Emergent BioSolutions Inc.
Form 10-K
February 22, 2019
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, 2018

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 ý No

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit 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. ý

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 ý Accelerated filer Non-accelerated filer Smaller reporting company Emerging growth 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, 2018 was approximately $2.1 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 15, 2019, the registrant had 51.2 million shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2019 annual meeting of stockholders scheduled to be held in May 2019, 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, 2018, 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 2019 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, 2018

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NOTE REGARDING COMPANY REFERENCES

References in this report to “Emergent,” the “Company,” “we,” “us,” and “our” refer to Emergent BioSolutions Inc. and its consolidated subsidiaries.

NOTE REGARDING TRADENAMES

BioThrax® (Anthrax Vaccine Adsorbed), RSDL® (Reactive Skin Decontamination Lotion Kit), BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)], Anthrasil® (Anthrax Immune Globulin Intravenous [human]), NuThrax™ (anthrax vaccine adsorbed with CPG 7909 adjuvant), VIGIV [Vaccinia Immune Globulin Intravenous (Human)], Trobigard™ (atropine sulfate, obidoxime chloride), ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live), Vivotif® (Typhoid Vaccine Live Oral Ty21a), Vaxchora® (Cholera Vaccine, Live, Oral), NARCAN® (naloxone HCI) Nasal Spray and any and all Emergent BioSolutions Inc. brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent BioSolutions Inc. or its subsidiaries in the United States or other countries. All other brands, products, services and feature names or trademarks are the property of their respective owners.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K and the documents we incorporate by reference include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding 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,” “es 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 products addressing public health threats;
- 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, or FDA;
- 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 procurement contracts that have expired or will be expiring;
- our ability and the ability of our collaborators to protect our intellectual property rights;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- our ability to successfully integrate and realize the benefits of our acquisitions of PaxVax Holding Company Ltd. and Adapt Pharma Limited, both of which were acquired in October 2018;
- 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 facilities;
- 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
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- 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 to civilian and military populations a portfolio of innovative preparedness and response products and solutions that address accidental, deliberate and naturally occurring public health threats ("PHTs," each a "PHT"). We were incorporated in the State of Michigan in May 1998 and subsequently reorganized as a Delaware corporation in June 2004.

We are focused on the following four distinct PHT categories: Chemical, Biological, Radiological, Nuclear and Explosives ("CBRNE"); emerging infectious diseases ("EID"); travelers' diseases; and opioids. We have a product portfolio of eleven products (vaccines, antibody therapeutics, and drug-device combination products) that generate a majority of our revenue. We also have a development pipeline consisting of a diversified mix of both pre-clinical and clinical stage product candidates (vaccines, antibody therapeutics, and drug-device combination products). Finally, we also have a fully-integrated portfolio of contract development and manufacturing services. The U.S. government (the "USG") is the largest purchaser of our products and provides us with substantial funding for the development of a number of our product candidates. We continue to pursue acquiring and developing products and solutions that provide an opportunity to serve both government customers and commercial (non-government) customers ("Dual Market").

STRATEGY

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

- Continue to leverage and expand our leadership position in the PHT market, now further expanded to encompass the opioid and travelers' markets as well as the CBRNE and EID markets;
- Grow through the acquisition of products and businesses, particularly those that are revenue-generating and accretive;
- Develop and manufacture innovative products and solutions, particularly with funding from governments and non-governmental organizations to defray research and development costs;
- Focus on globalization and related international commercial capabilities; and
- Diversify our product mix to include products that have Dual Market potential.

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

- Unique and valuable commercial and government solutions for PHTs through formation of public-private partnerships;
- Quality manufacturing across a spectrum of specialized and complex manufacturing processes, using multiple platform technologies;
- Specialized government relations and contracting operations to support our government contracting business;
- Successful completion of business and product acquisitions; and
- Financial discipline driven by a prudent capital allocation strategy focused on generating positive returns on invested capital.

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 products; (2) Dual-Market product opportunities, which are products that have both government and non-government / commercial market potential; 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, transactions and collaborations.

Adapt Pharma Limited

On October 15, 2018, we completed the acquisition of Adapt Pharma Limited ("Adapt"), and its NARCAN® (naloxone HCl) Nasal Spray marketed product, the first and only needle-free formulation of naloxone approved by the Food and Drug Administration ("FDA"), and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression. This acquisition includes the NARCAN® Nasal Spray marketed product and a development pipeline of new treatment and delivery options to address opioid overdose, and approximately 50 employees, located in the U.S., Canada, and Ireland, including those responsible for supply chain management, research and development, government affairs, and commercial operations.

We paid approximately $581.5 million in cash at the closing (inclusive of closing adjustments) and issued 733,309 shares of Common Stock, based on the volume-weighted average price per share of the Common Stock as reported on the New York Stock Exchange for the ten-trading day period ending two days before closing, or $65.28 per share (an aggregate total of $47.9 million, inclusive of adjustments). The remaining consideration payable for the acquisition consists of up to $100 million in cash based on the achievement of certain sales milestones through 2022. The Company funded the cash portion of the payments made at closing using a combination of cash-on-hand and borrowings under its Amended Credit Agreement, as described in the Long-term debt section below.

PaxVax Holding Company Ltd.

On October 4, 2018, we completed the acquisition of PaxVax Holding Company Ltd. ("PaxVax"), a company focused on developing, manufacturing, and commercializing specialty vaccines that protect against existing and emerging infectious diseases. This acquisition includes Vivotif® (Typhoid Vaccine Live Oral Ty21a), the only oral vaccine licensed by the FDA for the prevention of typhoid fever, Vaxchora® (Cholera Vaccine, Live, Oral), the only FDA-licensed vaccine for the prevention of cholera, an adenovirus 4/7 vaccine candidate being developed for military personnel under contract with the U.S. Department of Defense ("DoD") and additional clinical-stage vaccine candidates targeting chikungunya and other emerging infectious diseases, European-based current good manufacturing practices ("cGMP") biologics manufacturing facilities, and approximately 250 employees including those in research and development, manufacturing, and commercial operations with a specialty vaccines salesforce in the U.S. and in select European countries.

At the closing, we paid a cash purchase price of $273.1 million (inclusive of closing adjustments), using a combination of cash-on-hand and borrowings under our senior secured credit agreement.

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 a 10-year contract with the Centers for Disease Control and Prevention ("CDC"), which expired 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, reflecting the value of doses of ACAM2000 remaining to be delivered to the U.S. Strategic National Stockpile ("SNS"). As of December 31, 2018, there remains a portion of doses still to be delivered to the SNS under the current BARDA procurement contract. We expect to complete deliveries of such doses in 2019. We are negotiating a new multi-year contract with the Assistant Secretary for Preparedness and Response ("ASPR") to deliver additional doses into the 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, 2018, 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 ("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 bulk manufacturing of raxibacumab to our Bayview facility and the fill/finish process to our Camden 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.

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. ("Aptevo"). 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.

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. The acquisition also included a hyperimmune technology platform as part of a manufacturing site in Winnipeg, Manitoba, Canada (our Winnipeg site), and which is used to manufacture the BAT, Anthrasil and VIGIV products. 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.

Other Acquisitions and Collaborations

In recent years, we have also entered into the following other transactions.

- In August 2018, our collaboration with the Coalition for Epidemic Preparedness Innovations ("CEPI") and Profectus BioSciences, Inc. ("Profectus"), under which we intend to advance the development and manufacture of a vaccine against the Lassa virus;
- In November 2017, our agreement with Profectus to have the option to license multiple vector vaccine product candidates, including those for Nipah, and viral hemorrhagic fevers caused by Ebola, Marburg and Lassa viruses;
- In July 2017, our collaboration with Southwest Research Institute, an independent, nonprofit applied research and development organization headquartered in San Antonio, Texas, under which we are developing an intra-nasal spray device for the treatment of known or suspected acute cyanide poisoning; and

- In December 2015, our acquisition of Unither Virology LLC, which held a broad family of iminosugar small molecules that have activity against a variety of enveloped viruses.

OUR BUSINESS UNITS

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

Vaccines and Anti-Infectives

Products

Our Vaccines and Anti-Infectives business unit contains a portfolio of specialty vaccines and unique anti-infectives that address existing and emerging PHTs. The current portfolio consists of the following products.

