ 6,736	$ 9,916	$ 41,001
Additions	8,129	-	-	8,129
Balance at December 31, 2017	$ 32,478	$ 6,736	$ 9,916	$ 49,130

10. Long-term debt

2.875% Convertible senior notes due 2021

On January 29, 2014, the Company issued $250.0 million aggregate principal amount of 2.875% Convertible Senior Notes due 2021 (the "Notes"). The Notes bear interest at a rate of 2.875% per year, payable semi-annually in arrears on January 15 and July 15 of each year. The Notes mature on January 15, 2021, unless earlier purchased by the Company or converted. The original conversion rate is equal to 30.8821 shares of common stock per $1,000 principal amount of notes (which is equivalent to a conversion price of approximately $32.38 per share of common stock). The conversion rate is subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest. The Company incurred approximately $8.3 million in debt issuance costs associated with the Notes, which has been capitalized on the consolidated balance sheets and is

being amortized over seven years. As of August 1, 2016, certain conversion features were triggered due to the completion of the Aptevo spin-off. The conversion rate under the Notes was adjusted in accordance with the terms of the indenture. Effective August 12, 2016, the conversion rate was adjusted to 32.3860 shares of common stock per $1,000 principal amount of notes (which is equivalent to a conversion price of approximately $30.88 per share of common stock).

On November 14, 2017, the Company issued a notice of termination of conversion rights for its outstanding Notes, of which $250.0 million was outstanding as of the notice date. In connection with the notice of termination, bondholders were given the option to convert their notes into the Company's stock at a rate of 32.386 per $1,000 of principal outstanding, plus a make-whole of an additional 3.1556 shares per $1,000 principal outstanding, in accordance with the terms of the indenture. The Company was not obligated to pay accrued or unpaid interest on converted notes, and bondholders who did not convert by the deadline of December 28, 2017 would retain their bonds but lose the conversion rights associated with the Notes and be paid interest of 2.875% until the earlier of maturity of the Notes in 2021 or the bonds being called and repaid in full by the Company. Between July 15, 2017 and the notification of termination of conversion rights, the Company accrued interest on the converted Notes of $2.4 million which was recorded as an increase in additional paid-in-capital on the balance sheet. Between November 14, 2017 and December 28, 2017 (the "conversion period"), approximately $239.4 million of bonds were converted into 8.5 million shares of the Company's common stock, inclusive of shares issued as part of the make-whole provision. In addition, the Company recorded a reduction in additional paid-in-capital on the Company's balance sheet of $3.6 million associated with debt issuance costs attributable to the converted notes. After giving effect to the converted bonds, the outstanding principal balance of the Notes as of December 31, 2017 was $10.6 million.

Senior secured credit agreement

On September 29, 2017, the Company entered into a senior secured credit agreement (the "2017 Credit Agreement") with four lending financial institutions, which replaced the Company's prior senior secured credit agreement (the "2013 Credit Agreement"). The 2017 Credit Agreement provides for a senior secured credit facility of up to $200 million through September 29, 2022. The 2017 Credit Agreement also includes a $100 million accordion feature, which could provide an additional $100 million in revolver or incremental term loans, at the option of the Company, resulting in a potential aggregate commitment of up to $300 million, subject to certain conditions and requirements set forth in the 2017 Credit Agreement. As of December 31, 2017, no amounts were drawn under the 2017 Credit Agreement.

The Company's payment obligations under the 2017 Credit Agreement are secured by a lien on substantially all of the Company's assets, including the stock of all the Company's domestic subsidiaries, and the assets of the subsidiary guarantors. Borrowings under the 2017 Credit Agreement will bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.50% to 2.50% per annum, depending on the Company's consolidated net leverage ratio or (b) a base rate (which is the highest of the prime rate, the federal funds rate plus 0.50% and a eurocurrency rate for an interest period of one month plus 1%) plus a margin ranging from 0.50% to 1.50%, depending on the Company's consolidated net leverage ratio. The Company is required to make quarterly payments under the 2017 Credit Agreement of accrued and unpaid interest on the outstanding principal balance, based on the above interest rates. In addition, the Company is required to pay commitment fees ranging from 0.25% to 0.40% per annum, depending on the Company's consolidated net leverage ratio, in respect of daily unused commitments under the 2017 Credit Agreement.

The 2017 Credit Agreement contains affirmative and negative covenants customary for financings of this type. Negative covenants in the 2017 Credit Agreement, among other things, limit the Company's ability to incur indebtedness and liens; dispose of assets; make investments including loans, advances, guarantees, or acquisitions (other than permitted acquisitions, subject to compliance with the financial covenants and certain other conditions); and enter into certain mergers or consolidation transactions. The 2017 Credit Agreement also contains financial covenants, tested quarterly and in connection with any triggering events under the 2017 Credit Agreement: (1) a minimum consolidated debt service coverage ratio of 2.50 to 1.00, and (2) a maximum consolidated net leverage ratio of 3.50 to 1.00, which may be adjusted to 4.00 to 1.00 for a four-quarter period in connection with a permitted acquisition, subject to the terms and conditions of the 2017 Credit Agreement. Each of the ratios referred to in the foregoing clauses (1) and (2) is calculated on a consolidated basis for each consecutive four fiscal quarter periods. As of December 31, 2017, the Company is compliance with affirmative and negative covenants.

The Company entered into a standby letter of credit and guarantee arrangement with a bank in the amount of $1.0 million that is fully collateralized by cash, which is classified as restricted cash in the Company's consolidated balance sheet.

11. Stockholders' equity

Preferred stock

The Company is authorized to issue up to 15.0 million shares of preferred stock, $0.001 par value per share ("Preferred Stock"). Any Preferred Stock issued may have dividend rights, voting rights, conversion privileges, redemption characteristics, and sinking fund requirements as approved by the Company's board of directors.

Common stock

The Company currently has one class of common stock, $0.001 par value per share common stock ("Common Stock"), authorized and outstanding. The Company is authorized to issue up to 200.0 million shares of Common Stock. Holders of Common Stock are entitled to one vote for each share of Common Stock held on all matters, except as may be provided by law.

Stock options and restricted stock units

As of December 31, 2017, the Company had one equity award plan, the Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (the "2006 Plan"), which includes both stock options and restricted stock units.

In connection with the Separation on August 1, 2016 and in accordance with the employee matters agreement and the Emergent Plans, the Company made certain adjustments to the exercise price and number of equity awards. Continuing Emergent employees with equity awards issued prior to Distribution received an equitable adjustment reflecting a revised exercise price and number of equity awards granted. Continuing Aptevo employees who had been granted Emergent equity awards had their grants canceled and reissued as Aptevo equity awards with an adjusted exercise price.

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

	2006 Plan		
	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at December 31, 2016	2,559,331	$ 22.94	$ 25,348,245
Granted	427,821	31.13	
Exercised	(792,795)	19.95	
Forfeited	(72,952)	29.30	
Outstanding at December 31, 2017	2,121,405	$ 25.48	$ 44,518,585
Exercisable at December 31, 2017	1,307,330	$ 22.63	$ 31,170,967
Options expected to vest at December 31, 2017	632,954	$ 29.91	$ 10,480,716

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

	Number of Shares	Weighted-Average Grant Price	Aggregate Intrinsic Value
Outstanding at December 31, 2016	875,584	$ 28.94	$ 28,754,179
Granted	480,959	31.49	
Vested	(423,840)	30.52	
Forfeited	(80,983)	29.21	
Outstanding at December 31, 2017	851,720	$ 30.84	$ 39,579,428

The weighted average remaining contractual term of options outstanding as of December 31, 2017 and 2016 was 4.0 years and 4.0 years, respectively. The weighted average remaining contractual term of options exercisable as of December 31, 2017 and 2016 was 3.2 years and 3.2 years, respectively.

The weighted average grant date fair value of options granted during the years ended December 31, 2017, 2016, and 2015 was $10.53, $9.24 and $8.66, respectively. The total intrinsic value of options exercised during the years ended December 31, 2017, 2016, and 2015 was $13.9 million, $15.6 million and $20.2 million, respectively. The total fair value of awards vested during 2017, 2016 and 2015 was $17.9 million, $16.9 million and $14.4 million, respectively. As of the year ended December 31, 2017, the total compensation cost and weighted average period over which total compensation is expected to be recognized related to unvested equity awards was $17.9 million and 2.0 years, respectively.

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

(in thousands)	Year Ended December 31, 2017	2016	2015
Cost of product sales	$ 1,076	$ 997	$ 1,183
Research and development	2,526	2,297	2,324
Selling, general and administrative	11,611	14,062	11,234
Continuing operations	15,213	17,356	14,741
Discontinued operations	-	1,121	1,107
Total stock-based compensation expense	$ 15,213	$ 18,477	$ 15,848

On July 14, 2016, the Company's board of directors authorized management to repurchase, from time to time, up to an aggregate of $50 million of the Company's common stock under a board-approved share repurchase program. The term of the board authorization of the repurchase program is until December 31, 2017. Any repurchased shares will be available for use in connection with the Company's stock plans and for other corporate purposes. During the year ended December 31, 2017, the Company has repurchased 0.8 million shares of common stock for $33.1 million.

12. Income taxes

On December 22, 2017, the President of the United States signed into law the Tax Reform Act. The legislation significantly changes U.S. tax law by, among other things, lowering corporate income tax rates, implementing a territorial tax system and imposing a repatriation tax on deemed repatriated earnings of foreign subsidiaries. The Tax Reform Act permanently reduces the U.S. corporate income tax rate from a maximum of 35% to a flat 21% rate, effective January 1, 2018.

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. Valuation allowances are recorded as appropriate to reduce deferred tax assets to the amount considered likely to be realized. As a result of the reduction in the U.S. corporate income tax rate from 35% to 21% under the Tax Reform Act, the Company revalued its ending net deferred tax liabilities in the United States at December 31, 2017 and recognized a provisional $13.4 million tax benefit in the Company's consolidated statement of income for the year ended December 31, 2017.

The Tax Reform Act provided for a one-time deemed mandatory repatriation of post-1986 undistributed foreign subsidiary earnings and profits ("E&P") through the year ended December 31, 2017. The Company had an estimated $95.4 million of undistributed foreign E&P subject to the deemed mandatory repatriation and recognized a provisional transition tax of $13.6 million of income tax expense in the Company's consolidated statement of income for the year ended December 31, 2017. The Company expects to pay U.S. federal cash taxes on the deemed mandatory repatriation over eight years.

While the Tax Reform Act provides for a territorial tax system, beginning in 2018, it includes two new U.S. tax base erosion provisions, the global intangible low-taxed income ("GILTI") provisions and the base-erosion and anti-abuse tax ("BEAT") provisions.

The GILTI provisions require the Company to include in its U.S. income tax return foreign subsidiary earnings in excess of an allowable return on the foreign subsidiary's tangible assets. The Company expects that it will be subject to incremental U.S. tax on GILTI income beginning in 2018, due to Company's overall foreign loss position. The Company has elected to account for GILTI tax in the period in which it is incurred, and therefore has not provided any deferred tax impacts of GILTI in its consolidated financial statements for the year ended December 31, 2017.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Reform Act. The Company has recognized the provisional tax impacts related to deemed repatriated earnings and the revaluation of deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. The ultimate impact may differ from these provisional amounts, possibly materially, due to, among other things, additional analysis, changes in interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of the Tax Reform Act. The Company's estimates are provisional based upon utilization of foreign tax credits and validation of E&P. The accounting is expected to be complete when the 2017 U.S. corporate income tax return is filed in 2018.

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

(in thousands)	Year Ended December 31, 2017	2016	2015
Current			
Federal	$ 29,441	$ 29,244	$ 38,957
State	2,983	2,331	2,221
International	356	1,002	2,029
Total current	32,780	32,577	43,207
Deferred			
Federal	(6,045)	9,979	(119)
State	(592)	(272)	(111)
International	9,896	(5,587)	1,323
Total deferred	3,259	4,120	1,093
Total provision for income taxes	$ 36,039	$ 36,697	$ 44,300

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

(in thousands)	December 31, 2017	2016
Federal losses carryforward	$ 1,603	$ 4,130
State losses carryforward	17,234	13,682
Research and development carryforward	3,534	3,647
Scientific research and experimental development credit carryforward	16,493	16,594
Stock compensation	5,344	8,389
Foreign deferrals	34,072	58,647
Inventory reserves	1,607	2,273
Other	3,889	5,569
Deferred tax asset	83,776	112,931
Fixed assets	(23,121)	(30,728)
Intangible assets	(2,229)	(5,882)
Other	(10,451)	(16,047)
Deferred tax liability	(35,801)	(52,657)
Valuation allowance	(45,141)	(54,178)
Net deferred tax asset	$ 2,834	$ 6,096

As of December 31, 2017, the Company has a net U.S. deferred tax liability in the amount of $13.1 million and a foreign net deferred tax asset in the amount of $15.9 million. The Company had a net U.S. deferred tax liability in the amount of $18.3 million and a foreign net deferred tax asset in the amount of $24.4 as of December 31, 2016.