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, Germany, Singapore, UK, Germany, Netherlands, France, Poland, Italy and Canada.
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
Vaxchora® (Cholera Vaccine Live Oral)	Oral vaccine for the prevention of cholera.	United States
Vivotif® (Typhoid Vaccine Live Oral Ty21a)	Oral vaccine for the prevention of typhoid fever.	United States, Canada, Australia, New Zealand, Singapore, South Korea, Hong Kong, Malaysia, UK, France, Italy, Portugal, Spain, Switzerland, Belgium, Luxembourg, The Netherlands, Germany, Austria, Norway, Denmark, Finland, Sweden, The Czech Republic, Slovakia

BioThrax® (Anthrax Vaccine Adsorbed). BioThrax is the only vaccine licensed by the FDA for the general use prophylaxis (“GUP”), of anthrax disease. In April 2014, the FDA granted orphan drug designation to BioThrax for the post-exposure prophylaxis (“PEP”), indication, (please see “Regulation – Marketing Approval – Biologics, Drugs and Vaccines– Orphan Drugs”), giving it market exclusivity in the United States until November 2022. In November 2015, the FDA approved our supplemental Biologics License Application (“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. In the U.S., 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 ("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 up to $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 a 10-year CDC contract, which expired 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 and we are continuing to make deliveries under the prior contract. At acquisition, there was $160 million of remaining value on the prior contract subject to the availability of government funding, and we expect to fulfill the remaining product deliveries to the SNS in the first half of 2019. We are negotiating a new multi-year contract with ASPR to deliver additional doses into the SNS.

Vaxchora®. (Cholera Vaccine Live Oral) Vaxchora is a live attenuated cholera vaccine for oral administration and the first vaccine approved by the FDA for the prevention of cholera infection. Cholera, a potentially life-threatening bacterial infection that occurs in the intestines and causes severe diarrhea and dehydration, has a low incidence in the U.S., but a high incidence in Africa, Southeast Asia, and other locations around the world. These areas draw travelers from the U.S., so cholera can occur in patients who return to the U.S. from visits to these regions. Vaxchora is indicated for active immunization against cholera caused by the bacterium V. cholerae serogroup O1. Vaxchora is approved for use in patients 18–64 years of age who are traveling to known cholera-infected areas.

Vivotif®. (Typhoid Vaccine Live Oral Ty21a) Vivotif is a live attenuated vaccine for oral administration to prevent typhoid fever. The vaccine contains the attenuated strain Salmonella typhi Ty21a (1,2). Typhoid fever is a potentially severe and occasionally life-threatening febrile illness caused by Salmonella enterica serotype Typhi (S Typhi), a bacterium that only lives in humans. It is usually acquired by consumption of water or food that has been contaminated by feces of an infected person. Typhoid fever is uncommon in North America and Europe. However, travelers from North America and Europe going to Asia, Africa, and Latin America have been particularly at risk. Even short-term travel to high-incidence areas is associated with risk for typhoid fever. In the U.S., Vivotif is indicated for immunization of adults and children greater than 6 years of age against disease caused by S Typhi.

Product Candidates

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

Product Candidate	Partner	Platform	Threat Type
NuThrax™	HHS - BARDA	Vaccine	Biological

Next generation anthrax vaccine CHIKUNGUNYA Chikungunya VLP vaccine	--	Vaccine EID
ADENOVIRUS 4/7 Live, attenuated vaccine	DoD - USAMRAA	Vaccine EID
rVSV-Lassa Vaccine for prevention of Lassa fever	CEPI	Vaccine EID
rVSV-Marburg Vaccine for prevention of Marburg hemorrhagic fever	--	Vaccine Biological
rVSV-Sudan Vaccine for prevention of Sudan hemorrhagic fever	--	Vaccine Biological
rVSV-QUAD Vaccine for prevention of hemorrhagic fever caused by infection with Lassa, Ebola, Sudan or Marburg virus	NIAID (to Profectus)	Vaccine Biological
rVSV-Ebola Vaccine for prevention of Ebola hemorrhagic fever	--	Vaccine Biological

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 (“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 two-dose regimen, versus the BioThrax three-dose regimen, which 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: assay development and non-clinical activities through the preparation of an Investigational New Drug (“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 development contract with BARDA valued at $31 million to develop NuThrax for post-exposure prophylaxis of anthrax disease. In September 2016, we signed a combination development and procurement 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 (“EUA”) pre-approval by the FDA. We applied for EUA in the fourth quarter of 2018 and, although there can be no assurances, we anticipate that the FDA could grant EUA designation to NuThrax as early as this year, 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 all 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 2018” for additional details.

Chikungunya. We licensed the chikungunya virus (“CHKV”), a virus-like particle (“VLP”), vaccine product candidate from the Vaccine Research Center ("VRC") at the National Institutes of Health ("NIH"). VLPs for alphaviruses are comparable to the physical structure of the native virus, and contain repetitive, high density displays of viral surface proteins that present conformational viral epitopes that elicit strong B- and T-cell immune responses. Since VLPs cannot replicate, they provide a safer alternative to attenuated and inactivated vaccines throughout production and use and can be administered in unrestricted target populations. VRC has previously demonstrated in this product candidate both nonclinical and clinical (Phase 1) safety, immunogenicity and efficacy data. A key passive transfer study

demonstrated that mice dosed with purified antibody from VLP-immunized NHPs were protected from an otherwise lethal CHKV infection. We established and scaled a CHKV cGMP production process at our facilities in San Diego, California. A Phase 1 trial demonstrated that the vaccine elicits anti-CHKV neutralizing antibody responses in humans significantly above the level believed to be protective in the passive transfer study. Two Phase 2 safety and immunogenicity trials are currently ongoing. The NIH has sponsored a Phase 2 trial at multiple endemic sites in the Caribbean. The study is a double-blind, placebo-controlled study with 200 subjects, which was initiated in 2016. The subjects are currently being followed for safety, immunogenicity and efficacy. As of August 2018, we have completed enrollment of the Phase 2 study. The primary objectives are to assess safety and anti-CHKV neutralizing antibody responses with different doses, different formulations and different dosing schedules. The study will also assess duration of neutralizing antibody responses induced by different formulations and schedules. Upcoming development activities include Phase 3 development, including process validation and manufacture, Phase 3 clinical studies in the U.S. and CHKV endemic areas, supportive nonclinical toxicity and efficacy studies, and a BLA submission. Collectively, these studies are intended to provide clinical and regulatory data for U.S. licensure and possible World Health Organization prequalification.

Adenovirus 4/7. In 2014, we formed a partnership with the DoD to modernize the production of the Adenovirus vaccine ("ADVV-MP"). An IND application for a new ADVV-MP was submitted to the FDA on January 30, 2017 and a Phase 1 study has been completed that demonstrates high seroconversion rates for Ad 7, indicating vaccine efficacy. Further development activities of the ADVV-MP will be dependent upon a continued partnership with the DoD and subject to government funding.

rVSV-VHF (vector vaccines for hemorrhagic fever). In November 2017, we entered into an agreement with Profectus to have the option to license multiple vector vaccine product candidates, including those for Nipah, and viral hemorrhagic fevers caused by Ebola, Marburg and Lassa viruses. In April 2018, we exercised our development license for rVSV-Marburg and rVSV-Quad vaccines. In October 2018, we exercised our development rights to rVSV-Lassa, rVSV-Ebola and rVSV-Sudan. The rVSV-Quad vaccine development is currently being funded by a contract award to Profectus from the NIAID under which we are performing manufacturing activities.

In August 2018, CEPI announced a collaboration with us and Profectus, under which the parties may receive up to $36 million to advance the development and manufacture of a vaccine against the Lassa virus. Lassa virus infection—a single-stranded RNA virus belonging to the family Arenaviridae—can cause the acute viral hemorrhagic illness known as Lassa fever. The virus is spread to humans via contact with food or household items that have been contaminated with urine or feces from Mastomys rats. Under the terms of the Framework Partnering Agreement for the collaboration among the three parties, Profectus will receive development funding from CEPI for advancing its Lassa virus vaccine. CEPI will provide $4.3 million to support the first phase of the project, with options to invest up to a total of $36 million over five years, including procurement of the vaccine for stockpiling purposes. We will provide technical and manufacturing support for the CEPI-funded program. Through our agreement executed with Profectus in October 2018, we have exercised the option to license and to assume control of development activities for the rVSV-Lassa vaccine from Profectus.

Below is a brief description of the primary rVSV-VHF candidates.