As of December 31, 2017, the Company currently has approximately $7.6 million ($1.6 million tax effected) in net operating loss carryforwards along with $3.5 million in research and development tax credit carryforwards for U.S. federal tax purposes that will begin to expire in 2027 and 2024, respectively. The U.S. federal tax carryforwards are recorded with no valuation allowance. The Company has $264.1 million ($17.2 million tax effected) in state net operating loss carryforwards, primarily in Maryland, that will begin to expire in 2019. The U.S. state tax loss carryforwards are recorded with a valuation allowance of $193.5 million ($12.6 million tax effected). The Company has approximately $168.7 million ($32.5 million tax effected) in net operating losses from foreign jurisdictions (excluding Canada) that will have an indefinite life unless the foreign entities have a change in the nature or conduct of the business in the three years following a change in ownership. A valuation allowance in respect to these foreign losses has been recorded in the amount of $32.5 million. During the year the Company has utilized approximately $41.8 million ($11.3 million tax effected) in Canadian loss carryforwards. The Company currently has approximately $16.5 million in Manitoba scientific research and experimental development credit carryforwards that will begin to expire in 2025. The use of any of these net operating losses and research and development tax credit carryforwards may be restricted due to future changes in the Company's ownership.

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

	Year ended December 31,		
(in thousands)	**2017**	**2016**	**2015**
US	$ 80,690	$ 63,330	$ 117,385
International	37,943	35,891	18,331
Earnings before taxes on income	118,633	99,221	135,716
Federal tax at statutory rates	$ 41,522	$ 34,738	$ 47,475
State taxes, net of federal benefit	1,274	529	852
Impact of foreign operations	(2,168)	(9,937)	(1,640)
Change in valuation allowance	314	10,458	(950)
Tax credits	(1,918)	(1,572)	(2,088)
Transition tax	13,585	-	-
Change in U.S. tax rate	(13,403)	-	-
Stock compensation	(3,978)	-	-
Other differences	(118)	1,103	733
Permanent differences	929	1,378	(82)
Provision for income taxes	$ 36,039	$ 36,697	$ 44,300

The effective annual tax rate for the years ended December 31, 2017, 2016, and 2015 was 30%, 37% and 33%, respectively.

The effective annual tax rate of 30% in 2017 differs from statutory rate primarily due to the jurisdictional mix of earnings. Due to the impact of the Tax Reform Act enacted on December 22, 2017, the Company recognized a $13.4 million tax benefit as a result of revaluing the U.S. ending net deferred tax liabilities from 35% to the newly enacted U.S. corporate income tax rate of 21%. The tax benefit was fully offset by tax expense of $13.6 million for the transition tax on the deemed mandatory repatriation of undistributed earnings.

The increase in the effective annual tax rate in 2016 was primarily related to tax on the sale, within the Company's consolidated group, of assets from Canadian subsidiaries to U.S. subsidiaries in preparation of the spin-off of Aptevo, and a valuation allowance charge recorded in its continuing operations related to Aptevo deferred tax assets prior to the distribution. The Company determined that upon spin-off, the deferred tax assets of Aptevo would be unrealizable.

The Company recognizes interest in interest expense and recognizes potential penalties related to unrecognized tax benefits in selling, general and administrative expense. Of the total unrecognized tax benefits recorded at December 31, 2017 and 2016, $0.8 million and $0.5 million, respectively, is classified as a current liability and $1.2 million and $1.3 million, respectively, is classified as a non-current liability on the balance sheet.

The table below presents the gross unrecognized tax benefits activity for 2017, 2016 and 2015:

(in thousands)	
Gross unrecognized tax benefits at December 31, 2014	$ 1,248
Increases for tax positions for prior years	150
Decreases for tax positions for prior years	-
Increases for tax positions for current year	59
Settlements	-
Lapse of statute of limitations	-
Gross unrecognized tax benefits at December 31, 2015	1,457
Increases for tax positions for prior years	5
Decreases for tax positions for prior years	-
Increases for tax positions for current year	299
Settlements	-
Lapse of statute of limitations	-
Gross unrecognized tax benefits at December 31, 2016	1,761
Increases for tax positions for prior years	-
Decreases for tax positions for prior years	-
Increases for tax positions for current year	531
Settlements	(318)
Lapse of statute of limitations	-
Gross unrecognized tax benefits at December 31, 2017	$ 1,974

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

The Company's federal and state income tax returns for the tax years 2013 to 2016 remain open to examination. The Company's tax returns in the United Kingdom remain open to examination for the tax years 2008 to 2016, and tax returns in Germany remain open indefinitely. The Company's tax returns for Canada remains open to examination for the tax years 2010 to 2016.

As of December 31, 2017, the Company's Canadian 2016 Scientific Research and Experimental Development Claim is under audit. As of December 31, 2017, the Company's 2011 and 2012 federal income tax returns that were under audit are now resolved and closed.

13. 401(k) savings plan

The Company has established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers substantially all U.S. employees. Under the 401(k) Plan, employees may make elective salary deferrals. The Company currently provides for matching of qualified deferrals up to 50% of the first 6% of the employee's salary. During the years ended December 31, 2017, 2016, and 2015, the Company made matching contributions of approximately $2.7 million, $2.5 million and $2.2 million, respectively.

14. Leases

The Company leases fill/finish, manufacturing, laboratory, warehouse and office facilities, office equipment and vehicles under various operating lease agreements. The Company leases a fill/finish space in Rockville, Maryland under an operating lease that contains no escalation clause, which expires in May 2027. The Company leases office and warehouse space in Baltimore, Maryland under an operating lease that contains a 2.75% escalation clause, which expires in July 2027. The Company leases office and warehouse space in Canton, Massachusetts, under an operating lease that contains a 3.0% escalation clause, which expires in April 2023. The Company leases office space in Washington, D.C. under an operating lease that contains a 2.5% escalation clause, which expires in March 2027. For the years ended December 31, 2017, 2016, and 2015, total lease expense was $1.6 million, $1.4 million and $1.3 million, respectively.

Future minimum lease payments under operating lease obligations as of December 31, 2017 were as follows:

(in thousands)	
2017	$ 1,626
2018	1,391
2019	1,339
2020	1,343
2021	1,346
2022 and beyond	3,685
Total minimum lease payments	$ 10,730

15. Related party transactions

In November 2015, the Company entered into a consulting arrangement with a member of the Company's Board of Directors, amended in July 2016, to provide assistance in connection with the planned spin-off of Aptevo. The total compensation under the agreement was approximately $0.2 million per year. The consulting agreement terminated on August 1, 2016.

The Company entered into an agreement in February 2009 with an entity controlled by family members of the Company's Executive Chairman to sell BioThrax. The agreement was effective as of November 2008 and requires payment based on a percentage of net sales of biodefense products of 17.5% in Saudi Arabia and 15% in Qatar and United Arab Emirates, and reimbursement of certain expenses. No expenses were incurred under this agreement during the years ended December 31, 2017, 2016 and 2015.

16. Earnings per share

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

(in thousands, except share and per share data)	Years ended December 31, 2017	2016	2015
Numerator:			
Net income from continuing operations	$ 82,594	$ 62,524	$ 91,416
Interest expense, net of tax	2,606	3,255	3,019
Amortization of debt issuance costs, net of tax	681	781	868
Net income, adjusted from continuing operations	85,881	66,560	95,303
Net loss from discontinued operations	-	(10,748)	(28,546)
Net income, adjusted	$ 85,881	$ 55,812	$ 66,757
Denominator:			
Weighted-average number of shares-basic	41,816,431	40,184,159	38,595,435
Dilutive securities-equity awards	1,115,244	1,054,453	939,882
Dilutive securities-convertible debt	7,396,262	8,096,500	7,720,525
Weighted-average number of shares-diluted	50,327,937	49,335,112	47,255,842
Net income per share-basic from continuing operations	$ 1.98	$ 1.56	$ 2.37
Net loss per share-basic from discontinued operations	-	(0.27)	(0.74)
Net income per share-basic	$ 1.98	$ 1.29	$ 1.63
Net income per share-diluted from continuing operations	$ 1.71	$ 1.35	$ 2.02
Net loss per share-diluted from discontinued operations	-	(0.22)	(0.61)
Net income per share-diluted	$ 1.71	$ 1.13	$ 1.41

For the year ending December 31, 2017 and 2016, substantially all of the outstanding stock options to purchase shares of common stock were included in the calculation of diluted earnings per share. For the years ending December 31, 2015, outstanding stock options to purchase approximately 1.4 million shares of common stock, respectively, are not considered in the diluted earnings per share calculation because the exercise price of these options is greater than the average per share closing price during the year and their effect would be anti-dilutive.

17. Restructuring

In August 2016, the Company adopted a plan to restructure and reprioritize the operations of one of our facilities at the Emergent BioDefense Operations Lansing LLC ("EBOL") site due to the Company's large-scale manufacturing facility at EBOL commencing manufacturing operations. Severance and other related costs and asset-related charges are reflected within the Company's consolidated statement of income as a component of selling, general and administrative expense.

The Company has completed the EBOL restructuring. The costs of the EBOL restructuring for the year ended December 31, 2017 and recognized to date are detailed below:

(in thousands)	Incurred in 2017	Inception To Date
Termination benefits	$ 40	$ 5,286
Abandonment of equipment	-	3,749
Other costs	-	691
Total	$ 40	$ 9,726

During the year ended December 31, 2016, the Company abandoned certain equipment and associated assets at its EBOL facility related to the manufacturing process at Building 12 ("manufacturing process") asset group. During the third quarter of 2016, the Company recorded a charge for the manufacturing process asset group of $3.7 million. The additional expense is classified in the Company's statements of operations as selling, general and administrative expense.

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

(in thousands)	Termination Benefits
Balance at December 31, 2016	$ 4,357
Expenses incurred	40
Amount paid	(4,387)
Balance at December 31, 2017	$ 10

18. Segment information

On August 6, 2015, the Company announced its plan to separate into two independent publicly-traded companies. In anticipation of the spin-off, the Company realigned certain components of its biosciences business to the new Aptevo segment to be consistent with how the chief operating decision maker ("CODM"), allocates resources and makes decisions about the operations of the Company. Effective January 1, 2016, the Company changed its segment presentation to reflect this new structure, and recast all prior periods presented to conform to the new presentation. On August 1, 2016, the Company completed the spin-off of Aptevo. The results of operations and financial position of Aptevo are reflected as discontinued operations for all periods presented through the date of the spin-off.

For financial reporting purposes, in the periods following the spin-off of Aptevo, the Company reports financial information for one reportable segment. This reportable segment engages in business activities for which discrete financial information is provided to and resources are allocated by the CODM. The accounting policies of the reportable segment is the same as those described in the summary of significant accounting policies.

For the years ended December 31, 2017, 2016, and 2015, the Company's revenues within the United States comprised 89%, 94% and 96%, respectively, of total revenues. For the years ended December 31, 2017, 2016, and 2015, product revenues from BioThrax to the U.S. government comprised approximately 67%, 80% and 89%, respectively, of total product revenues. As of December 31, 2017, 2016, and 2015, there were no other product sales to an individual customer or for an individual product in excess of 10% of total product sales revenues.

For years ended December 31, 2017 and 2016, the Company had long-lived assets outside of the United States of approximately $28.6 million and $28.4 million, respectively, which are primarily located within Canada.

19. Quarterly financial data (unaudited)

Quarterly financial information for the years ended December 31, 2017 and 2016 is presented in the following tables:

	Quarter Ended			
(in thousands, except per share data)	March 31,	June 30,	September 30,	December 31,
2017:				
Revenue	$ 116,858	$ 100,772	$ 149,434	$ 193,809
Income from operations	14,910	8,529	47,769	53,077
Net income	10,485	4,616	33,551	33,942
Net income per share-basic	$ 0.26	$ 0.11	$ 0.81	$ 0.77
Net income per share-diluted	$ 0.23	$ 0.11	$ 0.68	$ 0.67
2016:				
Revenue	$ 102,964	$ 91,241	$ 142,914	$ 151,663
Income (loss) from operations	21,157	(2,042)	35,478	50,929
Net income (loss) from continuing operations	11,889	(2,042)	20,388	32,289
Net income (loss) from discontinued operations (1)	(7,898)	(8,905)	952	5,103
Net income (loss)	3,991	(10,947)	21,340	37,392
Net income (loss) per share from continuing operations-basic	$ 0.30	$ (0.05)	$ 0.50	$ 0.80
Net income (loss) per share from discontinued operations-basic	(0.20)	(0.22)	0.02	0.13
Net income (loss) per share-basic	$ 0.10	$ (0.27)	$ 0.52	$ 0.93
Net income (loss) per share from continuing operations-diluted	$ 0.26	$ (0.05)	$ 0.43	$ 0.67
Net income (loss) per share from discontinued operations-diluted	(0.16)	(0.22)	0.02	0.10
Net income (loss) per share-diluted	$ 0.10	$ (0.27)	$ 0.45	$ 0.77

(1) Reflects a change in estimate attributed to higher pretax income within continuing operations. According to the ordering rules of intraperiod tax allocation, the residual amount of change after determining the effective rate for continuing operations is allocated to discontinued operations.