- rVSV-Lassa, a recombinant vesicular stomatitis virus vectored vaccine for prevention of Lassa fever;
- rVSV-Marburg, a recombinant vesicular stomatitis virus vectored vaccine for prevention of viral hemorrhagic fever caused by infection with Marburgvirus;
- rVSV-Ebola, a recombinant vesicular stomatitis virus vectored vaccine for prevention of viral hemorrhagic fever caused by infection with Zaire ebolaviruses;
- rVSV-Sudan, a recombinant vesicular stomatitis virus vectored vaccine for prevention of viral hemorrhagic fever caused by infection with Sudan Ebolavirus; and
- rVSV-QUAD, a recombinant vesicular stomatitis virus vectored vaccine for prevention of hemorrhagic fever caused by infection with Lassa, Ebola, Marburg or Sudan virus infections.

Our Vaccines and Anti-Infectives business unit has other product candidates addressing PHTs, including influenza, anti-bacterials, and antivirals, among others.

Devices

Products

Our Devices business unit contains a broad portfolio of drug-device combination products that incorporate convergent technologies that enable both governments and patients (Dual Market) opportunities to address PHTs and challenging life-threatening conditions. The current portfolio consists of the following drug-device combination products.

DEVICES UNIT

Product	Indication(s)	Regulatory Approvals
NARCAN® (naloxone HCl)Nasal Spray	Emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression	· United States · Canada
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.	· United States (510k) · Canada · Australia · European Union · Israel
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.

NARCAN® (naloxone HCl) Nasal Spray. NARCAN® (naloxone HCl) Nasal Spray is the first and only needle-free formulation of naloxone approved by the FDA and Health Canada, for the emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression. The primary customers for NARCAN® Nasal Spray are state health departments, local law enforcement agencies, community-based organizations, substance abuse centers, federal agencies and consumers through physician directed or standing order prescriptions.

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 also been cleared as a medical device by Health Canada, has a current European Conformity (“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 USG, including the DoD and the National Guard. Our current contract with the DoD, awarded in September 2017 after the expiration of our initial DoD contract, 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. In addition to the DoD and other USG 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 USG 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 ("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 ("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.

Development Candidates from Adapt Acquisition. We acquired from Adapt multiple constructs in various stages of development focused on new treatments and delivery options for opioid overdose response.

In addition, we are continuing to look at opportunities to expand our portfolio of auto-injector product candidates and, eventually, product line.

Antibody Therapeutics

Products

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. The current portfolio consists of the following products.

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	Treatment of complications due to vaccinia vaccination, including: • Eczema vaccinatum;	United States,

[Vaccinia Immune Globulin Intravenous (Human)]	• Progressive vaccinia; • Severe generalized vaccinia; and • Aberrant infections induced by vaccinia virus (except in cases of isolated keratitis).	Canada

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 USG to ensure the uninterrupted supply of this medical countermeasure ("MCM") to the SNS. Under the terms of our acquisition agreements, we intend to 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 bulk manufacturing from GSK to our Bayview facility and fill/finish activities to our Camden 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 ("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 USG, specifically HHS. Anthrasil is procured by BARDA for delivery into the SNS. We have two current contracts with BARDA: a development and procurement contract that expires in April 2021 and a multiple award, indefinite delivery/indefinite quantity contract 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. BARDA issued a task order under this second contract for the collection of anti-anthrax plasma, which was completed in 2015. BARDA issued a second task order in 2018 under this contract to extend the plasma collection storage, and to include options for manufacturing and product delivery; these options are available to be exercised by BARDA through September 2023. 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 ("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 USG, specifically HHS. We are currently operating under a procurement contract with BARDA in support of the program; this contract also includes 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 continues to be sold internationally, with deliveries to over 15 foreign governments in 2018. 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 USG, specifically HHS. We are operating under a contract for the supply of VIGIV through early 2019 and anticipate negotiating a follow-on contract for the continued supply of VIGIV into the SNS.

Product Candidates

The chart below highlights our primary 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.

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. Development of an influenza immune globulin product could address the significant public health burden for severe hospitalized influenza. In 2017, a Phase 2 study was initiated as a randomized, double-blind, placebo-controlled dose ranging study evaluating the safety, pharmacokinetics and clinical benefit of FLU-IGIV in a targeted hospitalized influenza patient population. This study is currently ongoing at multiple sites in North America with a target completion in 2019.

ZIKV-IG (NP024). ZIKV-IG is a sterile purified liquid immunoglobulin preparation containing a standardized amount of neutralizing antibody to Zika Virus. It is produced from plasma collected from healthy donors who have recovered from Zika infection (convalescent) and have high levels of neutralizing antibody for ZIKV; such collection is being done out of FDA licensed plasma collection establishments. The Phase 1 trial to evaluate the safety of ZIKV-IG completed enrollment in 2018. Several non-clinical studies are ongoing to evaluate efficacy and safety of ZIKV-IG in collaboration with several academic partners who have received funding from NIAID and other agencies.

Our Antibody Therapeutics business unit also has other product candidates addressing PHTs, including viral hemorrhagic fevers caused by Filoviruses (Ebola, Marburg and Sudan), among others.

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, directed to both internal products owned by us as well as 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, 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 30 licensed products which are currently sold in approximately 50 countries. Our third-party customers range from small biopharmaceutical companies to major multinational pharmaceutical companies. We perform work for this business unit 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 ("CIADM") through a contract with BARDA in June 2012, one of three such sites in the U.S. 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 USG, 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.
- 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 operation ("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 other customers.

Marketing and Sales

Our product sales can be divided into two primary categories: i) sales to the U.S. Government; and ii) commercial sales.

Government Procurement

For our Vaccines and Anti-Infectives, Antibody Therapeutics and Devices business units, our largest customers are the USG 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.

Commercial Sales

NARCAN® Nasal Spray is sold commercially through physician directed or standing order prescriptions at retail pharmacies.

Vivotif and Vaxchora are vaccines intended for use by travelers heading to regions where there is a risk of exposure to certain infectious diseases and therefore are sold to channels that address travel health. We sell to both wholesalers and distributors as well as directly to healthcare practitioners. The primary commercial customers of Vivotif and Vaxchora are private travel clinics, retail pharmacies and integrated hospital networks.

Competition

Our products and product candidates intended for the treatment or prevention of CBRNE, EID threats, travelers' diseases and opioids 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 USG if such products are approved. Altimmune, Inc., Pfenex Inc., Soligenix, Inc., Immunovaccine Inc. and NanoBio Corporation are each currently developing anthrax vaccine product candidates. The majority of these product candidates are in Phase 2 and we will continue to monitor the competitive landscape as we move NuThrax into Phase 3 and through to licensure.
- NARCAN® (naloxone HCl) Nasal Spray. With respect to NARCAN® Nasal Spray, we face competition from injectable naloxone, auto-injectors and improvised nasal kits. Amphastar Pharmaceuticals, Inc. competes with NARCAN® Nasal Spray with their naloxone injection product. Kaléo competes with NARCAN® Nasal Spray with their auto-injector known as EVZIO™ (naloxone HCl injection) Auto-Injector. In 2016, Teva Pharmaceuticals Industries Ltd. ("Teva") filed, and in 2018 Perrigo UK FINCO Limited Partnership ("Perrigo"), filed Abbreiviated New Drug Applications ("ANDAs," each an "ANDA") with the FDA seeking regulatory approval to market a generic version of NARCAN® Nasal Spray. Although NARCAN® Nasal Spray was the first FDA-approved naloxone nasal spray for the emergency reversal of opioid overdoses and has advantages over certain other treatments, we expect the treatment to face additional competition.
- ACAM2000. ACAM2000 is the only FDA-licensed approved 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 where it is marketed under the trade name Imvanex®. It was designed for use in people for whom replicating smallpox vaccines are contraindicated and is indicated for use in immunocompromised patients, including HIV-infected individuals and those undergoing immunosuppressive therapy. A BLA was submitted by Bavarian Nordic to the FDA in October 2018.

- 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 approved 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 approved 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.
- Vivotif®. Vivotif is the only licensed FDA-approved oral typhoid vaccine globally. In the markets where Vivotif is licensed, it competes with Sanofi Pasteur's Typhim VI® vaccine, an injectable polysaccharide typhoid vaccine.
- Vaxchora®. In the United States, Vaxchora is the only FDA-licensed approved vaccine available indicated to prevent cholera. Dukoral®, an injectable cholera vaccine manufactured by Valneva, is available outside of the U.S.
- 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 USG 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.