20. Litigation

On July 19, 2016, Plaintiff William Sponn, or Sponn, filed a putative class action complaint in the United States District Court for the District of Maryland on behalf of purchasers of the Company's common stock between January 11, 2016 and June 21, 2016, inclusive, or the Class Period, seeking to pursue remedies under the Securities Exchange Act of 1934 against the Company and certain of its senior officers and directors, collectively, the Defendants. The complaint alleges, among other things, that the Company made materially false and misleading statements about the government's demand for BioThrax and expectations that the Company's five-year exclusive procurement contract with HHS would be renewed and omitted certain material facts. Sponn is seeking unspecified damages, including legal costs. On October 25, 2016, the Court added City of Cape Coral Municipal Firefighters' Retirement Plan and City of Sunrise Police Officers' Retirement Plan as plaintiffs and appointed them Lead Plaintiffs and Robins Geller Rudman & Dowd LLP as Lead Counsel. On December 27, 2016, the Plaintiffs filed an amended complaint that cites the same class period, names the same defendants and makes similar allegations to the original complaint. The Company filed a Motion to Dismiss on February 27, 2017. The Plaintiffs filed an opposition brief on April 28, 2017. The Company's Motion to Dismiss was heard and denied on July 6, 2017. The Company filed its answer on July 28, 2017. The parties are currently in the process of exchanging discovery. The Plaintiffs' filed an amended motion for class certification and appointment of Sponn and Geoffrey L. Flagstad as lead plaintiffs on December 20, 2017. A hearing on that motion is set for May 2, 2018. The Defendants believe that the allegations in the complaint are without merit and intend to defend themselves vigorously against those claims. As of the date of this filing, the range of potential loss cannot be determined or estimated.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2017. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2017, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework* (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2017, our internal control over financial reporting was effective based on those criteria.

Management's assessment of and conclusion on the effectiveness of disclosure controls and procedures and internal controls over financial reporting did not include the internal controls related to the operations acquired in the acquisition of ACAM2000 which is included in the 2017 consolidated financial statements of Emergent BioSolutions Inc. The aggregated total assets and total operating revenues of these operations represent approximately 11% and 2%, respectively, of the consolidated financial statements as of and for the year ended December 31, 2017.

Ernst & Young LLP, the independent registered public accounting firm that has audited our consolidated financial statements included herein, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2017, a copy of which is included in this annual report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f)) identified in connection with the evaluation required by Rule 13a-15(d) of the Exchange Act that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Emergent BioSolutions Inc. and subsidiaries

Opinion on Internal Control over Financial Reporting

We have audited Emergent BioSolutions Inc. and subsidiaries' internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Emergent BioSolutions Inc. and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

As indicated in the accompanying Management's Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of ACAM2000, which is included in the 2017 consolidated financial statements of the Company and constituted 11% of total assets as of December 31, 2017 and 2% of total operating revenues for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of ACAM2000.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive income, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and financial statement schedule listed in the Index at Item 15 and our report dated February 22, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

Tysons, Virginia
February 22, 2018

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Code of Ethics

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

The remaining information required by Item 10 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2018 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2018 annual meeting of stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

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

The information required by Item 12 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2018 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

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

The information required by Item 13 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2018 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 is hereby incorporated by reference from our Definitive Proxy Statement relating to our 2018 Annual Meeting of Stockholders, to be filed with the SEC within 120 days following the end of our fiscal year.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statements

The following financial statements and supplementary data are filed as a part of this annual report on Form 10-K in Part I, Item 8.

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets at December 31, 2017 and 2016
Consolidated Statements of Operations for the years ended December 31, 2017, 2016 and 2015
Consolidated Statements of Comprehensive Income for the years ended December 31, 2017, 2016 and 2015
Consolidated Statements of Cash Flows for the years ended December 31, 2017, 2016 and 2015
Consolidated Statement of Changes in Stockholders' Equity for the years ended December 31, 2017, 2016 and 2015
Notes to Consolidated Financial Statements

Financial Statement Schedules

Schedule II - Valuation and Qualifying Accounts for the years ended December 31, 2017, 2016 and 2015 has been filed as part of this annual report on Form 10-K. All other financial statement schedules are omitted because they are not applicable or the required information is included in the financial statements or notes thereto.

Exhibits

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

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS

(in thousands)	Beginning Balance	Charged to costs and expenses	Deductions	Ending Balance
Year Ended December 31, 2017				
Inventory allowance	$ 3,535	$ 8,846	$ (8,532)	$ 3,849
Prepaid expenses and other current assets allowance	4,868	466	-	5,334
Year Ended December 31, 2016				
Inventory allowance	$ 1,637	$ 9,950	$ (8,052)	$ 3,535
Prepaid expenses and other current assets allowance	1,981	2,887	-	4,868
Year Ended December 31, 2015				
Inventory allowance	$ 1,314	$ 6,258	$ (5,935)	$ 1,637
Prepaid expenses and other current assets allowance	1,885	96	-	1,981

Exhibit Index

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

Exhibit Number		Description
2.1		Contribution Agreement, dated July 29, 2016, by and among Emergent BioSolutions Inc., Aptevo Therapeutics Inc., Aptevo Research and Development LLC and Aptevo BioTherapeutics LLC (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed on August 4, 2016).
2.2		Separation and Distribution Agreement, dated July 29, 2016, by and between Emergent BioSolutions Inc. and Aptevo Therapeutics Inc. (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K, filed on August 4, 2016).
2.3		Asset Purchase Agreement, dated July 14, 2017, among Sanofi Pasteur Biologics, LLC, Acambis Research Ltd. and Emergent BioSolutions Inc. (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on July 14, 2017).
2.4		Asset Purchase Agreement, dated July 19, 2017, among GlaxoSmithKline LLC, Human Genome Sciences, Inc., and Emergent BioSolutions Inc. (incorporated by reference to Exhibit 2 to the Company's Current Report on Form 8-K, filed on October 3, 2017).
3.1		Third Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3 to the Company's Quarterly Report on Form 10-Q filed on August 5, 2016).
3.2		Amended and Restated By-laws of the Company (incorporated by reference to Exhibit 3 to the Company's Current Report on Form 8-K filed on August 16, 2012).
4.1		Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 3 to the Company's Registration Statement on Form S-1 filed on October 20, 2006) (Registration No. 333-136622).
4.2		Registration Rights Agreement, dated as of September 22, 2006, among the Company and the stockholders listed on Schedule 1 thereto (incorporated by reference to Exhibit 4.3 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on September 25, 2006) (Registration No. 333-136622).
4.3		Indenture, dated as of January 29, 2014, between the Company and Wells Fargo Bank, National Association, including the form of 2.875% Convertible Senior Notes due 2021 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 29, 2014).
9.1		Voting and Right of First Refusal Agreement, dated as of October 21, 2005, between the William J. Crowe, Jr. Revocable Living Trust and Fuad El-Hibri (incorporated by reference to Exhibit 9.1 to the Company's Registration Statement on Form S-1 filed on August 14, 2006) (Registration No. 333-136622).
10.1		Credit Agreement, dated September 29, 2017, among Emergent BioSolutions Inc., the lenders party thereto from time to time, and Wells Fargo Bank, National Association, as the Administrative Agent (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K, filed on October 2, 2017).
10.2	*	Emergent BioSolutions Inc. Employee Stock Option Plan, as amended and restated on January 26, 2005 (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 filed on August 14, 2006) (Registration No. 333-136622).

10.3	*	Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 5 to the Company's Registration Statement on Form S-1 filed on October 30, 2006) (Registration No. 001-33137).
10.4	*	Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 7, 2009).
10.5	*	Second Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Appendix A to the Company's definitive proxy statement on Schedule 14A filed on April 6, 2012).
10.6	*	Third Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Appendix A to the Company's definitive proxy statement on Schedule 14A filed on April 7, 2014).
10.7	*	Fourth Amended and Restated Emergent BioSolutions Inc. 2006 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 5, 2016).
10.8	*	Form of Director Nonstatutory Stock Option Agreement (incorporated by reference to Exhibit 10.5 to the Company's Annual Report on Form 10-K filed on March 8, 2013).
10.9	#*	Form of Director Restricted Stock Unit Agreement.
10.10	*	Form of Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on March 8, 2013).
10.11	#*	Form of Restricted Stock Unit Agreement
10.12	#*	Form of Restricted Stock Unit Award Agreement – Canadian Participant.
10.13	*	Form of Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 21, 2017).
10.14	*	Form of 2018-2020 Performance-Based Stock Unit Award Agreement (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on February 14, 2018).
10.15	*	Form of Indemnity Agreement for directors and senior officers (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on January 18, 2013).
10.16	*	Director Compensation Program (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K filed on March 8, 2013).
10.17	*	Annual Bonus Plan for Executive Officers (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K filed on March 5, 2010).
10.18	*	Amended and Restated Senior Management Severance Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 22, 2011).
10.19	*	Second Amended and Restated Senior Management Severance Plan (incorporated by reference to Exhibit 10 to the Company's Current Report on Form 8-K filed on July 16, 2015).
10.20		Amended and Restated Marketing Agreement, dated as of November 5, 2008, between Emergent Biodefense Operations Lansing LLC (formerly known as Emergent Biodefense Operations Lansing Inc.) and Intergen N.V. (incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed on March 6, 2009).
10.21	†	Solicitation/Contract/Order for Commercial Items (the "CDC BioThrax Procurement Contract"), effective December 8, 2016, from the Centers for Disease Control and Prevention to Emergent Biodefense Operations Lansing LLC (incorporated by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K, filed on February 28, 2017).
10.22	#	Modification No. 1, effective January 27, 2017, to the CDC BioThrax Procurement Contract
10.23	#††	Modification No. 2, effective February 23,2017, to the CDC BioThrax Procurement Contract
10.24	#	Modification No. 3, effective March 22, 2017, to the CDC BioThrax Procurement Contract
10.25	#††	Modification No. 4, effective April 5, 2017, to the CDC BioThrax Procurement Contract
10.26	†	Modification No. 5, effective September 8, 2017, to the CDC BioThrax Procurement Contract (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 3, 2017).
10.27	#††	Modification No. 6, effective September 21, 2017, to the CDC BioThrax Procurement Contract
10.28	†	Award/Contract (the "BARDA NuThrax Contract"), effective September 30, 2016, from the BioMedical Advanced Research and Development Authority to Emergent Product Development Gaithersburg Inc. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2016).
10.29	†	Modification No. 1 to the BARDA NuThrax Contract, effective March 16, 2017 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2016) (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 5, 2017).
10.30	†	Award/Contract (the "BARDA BioThrax Contract"), effective March 16, 2017, between the BioMedical Advanced Research and Development Authority and Emergent Biodefense Operations Lansing LLC. (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on May 5, 2017).
12	#	Ratio of Earnings to Fixed Charges.
21	#	Subsidiaries of the Company.

23	#	Consent of Independent Registered Public Accounting Firm.
31.1	#	Certification of the Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a).
31.2	#	Certification of the Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).
32.1	#	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	#	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS		XBRL Instance Document
101.SCH		XBRL Taxonomy Extension Schema Document
101.CAL		XBRL Taxonomy Calculation Linksbase Document
101.DEF		XBRL Taxonomy Definition Linksbase Document
101.LAB		XBRL Taxonomy Label Linksbase Document
101.PRE		XBRL Taxonomy Presentation Linksbase Document

Filed herewith

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

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

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

Attached as Exhibit 101 to this Annual Report on Form 10-K are the following formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2017 and 2016, (ii) Consolidated Statements of Operations for the Years Ended December 31, 2017, 2016 and 2015, (iii) Consolidated Statements of Comprehensive Income for the Years Ended December 31, 2017, 2016 and 2015 (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2017, 2016 and 2015, (v) Consolidated Statements of Changes in Stockholders' Equity for the Years ended December 31, 2017, 2016 and 2015, and (vi) Notes to Consolidated Financial Statements.

SIGNATURES

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

EMERGENT BIOSOLUTIONS INC.