Geographical Reliance

For the years ended December 31, 2018, 2017 and 2016, our product sales revenue from U.S. customers as a percentage of total revenues were 73%, 67% and 58%, respectively.

MANUFACTURING

Our Lansing, Michigan site is a vertically integrated manufacturing campus 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 physical footprint to add an additional manufacturing train, 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 Contract Development and Manufacturing 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 our RSDL lotion. At these facilities, we also 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 facility is one of three centers designated by HHS to provide advanced development and manufacturing of MCMs to support the USG's national security and public health emergency needs. This facility has also been and will continue to be marketed to non-USG clients in need of bulk manufacturing services. We are currently in the process of pursuing FDA licensure for the transfer of bulk 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.

In October 2018, in connection with our acquisition of PaxVax, we acquired a live viral manufacturing facility located in Bern, Switzerland and a fill/finish facility located in San Diego, California.

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 processes.

We utilize single source suppliers for all components of NARCAN® Nasal Spray. It is manufactured by a third party, which operates a full service offering from formulation to final packaging. Materials for production of NARCAN® Nasal Spray, such as Naloxone API and other excipients, along with the vial, stopper and device are produced around the world by other third parties and delivered to the primary manufacturer and released to manufacturing following appropriate testing.

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 duration of and the type of 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 or administrative term adjustments, 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 certain intellectual property is to retain proprietary information as trade secrets rather than apply for patent protection, which requires disclosure of the proprietary information to the public. We take a number of measures to protect our trade secrets and other 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, trademarks, 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 sometimes 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 USG contractor means that we are subject to various statutes and regulations, including:

- the Federal Acquisition Regulation (“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 (“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 (“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.

USG 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 ("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 ("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 ("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 and immunogenicity as well as 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 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 and trial designs vary depending on the Therapeutic or Prophylactic nature of the product. 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 ("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 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 new drug application ("NDA") filing. 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 ("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 ("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 ("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 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 ("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, upon approval of a qualified product, 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 may have the potential for a PRV under the Neglected Tropical Disease PRV program. We believe that the Chikungunya VLP vaccine, being developed for prevention of disease caused by chikungunya infections, may have the potential for a PRV under the Neglected

Tropical Disease PRV program and under the MCM PRV program. We also believe that rVSV-Quad, rVSV-Lassa, rVSV-Ebola, rVSV-Marburg and rVSV-Sudan, the candidate viral hemorrhagic fever virus vaccines, may have potential for a PRV under either the Neglected Tropical Disease PRV program or the MCM PRV program. However, there can be no assurances that any of these candidates will obtain PRV status.

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 ("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 ("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 ("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 ("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.

Abbreviated New Drug Applications and Section 505(b)(2) New Drug Applications. Most drug products obtain FDA marketing approval pursuant to an NDA for innovator products, or an ANDA for generic products. Relevant to ANDAs, the Hatch-Waxman amendments to the FDCA established a statutory procedure for submission and FDA review and approval of ANDAs for generic versions of branded drugs previously approved by the FDA (such previously approved drugs are also referred to as listed drugs). Because the safety and efficacy of listed drugs have already been established by the brand company (sometimes referred to as the innovator), the FDA does not require a demonstration of safety and efficacy of generic products. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. The bioequivalence studies for orally administered, systemically available drug products assess the rate and extent to which the API is absorbed into the bloodstream from the drug product and becomes available at the site of action. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the listed drug. In addition to the bioequivalence data, an ANDA must contain patent certifications and chemistry, manufacturing, labeling and stability data.

The third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA’s findings of safety and efficacy of an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA’s findings with respect to certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for certain label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents of the applicant or that are held by third parties whose claims cover the applicant’s product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any subsequent applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must make one of the following certifications to the FDA concerning patents: (1) the patent information concerning the reference listed drug product has not been submitted to the FDA; (2) any such patent that was filed has expired; (3) the date on which such patent will expire; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the

certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder or patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired. Thus approval of a Section 505(b)(2) NDA or ANDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA or Section 505(b)(2) applicant.

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 European Union ("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 ("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 15, 2019, we had 1,705 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

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. 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 (the “Exchange Act”) as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the Securities and Exchange Commission (the “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 largest customer, the USG. If the USG’s demand for and/or funding for procurement of BioThrax is substantially reduced, our business, financial condition, operating results and cash flows would be materially harmed.

We derive a substantial portion of our current and expected future revenues from sales of BioThrax, our anthrax vaccine licensed by the FDA to the USG. 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 and cash flows would be materially harmed. The success of our business and our future operating results are significantly dependent on funding for the procurement of BioThrax and the terms of our BioThrax sales to the USG, 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 procurement of NuThrax.

In September 2016, we entered into a contract with HHS through BARDA for the advanced development and procurement 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 recently submitted an application with the FDA for EUA pre-approval of NuThrax, and although there can be no assurances, we currently anticipate that the FDA could authorize NuThrax for emergency use as early this year, triggering deliveries of NuThrax to the SNS for use in an emergency situation as early as this year. However, the FDA does not have review deadlines with respect to such submissions and, therefore, the timing of any approval of our 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, operating results and cash flows could be materially harmed.

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

The USG 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 USG 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 USG development contracts and grants. Over its lifetime, a USG 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 USG 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 USG otherwise declines to exercise its options under our existing contracts, our revenues would suffer, as well as our business, financial condition, operating results and cash flows.

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

The majority of our revenue is substantially dependent upon product procurement contracts with the USG 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 revenues and our business, financial condition, operating results and cash flows could be harmed. For example, although there are remaining deliverables under the contract, the CDC procurement contract for ACAM2000 that we acquired in our acquisition of the ACAM2000 business from Sanofi expired on March 31, 2018. The BARDA procurement contract for raxibacumab that we acquired in our acquisition of raxibacumab from Human Genome Sciences, Inc. and GlaxoSmithKline LLC, collectively referred to as GSK, will expire in November 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, including our procurement contract for ACAM2000, but there can be no assurance that we will be successful obtaining any follow-on contracts. 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, and our business, financial condition, operating results and cash flows could be harmed.

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 many 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 USG 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 and cash flows could be materially and adversely affected.

Laws and regulations affecting government contracts make it costlier and more 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 USG, which could have a material adverse effect on our business, financial condition, operating results and cash flows.

As a manufacturer and supplier of MCMs to the USG 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 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.

USG 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 USG 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, operating results and cash flows.

Government contracts customarily contain provisions that give the USG substantial rights and remedies, many of which are not typically found in commercial contracts, including provisions that allow the USG 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 USG's convenience. Under general principles of government contracting law, if the USG 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 USG 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 USG, are terminable at the USG's convenience with these potential consequences.

In addition, our USG contracts grant the USG 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 USG. Under our USG 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 USG.

The loss of any of our non-exclusive, sole-source or single source suppliers or an increase in the price of inventory supplied to us could have an adverse effect on our business, financial condition and results of operations.

We purchase certain supplies used in our manufacturing processes from non-exclusive, or single sources due to quality considerations, costs or constraints resulting from regulatory requirements, including key components for NARCAN® Nasal Spray (Naloxone API, along with the vial, stopper and device). Where a particular single-source supply relationship is terminated, we may not be able to establish additional or replacement suppliers for certain components or materials quickly. This is largely due to the FDA approval system, which mandates validation of materials prior to use in our products, and the complex nature of manufacturing processes. In addition, we may lose a sole-source supplier due to, among other things, the acquisition of such a supplier by a competitor (which may cause the supplier to stop selling its products to us) or the bankruptcy of such a supplier, which may cause the supplier to

cease operations. Any reduction or interruption by a sole-source supplier of the supply of materials or key components used in the manufacturing of our products or an increase in the price of those materials or components could adversely affect our business, financial condition and results of operations.

Additionally, any failure by us to forecast demand for, or our suppliers to maintain an adequate supply of, the raw material and finished product for producing NARCAN® Nasal Spray could result in an interruption in the supply of NARCAN® Nasal Spray and a decline in sales of the product.