By: /s/ Daniel J. Abdun-Nabi
Daniel J. Abdun-Nabi
President and Chief Executive Officer
Date: February 22, 2018

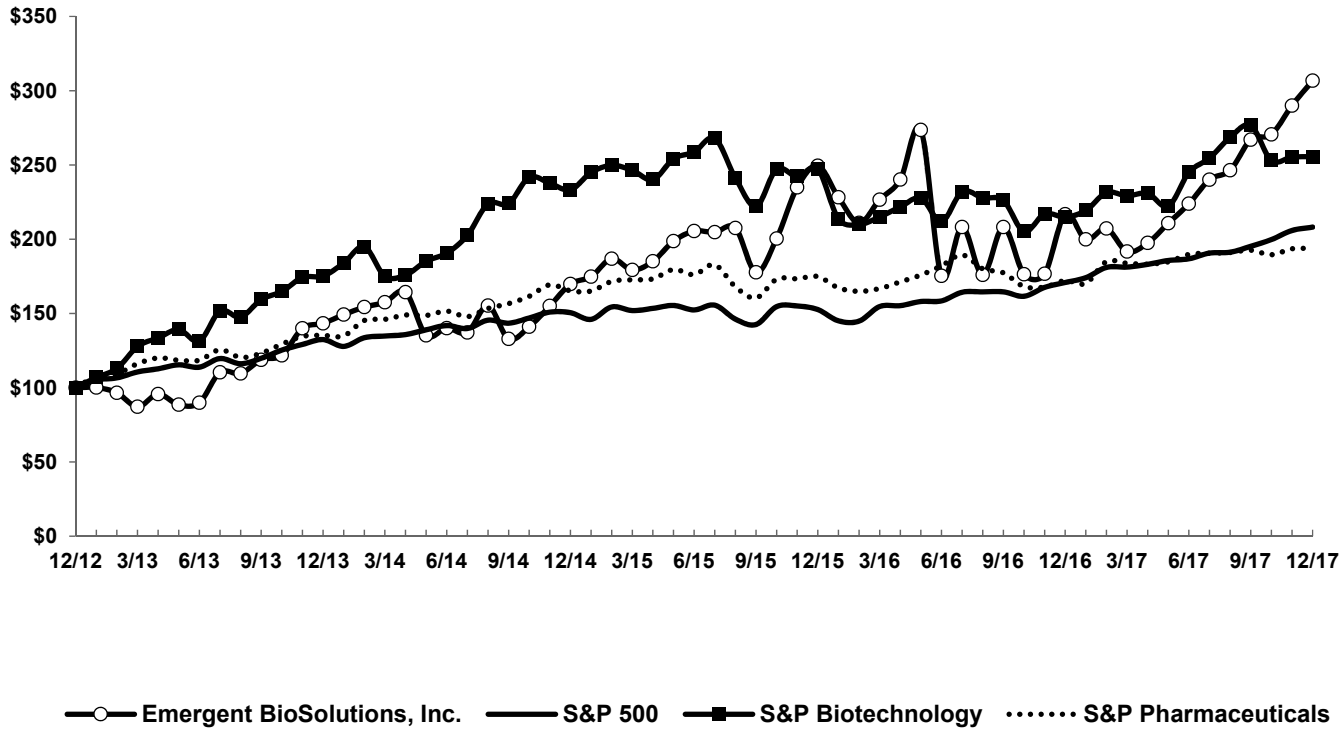
Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/Daniel J. Abdun-Nabi Daniel J. Abdun-Nabi	President, Chief Executive Officer and Director (Principal Executive Officer)	February 22, 2018
/s/Robert G. Kramer, Sr Robert G. Kramer, Sr	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 22, 2018
/s/Fuad El-Hibri Fuad El-Hibri	Executive Chairman of the Board of Directors	February 22, 2018
/s/Zsolt Harsanyi, Ph.D. Zsolt Harsanyi, Ph.D.	Director	February 22, 2018
/s/Kathryn Zoon, Ph.D. Kathryn Zoon, Ph.D.	Director	February 22, 2018
/s/Ronald B. Richard Ronald B. Richard	Director	February 22, 2018
/s/Louis W. Sullivan, M.D. Louis W. Sullivan, M.D.	Director	February 22, 2018
/s/Dr. Sue Bailey Dr. Sue Bailey	Director	February 22, 2018
/s/George Joulwan George Joulwan	Director	February 22, 2018
/s/Jerome Hauer, Ph.D. Jerome Hauer, Ph.D.	Director	February 22, 2018

The graph below matches Emergent BioSolutions, Inc.'s cumulative 5-Year total shareholder return on common stock with the cumulative total returns of the S&P 500 index, the S&P Biotechnology index, and the S&P Pharmaceuticals index. The graph tracks the performance of a $100 investment in our common stock and in each index (with the reinvestment of all dividends) from 12/31/2012 to 12/31/2017.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Emergent BioSolutions, Inc., the S&P 500 Index,
the S&P Biotechnology Index and the S&P Pharmaceuticals Index



*$100 invested on 12/31/12 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

	12/12	1/13	2/13	3/13	4/13	5/13	6/13	7/13	8/13	9/13	10/13
Emergent BioSolutions,dn	100.00	100.06	96.57	87.16	95.64	88.53	89.90	110.29	109.60	118.77	121.76
S&P 500	100.00	105.18	106.61	110.61	112.74	115.37	113.82	119.62	116.15	119.79	125.30
S&P Biotechnology	100.00	106.87	112.96	127.69	133.55	139.09	131.39	151.60	147.57	159.34	164.75
S&P Pharmaceuticals	100.00	107.62	109.26	116.13	120.04	118.47	118.49	125.54	120.37	123.21	129.35

11/13	12/13	1/14	2/14	3/14	4/14	5/14	6/14	7/14	8/14	9/14	10/14	11/14	12/14
139.96	143.33	149.19	154.24	157.54	164.34	135.22	140.02	137.16	155.24	132.86	141.02	154.99	169.76
129.12	132.39	127.81	133.66	134.78	135.78	138.96	141.84	139.88	145.48	143.43	146.94	150.89	150.51
174.21	175.19	183.89	194.89	175.06	175.84	185.17	190.59	202.61	223.77	224.00	241.65	237.63	233.30
134.56	135.23	134.87	145.25	146.02	148.97	148.66	151.58	147.85	153.35	156.61	161.55	169.27	165.27