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, operating results and cash flows 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 3 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 acquired from GSK, to our bulk and fill finish 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 November 2019. We intend to seek FDA approval to transfer the manufacturing of raxibacumab to our Baltimore, Maryland bulk and fill finish 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 revenues and our business, financial condition, operating results and cash flows could be harmed. 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. Following several of these inspections, regulatory authorities have 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. Regulatory approval may also 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, operating results and cash flows 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 USG), 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 business, financial condition, operating results and cash flows, and damage our reputation.

One or more of our products could be subject to early generic competition.

One or more of our products is approved under the provisions of the FDCA, which renders it susceptible to potential competition from generic manufacturers via the Hatch-Waxman Act and ANDA process. Generic manufacturers pursuing ANDA approval are not required to conduct costly and time-consuming clinical trials to establish the safety and efficacy of their products; rather, they are permitted to rely on the innovator's data regarding safety and efficacy. Additionally, generic drug companies generally do not expend significant sums on sales and marketing activities, instead relying on physicians or payers to substitute the generic form of a drug for the branded form. Thus, generic manufacturers can sell their products at prices much lower than those charged by the innovative pharmaceutical or biotechnology companies who have incurred substantial expenses associated with the research and development of the drug product and who must spend significant sums marketing a new drug.

The ANDA procedure includes provisions allowing generic manufacturers to challenge the innovator's patent protection by submitting "Paragraph IV" certifications to the FDA in which the generic manufacturer claims that the innovator's patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product. A patent owner who receives a Paragraph IV certification may choose to sue the generic applicant for patent infringement. If the patent owner files suit within 45 days of receiving notice from an ANDA filer, the patent owner is entitled to receive a 30 month stay on the FDA's ability to give final approval for the generic product that is the subject of the ANDA.

In recent years, generic manufacturers have used Paragraph IV certifications extensively to challenge the applicability of patents listed in the FDA's Approved Drug Products List with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book, on a wide array of innovative therapeutic products. We expect this trend to continue and to affect drug products with even relatively modest revenues.

Although we intend to vigorously enforce our intellectual property rights, there can be no assurance that we will prevail in our enforcement or defense of our patent rights. Our existing patents could be invalidated, found unenforceable, or found not to cover a generic form of our product.

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 and recently received market authorization under the mutual recognition procedure to sell BioThrax, in France, Italy, the Netherlands, Poland, and the U.K. To market our products in foreign jurisdictions under normal circumstances, we may need to obtain separate regulatory approvals and comply with numerous and varying requirements or use alternative "emergency use" or other exemptions from general approval and import requirements. Approval by the FDA in the United States or the mutual recognition

procedure in the European member states does not ensure approval by all 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 or under the mutual recognition procedure. We and our collaborators may not be able to obtain foreign regulatory approvals on a timely basis, if at all, and we may be unable to successfully commercialize our products internationally if no alternate procurement pathway is identified for authorized government customers in a particular jurisdiction. 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 continue to expand our commercialization activities outside of the United States, we are subject to an increased risk of inadvertently conducting activities in a manner that violates the U.S. Foreign Corrupt Practices Act (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, operating results, cash flows and growth prospects.

The expansion of our international operations increases our risk of exposure to credit losses.

As we continue to expand our business activities with foreign governments in certain countries that have experienced deterioration in credit and economic conditions or otherwise, our exposure to uncollectible accounts will rise. Global economic conditions and liquidity issues in certain countries have resulted and may continue to result in delays in the collection of accounts receivables and may result in credit losses. Future governmental actions and customer specific actions may require us to re-evaluate the collectability of our accounts receivable and we may potentially incur credit losses that may materially impact our operating results.

MANUFACTURING RISKS

Disruption at, damage to or destruction of our manufacturing facilities could impede our ability to manufacture BioThrax or our other products, as well as deliver our contract development and manufacturing services, which would harm our business, financial condition, operating results and cash flows.

An interruption in our manufacturing operations could result in our inability to produce our PHT countermeasures 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 USG 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 these 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 in Camden; facilities in Canton, Massachusetts; Rockville, Maryland; and Hattiesburg, Mississippi. We do not have any redundant manufacturing facilities for any of our marketed products. Accordingly, any disruption, damage, or destruction of these facilities could impede our ability to manufacture our marketed 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, operating results and cash flows.

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.

Problems may arise during the production of our marketed products and product candidates due to the complexity of the processes involved in their manufacturing and shipment. Significant delays in product manufacturing or development could cause delays in revenues, which would harm our business, financial condition, operating results and cash flows.

BioThrax, raxibacumab, ACAM2000, Anthrasil, BAT, VIGIV, Vivotif, Vaxchora, 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-downs, 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-downs, 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, which would harm our business, financial condition, operating results and cash flows.

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 and ACAM2000, which may not be obtained on a timely basis or at all.

FDA approval is required for the release of each lot of BioThrax and ACAM2000. 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 and each lot of ACAM2000 is performed against qualified control lots that we maintain. We continually monitor the status of our reference lots 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 or ACAM2000, our ability to sell BioThrax or ACAM2000 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, operating results and cash flows.

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, operating results and cash flows. 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.

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, business, financial condition, operating results and cash flows.

Our failure to successfully integrate acquired businesses and/or 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, including our recent acquisitions of Adapt and PaxVax. 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, financial condition, operating results and cash flows.

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 USG 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, operating results and cash flows.

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

Competition for BioThrax, raxibacumab, ACAM2000, Anthrasil, BAT, VIGIV, Vivotif and Vaxchora 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, operating results and cash flows.

We expect our recently acquired NARCAN® Nasal Spray marketed product to face future competition from other treatments.

Our marketed product NARCAN® Nasal Spray faces substantial competition from other treatments, including injectable naloxone, auto-injectors and improvised nasal kits. In addition, other entrants may seek approval to market generic versions of NARCAN® Nasal Spray before the underlying patents expire. For example, in 2016 Teva filed, and in 2018 Perrigo filed, ANDAs which seek regulatory approval to market generic versions of NARCAN® Nasal Spray before the expiration of certain underlying patents. Additionally, in January 2019, the FDA released new proposed template Drug Facts Labels to assist sponsors of investigation naloxone nasal sprays and auto-injectors seeking approval from the FDA for over-the-counter naloxone products. Any reduction in demand for NARCAN® Nasal Spray in favor of a competing product, or unsuccessful efforts to defend underlying patents from infringement by generic entrants, could lead to a loss of market share and cause reduced revenues, margins and levels of profitability for us, which could adversely affect our business, financial condition, operating results and cash flows.

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 business, financial condition, operating results and cash flows.

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, operating results and cash flows.

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 USG'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 government 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 the FDA or other regulatory authorities. In the United States, 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 the 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, government 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 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, which would adversely affect our business, financial condition, operating results 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, operating results 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 business 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, operating results, and cash flows could be materially harmed.

Our success will depend, in large part, on our ability to obtain and maintain protection in the United States and other countries for the intellectual property incorporated into or covering our technology, products, and product candidates. Obtaining and maintaining protection of our intellectual property 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, and such happenings 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, 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 or stop infringement or to otherwise protect or enforce our proprietary rights could be substantial and, from time to time, our patents may be subjected to opposition proceedings or validity challenges. Some of our competitors may choose to or be better able to sustain the costs of complex patent litigation. Intellectual property lawsuits are expensive and unpredictable and consume management's time and attention and other resources, even if the outcome is successful. In addition, there is a risk that a court could decide that our patents are not valid, are unenforceable, or are not infringed by a competitor product. There is also a risk that, even if the validity of a patent is upheld, a court could 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 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 that 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 adsorbed with CPG 7909 adjuvant) anthrax vaccine product candidate.
- Opiant Pharmaceuticals, Inc. formulations of naloxone, for use in our NARCAN® Nasal Spray.
- Pharma Consult GmbH autoinjectors, including the autoinjector used for our Trobigard® (atropine sulfate, obidoxime chloride) autoinjector.*

*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 US. This product is not distributed in the US.

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 could 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 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 is 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 a 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 are 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 license 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, or if others independently develop our proprietary information or processes, 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

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

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. 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 credit facilities, 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.

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

In connection with the acquisition of Adapt, we entered into an amendment and restatement of our 2017 credit agreement to provide for new five-year syndicated senior secured credit facilities that replaced our existing facility. The senior secured credit facilities include a $450 million Term Loan and the ability to borrow up to a $600 million revolver, of which we have drawn down $450 million and $318 million, respectively. 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:

- 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;
- the extent to which we repurchase additional common stock under our authorized share repurchase program; and
- the costs of commercialization activities, including product marketing, sales and distribution.