1/15	2/15	3/15	4/15	5/15	6/15	7/15	8/15	9/15	10/15	11/15	12/15	1/16	2/16
174.75	186.85	179.30	185.10	198.63	205.42	204.68	207.54	177.62	200.44	234.85	249.44	228.18	210.91
145.99	154.38	151.94	153.40	155.37	152.36	155.56	146.17	142.55	154.58	155.04	152.59	145.02	144.82
244.87	249.72	246.38	240.11	254.12	258.77	267.91	241.32	222.08	247.13	242.22	247.12	213.65	209.86
165.05	171.56	172.65	173.29	179.59	176.17	182.79	167.96	160.40	173.00	173.36	174.84	167.20	164.91

3/16	4/16	5/16	6/16	7/16	8/16	9/16	10/16	11/16	12/16	1/17	2/17	3/17	4/17
226.62	240.15	273.57	175.31	208.17	175.92	208.14	176.38	176.65	216.78	199.82	207.15	191.70	197.44
154.65	155.25	158.04	158.45	164.29	164.52	164.55	161.55	167.53	170.84	174.08	181.00	181.21	183.07
215.02	221.71	227.61	211.94	231.93	227.84	226.07	205.20	216.95	214.95	219.29	231.39	229.19	230.78
166.78	171.26	175.88	182.10	189.44	180.05	177.35	168.06	167.79	172.10	170.23	184.92	183.74	183.22

5/17	6/17	7/17	8/17	9/17	10/17	11/17	12/17
210.78	223.85	240.08	246.42	267.02	270.58	289.99	306.76
185.64	186.80	190.64	191.23	195.17	199.73	205.85	208.14
222.22	244.93	254.64	268.57	276.56	253.06	255.25	255.60
184.76	189.75	190.55	191.03	192.59	189.53	193.54	193.74

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Directors, Officers and Senior Management

BOARD OF DIRECTORS

Fuad El-Hibri (5*)
Executive Chairman,
Emergent BioSolutions Inc.

Daniel J. Abdun-Nabi (5)
Chief Executive Officer,
Emergent BioSolutions Inc.

Dr. Sue Bailey (2,3,4)
Former Advisor to the Director of the National Cancer Institute;
Former Assistant Secretary of Defense (Health Affairs)

Zsolt Harsanyi, Ph.D. (1*,4,5)
Chairman of the Board, N-Gene Research Laboratories, Inc.

Jerome M. Hauer, Ph.D. (4*,2,5)
Senior Advisor, Teneo Risk; Former New York Commissioner, Division of Homeland Security; Chairman of the Executive Committee on Counterterrorism

General George A. Joulwan (1,2,3)
U.S. Army (retired);
President, One Team, Inc.

Ronald B. Richard (1,3*,5,6)
President and Chief Executive Officer, The Cleveland Foundation

Louis W. Sullivan, M.D. (1,2*,3)
President Emeritus, Morehouse School of Medicine; Former Secretary, Department of Health and Human Services

Kathryn C. Zoon, Ph.D. (4,5)
Scientist Emeritus, National Institute of Allergy and Infectious Diseases at the National Institutes of Health

1 Audit Committee
2 Compensation Committee
3 Nominating & Corporate Governance Committee
4 Scientific Review Committee
5 Strategic Operations Committee
6 Lead Independent Director
* Chairperson of Committee

CORPORATE OFFICERS AND SENIOR MANAGEMENT

Fuad El-Hibri*
Executive Chairman of the Board of Directors

Daniel J. Abdun-Nabi*
Chief Executive Officer and Director

Robert G. Kramer Sr.*
President and
Chief Operating Officer

Adam R. Havey*
Executive Vice President,
Business Operations

Richard S. Lindahl*
Executive Vice President,
Chief Financial Officer and Treasurer

Atul Saran*
Executive Vice President,
Corporate Development and General Counsel

Katy Strei*
Executive Vice President,
Chief Human Resources Officer

John H. Ducote
Senior Vice President,
Global Quality

Christopher W. Frech
Senior Vice President,
Global Government Affairs

W. James Jackson, Ph.D.
Senior Vice President,
Chief Scientific Officer

Laura K. Kennedy
Senior Vice President,
Chief Ethics and Compliance Officer

Sean Kirk
Senior Vice President,
Manufacturing Operations and CDMO Business Unit Head

Laura Saward, Ph.D.
Senior Vice President,
Antibody Therapeutics Business Unit Head

Sharon Solomon
Senior Vice President,
Chief Information Officer

Barbara Solow, Ph.D.
Senior Vice President,
External Development and Government Contracting

Doug White
Senior Vice President,
Devices Business Unit Head

* Executive Officer

Corporate Information

CORPORATE HEADQUARTERS

400 Professional Drive, Suite 400
Gaithersburg, MD 20879
Tel: 240-631-3200
Fax: 240-631-3203

Additional copies of the company's Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission, and copies of the exhibits thereto, are available without charge upon written request to Investor Relations, Emergent BioSolutions, 400 Professional Drive, Suite 400, Gaithersburg, MD 20879, by calling (240) 631-3200, or by accessing the company's website at www.emergentbiosolutions.com.

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young LLP, Tysons, VA, United States

STOCK TRANSFER AGENT AND REGISTRAR

Investors with questions concerning account information, new certificate issuances, lost or stolen certificate replacement, securities transfers, or the processing of a change of address should contact:

Broadridge Corporate Issuer Solutions, Inc.
P.O. Box 1342
Brentwood, NY 11717
1-877-830-4936 or 1-720-378-5591
shareholder@broadridge.com

INVESTOR RELATIONS

Robert G. Burrows, Vice President, Investor Relations
E-mail: burrowsr@ebsi.com Tel: 240-631-3280 Fax: 240-631-3203

MARKET INFORMATION

Emergent BioSolutions Inc. common stock trades on the New York Stock Exchange under the trading symbol EBS.

ANNUAL MEETING

Thursday, May 24, 2018, 9 a.m., Eastern Time
Gaithersburg Marriott Washingtonian Center
9751 Washingtonian Boulevard, Gaithersburg, MD 20878

CORPORATE GOVERNANCE

Our Chief Executive Officer intends to submit his annual chief executive officer certification to the New York Stock Exchange within 30 days of the date of our Annual Meeting of Stockholders in accordance with the New York Stock Exchange listing requirements. Emergent BioSolutions Inc. is strongly committed to the highest standards of ethical conduct and corporate governance. Our Board of Directors has adopted Corporate Governance Guidelines, along with the charters of the Board Committees and a Code of Conduct and Business Ethics for directors, officers and employees, all of which are available on the company's website at www.emergentbiosolutions.com.

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400 Professional Drive, Suite 400, Gaithersburg, Maryland 20879 USA
www.emergentbiosolutions.com