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.

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 August 2018, 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 (which include, among other things, the timely filing of our reports under the Exchange Act and maintenance of at least $700 million of public float or issuing an aggregate amount of $1 billion of non-convertible securities, other than common stock, in registered offerings for cash during the past three years), this shelf registration statement, effective until August 8, 2021, 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 August 8, 2021, 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 credit facilities, 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 ("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 facilities restrict 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, operating results, financial condition and cash flows 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 2018, 2015, 2014 and 2013. 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 USG. 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 (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 (the "Code"). In anticipation of the Distribution, we received a favorable private letter ruling from the Internal Revenue Service (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 stockholders exceeded our tax basis in the Aptevo shares and (ii) each of our stockholders 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 stockholder.

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, which expired on August 2, 2018, restricted 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 was 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 adequately complied with these restrictions. If a finding is made by the IRS through a tax audit that Aptevo failed to satisfy its obligations, this 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, operating results, financial condition and cash flows.

OTHER BUSINESS RISKS

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

We face an inherent risk of product liability exposure related to the sale of our products, any other products that we successfully acquire or develop and the testing of our product candidates in clinical trials.

One measure of protection against such lawsuits is coverage under the 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 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 USG 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. Additionally, potential product liability claims related to our commercial products, including NARCAN® Nasal Spray, Vivotif and Vaxchora, may be made by patients, health care providers or others who sell or consume these products. Such claims may be made even with respect to those products that possess regulatory approval for commercial sale. Claims or losses in excess of our product liability insurance coverage could have a material adverse effect on our business, financial condition, operating results and cash flows.

The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. A material weakness in our internal control over financial reporting 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, or the internal controls of other companies we may acquire, 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 15, 2019, 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 (“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 15, 2019, our common stock has traded as high as $73.89 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 USG 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 facilities limit 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 15, 2019, have the right to require us to register these shares of common stock under specified circumstances.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We own and lease approximately 1.8 million square feet of building space for manufacturing, laboratories, fill/finish facility services, offices and warehouse space for the conduct of our businesses at 19 locations in North America and Europe. In North America, we own and lease approximately 1.1 million square feet and 0.2 million square feet of building space, respectively, at 17 locations. Leased properties expire on various dates from 2019 to 2027. Principal locations include:

Location	Use	Approximate square feet	Owned/leased
Bern, Switzerland	Manufacturing facilities and office and laboratory space	511,000	Owned
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 (Bayview)	Manufacturing facilities and office and laboratory space	112,000	Owned

Each property is considered to be in good condition, adequate for its purpose, and suitably utilized according to the individual nature and requirements of the relevant operations. Our policy is to improve and replace property as considered appropriate to meet the needs of the individual operation.

ITEM 3. LEGAL PROCEEDINGS

ANDA Litigation

On September 14, 2018, Adapt Pharma Inc., Adapt Pharma Operations Limited and Adapt Pharma Ltd., or collectively, Adapt Pharma, and Opiant Pharmaceuticals, Inc., or Opiant, received notice from Perrigo UK FINCO Limited Partnership, or Perrigo, that Perrigo had filed an Abbreviated New Drug Application, or ANDA, with the United States Food and Drug Administration, or FDA, seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4mg/spray before the expiration of U.S. Patent Nos. 9,211,253, or the ‘253 Patent, 9,468,747, or the ‘747 Patent, 9,561,177, or the ‘177 Patent, 9,629,965, or the ‘965 Patent, and 9,775,838, or the ‘838 Patent. On or about October 25, 2018, Perrigo sent a subsequent notice letter relating to U.S. Patent No. 10,085,937, or the ‘937 Patent. Perrigo’s notice letters assert that its generic product will not infringe any valid and enforceable claim of these patents.

On October 25, 2018, Emergent BioSolutions' Adapt Pharma subsidiaries and Opiant, or collectively, Plaintiffs, filed a complaint for patent infringement of the '253, '747, '177, '965, and the '838 Patents against Perrigo in the United States District Court for the District of New Jersey arising from Perrigo's ANDA filing with the FDA. Plaintiffs filed a second complaint against Perrigo on December 7, 2018, for the infringement of the '937 Patent. As a result of timely filing the first lawsuit in accordance with the Hatch-Waxman Act, a 30-month stay of approval will be imposed by the FDA on Perrigo's ANDA, which is expected to remain in effect until March 2021 absent an earlier judgment, unfavorable to the Plaintiffs, by the Court.

On or about February 27, 2018, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva Pharmaceuticals Industries Ltd. and Teva Pharmaceuticals USA, Inc., or collectively Teva, that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 2 mg/spray before the expiration of U.S. Patent No. 9,480,644, or the '644 Patent, and U.S. Patent No. 9,707,226, or the '226 Patent. Teva's notice letter asserts that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '644 Patent or the '226 Patent, or that the '644 Patent and '226 Patent are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey.

On or about September 13, 2016, Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received notice from Teva that Teva had filed an ANDA with the FDA seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray 4 mg/spray before the expiration of U.S. Patent No. 9,211,253, or the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant received additional notices from Teva relating to the '747, the '177, the '965, the '838, and the '937 Patents. Teva's notice letters assert that the commercial manufacture, use or sale of its generic drug product described in its ANDA will not infringe the '253, the '747, the '177, the '965, the '838, or the '937 Patent, or that the '253, the '747, the '177, the '965, the '838, and the '937 Patents are invalid or unenforceable. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant filed a complaint for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '253 Patent. Adapt Pharma Inc. and Adapt Pharma Operations Limited and Opiant also filed complaints for patent infringement against Teva in the United States District Court for the District of New Jersey with respect to the '747, the '177, the '965, and the '838 Patents. All five proceedings have been consolidated. As of February 21, 2019, Adapt Pharma Inc., Adapt Pharma Operations Limited, and Opiant, are evaluating Teva's notice letter related to the '937 Patent.

In the complaints described in the paragraphs above, the Plaintiffs seek, among other relief, orders that the effective date of FDA approvals of the Teva ANDA products and the Perrigo ANDA product be a date not earlier than the expiration of the patents listed for each product, equitable relief enjoining Teva and Perrigo from making, using, offering to sell, selling, or importing the products that are the subject of Teva and Perrigo's respective ANDAs, until after the expiration of the patents listed for each product, and monetary relief or other relief as deemed just and proper by the court.

Shareholder Class Action Lawsuit filed July 19, 2016

On July 19, 2016, Plaintiff William Sponn ("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 (the "Class Period"), seeking to pursue remedies under the Exchange Act against the Company and certain of its senior officers and directors (collectively, the "Defendants"). The complaint alleged, among other things, that the Defendants 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 sought 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 Robbins Geller Rudman & Dowd LLP as Lead Counsel. On December 27, 2016, the Plaintiffs filed an amended complaint that cited the same class period, named the same defendants and made similar allegations to the original complaint. The Defendants filed a Motion to Dismiss on February 27, 2017. The Plaintiffs filed an opposition brief on April 28, 2017. The Defendants' Motion to Dismiss was heard and denied on July 6, 2017. The Defendants filed an answer on July 28, 2017. The parties then engaged in the process of exchanging discovery. The Plaintiffs filed an amended motion for class certification and appointment of Lead Plaintiffs, Sponn, and Geoffrey L. Flagstad ("Flagstad") as Class Representatives on December 20, 2017. A hearing on that motion was heard on May 2, 2018. On June 8, 2018 the Court granted class certification with a shortened class period, May 5, 2016 to June 21, 2016. In that same order, the court appointed Flagstad as Class Representative and Robbins Geller Rudman & Dowd LLP as Class Counsel. The Defendants have denied, and continue to deny, any and all allegations of fault, liability, wrongdoing, or damages. However, recognizing the risk, time, and expense of litigating any case to trial, on August 27, 2018, the Defendants reached an agreement in principle with Plaintiffs to settle all of the related claims of any individual plaintiff that purchased or acquired Company stock from January 11, 2016 to June 21, 2016, for $6.5 million, an amount that was paid by the Company's insurance carrier. The settlement required no payment by any of the Defendants. The Defendants continue to deny any and all liability. The parties executed the settlement agreement on October 16, 2018 and filed the agreement with the court on October 17, 2018. The court granted preliminary approval of the settlement on October 18, 2018, issued an amended preliminary approval of the settlement on October 25, 2018, and scheduled a hearing regarding final approval for January 22, 2019. At the time of the final approval hearing on January 22, 2019, there were no objections to the settlement, but there were two shareholders who had submitted opt-outs so that they could be excluded from the settlement. On January 25, 2019, the court issued an order and final judgment approving the settlement. Although the court has approved the settlement, the court's decision can be appealed for a period of time. In addition, the shareholders who opted out could try to bring their own claims. The Company, therefore, at this time, cannot predict the results of this lawsuit and possible other legal proceedings with certainty. Defendants continue to believe that the allegations in the complaint are without merit.

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".

As of February 15, 2019, the closing price per share of our common stock on the New York Stock Exchange was $66.16 and we had 30 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividend Policy

We have not declared or paid any cash dividends on our common stock since becoming a publicly traded company in November 2006. We currently have no plans to pay dividends.

Recent Sales of Unregistered Securities

On October 15, 2018, we issued 733,309 shares of common stock in a private placement under Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder, as partial consideration for our acquisition of Adapt based on the volume-weighted average price per share of the Common Stock as reported on the New York Stock Exchange for the ten-trading day period ending two days before closing, or $65.28 per share (an aggregate total of $47.9 million, inclusive of adjustments).

Use of Proceeds

Not applicable.

Purchases of Equity Securities

There were no repurchases of common stock that were made through open market transactions during the three months ended December 31, 2018.

Issuer Purchases of Equity Securities
(in millions, except for per share data)

Period	Total number of shares (or units) purchased	Average price paid per share (or unit)(a)	Total number of shares (or units) purchased as part of publicly announced plans or programs(b)	Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs (a)(b)
October 1, 2018 - October 31, 2018	-	$ -	-	$ -
November 1, 2018 - November 30, 2018	-	-	-	-
December 1, 2018 - December 31, 2018	-	-	-	-
Total	-	$ -	-	$ 50.0

(a) The amounts do not give effect to any fees, commissions or other costs associated with repurchases of shares.

(b) Under the stock repurchase program, management was authorized to purchase shares of the Company's common stock, from time to time, through open market purchases or privately negotiated transactions at prevailing prices or pursuant to one or more accelerated stock repurchase agreements or other derivative arrangements as permitted by securities laws and other legal requirements, and subject to stock price, business and market conditions and other factors. In March 2018, 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 authorization expires on December 31, 2019. Any repurchased shares will be available for use in connection with our stock plans and for other corporate purposes. As of December 31, 2018, we have not made any repurchases under this program. We historically have funded and in the future may fund stock repurchases through a combination of cash on hand and cash generated by operations and our senior secured credit facilities or future financing transactions.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

	Year Ended December 31,				
(in millions, except per share data)	2018	2017	2016	2015	2014

Statements of operations data:					
Revenues:					
Product sales	$606.5	$421.5	$296.3	$329.0	$281.8
Contract manufacturing	98.9	68.9	49.1	43.0	30.9
Contracts and grants	77.0	70.5	143.4	117.3	91.8
Total revenues	782.4	560.9	488.8	489.3	404.5
Operating expenses:					
Cost of product sales and contract manufacturing	322.3	187.7	126.3	102.1	96.6
Research and development	142.8	97.4	106.9	117.8	103.5
Selling, general & administrative	202.5	142.9	143.1	120.6	108.1
Amortization of intangible assets	25.0	8.6	7.0	7.3	7.1
Total operating expenses	692.6	436.6	383.3	347.8	315.3
Income from operations	89.8	124.3	105.5	141.5	89.2
Other income (expense):					
Interest expense	(9.9)	(6.6)	(7.6)	(6.5)	(8.2)
Other income (expense), net	1.6	0.9	1.3	0.7	3.2
Total other income (expense), net	(8.3)	(5.7)	(6.3)	(5.8)	(5.0)
Income from continuing operations before provision for income taxes	81.5	118.6	99.2	135.7	84.2
Provision for income taxes	18.8	36.0	36.7	44.3	29.9
Net income from continuing operations	62.7	82.6	62.5	91.4	54.3
Net loss from discontinued operations	-	-	(10.7)	(28.5)	(17.6)
Net income	$62.7	$82.6	$51.8	$62.9	$36.7
Net income per share from continuing operations-basic	$1.25	$1.98	$1.56	$2.37	$1.45
Net loss per share from discontinued operations-basic	-	-	(0.27)	(0.74)	(0.47)
Net income per share-basic	$1.25	$1.98	$1.29	$1.63	$0.98
Net income per share from continuing operations-diluted	$1.22	$1.71	$1.35	$2.02	$1.26
Net loss per share from discontinued operations-diluted	-	-	(0.22)	(0.61)	(0.38)
Net income per share-diluted (1)	$1.22	$1.71	$1.13	$1.41	$0.88
Weighted average number of shares — basic	50.1	41.8	40.2	38.6	37.3
Weighted average number of shares — diluted	51.4	50.3	49.3	47.3	45.8

	As of December 31,				
(in millions)	2018	2017	2016	2015	2014
Balance Sheet Data:					
Cash and cash equivalents	$112.2	$178.3	$271.5	$308.3	$276.8
Working capital	420.4	385.3	404.4	425.9	312.8
Total assets	2,229.4	1,070.2	970.1	931.8	815.6
Total long-term liabilities	1,018.1	57.8	268.1	274.6	281.5
Total stockholders’ equity	1,010.9	912.2	596.2	575.0	454.5

(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.

Business Overview

We are a global life sciences company focused on providing to civilian and military populations a portfolio of innovative preparedness and response products and solutions that address accidental, deliberate and naturally occurring public health threats ("PHTs").

We are focused on the following four distinct public health threat categories: CBRNE; EID; travelers' diseases; and opioids. We have a product portfolio of eleven products (vaccines, antibody therapeutics, and drug-device combination products) that generate a majority of our revenue. We also have a development pipeline consisting of a diversified mix of both pre-clinical and clinical stage product candidates (vaccines, antibody therapeutics, and drug-device combination products). Finally, we also have a fully-integrated portfolio of contract development and manufacturing services. We continue to pursue acquiring and developing products and solutions that provide an opportunity to serve both government customers and commercial (non-government) customers. Our recently acquired products for opioid overdose and travelers' diseases are further expanding our revenue while also contributing to the diversification of the sources of our revenue expanding the commercial (non-government) component of our business.

Our Vaccines and Anti-infective ("VAI") products are BioThrax, ACAM2000, Vivotif and Vaxchora. Our Devices products are NARCAN® Nasal Spray, RSDL and Trobigard. Our Antibody Therapeutic ("ATB") products are raxibacumab, Anthrasil, BAT and VIGIV. See Item 1 "Overview" in this Annual Report on Form 10-K for an additional discussion of our products.

Revenues

We generate revenues from the sale of our eleven marketed products, the performance of contract development and manufacturing services, and our performance of research and development services under contracts and grants that we receive from the U.S. government ("USG") and others.

The USG is the largest purchaser of our CBRNE products and primarily purchases our products for the SNS, a national repository of medical countermeasures including critical antibiotics, vaccines, chemical antidotes, antitoxins, and other critical medical supplies. The USG primarily purchases our products under long-term firm fixed price procurement contracts. BioThrax sales to the USG derive the majority of our historical product sales.

Our travelers' disease products, primarily Vivotif and Vaxchora, are sold to wholesalers and distributors, as well as directly to healthcare practitioners. We sell Vivotif and Vaxchora to private travel clinics, retail pharmacies and integrated hospital networks. Our opioid overdose treatment, NARCAN® Nasal Spray, is sold commercially through physician directed or standing order prescriptions at retail pharmacies.

We also earn revenue from the performance of contract development and manufacturing services for third-parties. Our services include fill/finish activities as well as the production of bulk drug substances on behalf of our customers.

We have received contract and grants funding from the USG and other non-governmental organizations to perform research and development activities related to certain emerging infectious diseases.

Our revenue, operating results and profitability have varied, and we expect that they will continue to vary on a quarterly basis

Cost of Product Sales and Contract Manufacturing

The primary expenses that we incur to deliver our VAI products and ATB products to our customers and to perform contract manufacturing services for our customers consist of fixed and variable costs. Variable manufacturing costs primarily consist 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), shipping, and logistics.

We use the same manufacturing facilities and methods of production for our own products as well as for fulfillment of our contract manufacturing contracts. We operate nine manufacturing facilities, five of which perform manufacturing activities for contract manufacturing customers. As a result, management reviews expenses associated with manufacturing our own products as well contract manufacturing contracts on an aggregate basis when analyzing the financial performance of its manufacturing facilities. Our manufacturing process for our own products and our contract manufacturing business includes the production of bulk material and performing “fill finish” work for containment and distribution of biological products. For “fill finish” customers, we receive work in process inventory to be prepared for distribution. When producing bulk material, we procure raw materials, manufacture the product and retain the risk of loss through the manufacturing and review process until delivery.

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.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel-related costs and professional fees in support of our executives, 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.

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. This allowed the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. The Company previously provided a provisional estimate of the effect of the Tax Act in our financial statements in 2017 in the amount of $0.2 million comprising a transition tax of $13.6 million offset by a $13.4 million benefit related to the remeasurement of certain deferred tax assets and liabilities. December 22, 2018 marked the end of the measurement period for purposes of SAB 118. As such, we completed our analysis to determine the effect of the Tax Act and recorded a $0.2 million reduction of the transition tax and an additional $4.5 million benefit on the remeasurement of certain deferred tax assets and liabilities 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, 2018, income tax expense totaled $18.8 million. For every 1% change in the 2018 effective rate, income tax expense would have changed by approximately $0.8 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.

Results of Operations

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

Revenue

	Year ended December 31,			
(in millions)	2018	2017	$ Change	% Change
Product sales:				
BioThrax	$278.0	$286.6	$(8.6)	(3%)
ACAM2000	116.7	11.5	105.2	915%
Other	211.8	123.4	88.4	72%
Total product sales	606.5	421.5	185.0	44%
Contract manufacturing	98.9	68.9	30.0	44%
Contracts and grants	77.0	70.5	6.5	9%
Total revenues	$782.4	$560.9	$221.5	39%

Product sales:

Substantially all of our sales of BioThrax are made to the USG under long-term procurement contracts at a consistent value per dose. The fluctuations in BioThrax revenue are related to changes in volume depending on when the USG requests delivery. The USG retains a level of BioThrax, as it deems necessary. The price per unit of BioThrax sold was consistent year over year and as such the change in revenue is due to a variance in the number of units sold and the overall long-term contract value remains consistent with prior periods.

ACAM2000 was acquired in October 2017 and as such the increase is due to a full year of results in 2018 compared to a partial year in 2017. Similar to BioThrax, ACAM2000 is sold over a long-term contract requiring delivery to the SNS as ordered.

The increase in other product sales relates primarily to the contribution of recently acquired products which resulted in a $96.0 million increase in other product sales for 2018. Recently acquired products include:

§ raxibacumab, acquired in October 2017;
§ NARCAN® Nasal Spray, acquired in October 2018;
§ Vivotif, acquired in October 2018; and
§ Vaxchora; acquired in October 2018.

Contract manufacturing:

The increase in Contract manufacturing revenue is primarily due to:

§ fill/finish services provided to third parties;

- the design, construction and validation of manufacturing capability for a third party at our Lansing, Michigan site; and
- manufacturing services performed at our Canton, Massachusetts facility.

Contracts and grants:

The revenues within our Contracts and grants revenues are primarily related to our cost-plus fixed fee contracts with the USG. The increase in Contracts and grants revenues was primarily due to an increase in R&D activities related to ACAM2000 (acquired October 2017), which were conducted pursuant to an existing multi-year development contract with BARDA. R&D activities vary as completed projects end and new projects begin. Excluding the impact of acquisitions, contract and grant revenue was consistent with prior years.

Cost of Product Sales and Contract Manufacturing

Cost of product sales and contract manufacturing increased by $134.6 million, or 72%, to $322.3 million for 2018 from $187.7 million for 2017. The increase was primarily attributable to our acquired products ACAM2000 and raxibacumab (both acquired October 2017), as well as NARCAN® Nasal Spray, Vivotif and Vaxchora (acquired October 2018).

We have reclassified amortization of intangible assets for the years ended December 31, 2017 and 2016 from cost of product sales and contract manufacturing to amortization of intangible assets to conform to the current period presentation on our consolidated statements of operations.

Research and Development Expenses

Research and development expenses increased by $45.4 million, or 47%, to $142.8 million for 2018 from $97.4 million for 2017. This increase was due primarily to higher contract development services costs. Manufacturing development activities of $25.3 million was attributable to our recently acquired product candidates. Excluding our acquired product candidates, the increase in research and development expense was primarily attributable to:

- manufacturing development activities related to our NuThrax product candidate;
- timing of a Phase 2 clinical study and related activities for our FLU-IGIV (NP025) program; and
- timing of manufacturing development activities and toxicology/safety studies for our SIAN product candidate.

We seek funding for development activities from external sources and third parties, such as governments and non-governmental organizations, or through collaborative partnerships. This funding lowers our overall financial exposure for certain development programs. Management reviews our research and development expenses net of contracts and grants revenues to assess increases in investment spending. During the years ended December 31, 2018 and 2017, we incurred net research and development expenses of $65.8 million and $27.0 million, respectively.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $59.6 million, or 42%, to $202.5 million for 2018 from $142.9 million for 2017. The increase was primarily attributable to an increase in acquisition-related costs (transaction and integration) of $21.8 million, expenses associated with the operations from PaxVax and Adapt (both acquired in October 2018) of $19.8 million and an increase in compensation related costs.

Amortization of Intangible Assets

Amortization of intangible assets increased by $16.4 million to $25.0 million for 2018 from $8.6 million for 2017. The increase was entirely due to the acquisitions of PaxVax and Adapt in October 2018 and ACAM2000 and

raxibacumab in October of 2017.

Total Other Income (Expense), Net

Total other income (expense), net increased by $2.6 million, or 46%, to $8.3 million for 2018 from $5.7 million for 2017. The increase was primarily attributable to an increase in interest expense due to borrowings to fund our acquisitions of PaxVax and Adapt in October 2018.

Income Taxes

Provision for income taxes decreased by $17.2 million, or 48%, to $18.8 million for 2018 from $36.0 million for 2017. The income tax expense for the years ended December 31, 2018 and 2017 is attributable to the U.S. federal, state and foreign income taxes on our profitable operations. During the years ended December 31, 2018 and 2017, the effective rate was 23% and 30%, respectively. During 2018, the Company recognized a $4.7 million benefit relating to adjustments to provisional amounts under SAB 118. The tax benefit was fully offset by the impact of acquisition transaction costs of $5.4 million. The decrease in the effective tax rate during 2018 was primarily attributable to the decrease to the U.S. statutory rate from 35% to 21%, partially offset by the repeal of the Domestic Production Activities benefit, the impacts of GILTI, and the increase in disallowed deductions for officers compensation, all of which are a result of The Tax Reform Act.

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

Revenues

	Year ended December 31,			
(in millions)	2017	2016	$ Change	% Change
Product sales:				
BioThrax	$286.6	$237.0	$49.6	21 %
Other	134.9	59.3	75.6	127 %
Total product sales	421.5	296.3	125.2	42 %
Contract manufacturing	68.9	49.1	19.8	40 %
Contracts and grants	70.5	143.4	(72.9)	(51 %)
Total revenues	$560.9	$488.8	$72.1	15 %

The increase in BioThrax sales was substantially due to changes in volume and those changes in volume are driven by the timing of deliveries to the SNS and acceptance of product by the USG. Substantially all of the BioThrax product sales revenues during the year ended December 31, 2017 and 2016 consisted of sales to the USG. The price per unit of BioThrax sold was consistent year over year and as such the change in revenue is due to a variance in the number of units sold.

The increase in other product sales relates primarily to:

- the timing of BAT deliveries of $28.4 million to the SNS;
- international sales for VIGIV and Trobigard of $25.3 million; and
- sales of ACAM2000® and raxibacumab, both acquired in October 2017, of $20.5 million.

Contract manufacturing:

The increase in Contract manufacturing is primarily due to:

- manufacturing 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.

We have reclassified amortization of intangible assets for the years ended December 31, 2017 and 2016 from cost of product sales and contract manufacturing to amortization of intangible assets to conform to the current period presentation on our consolidated statements of operations.

Research and Development Expenses

Research and development expenses decreased by $10.9 million, or 10%, to $97.4 million for 2017 from $108.3 million for 2016.

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

- manufacturing development of Ebola monoclonal antibodies related to our CIADM task orders; and
- plasma collection related to our VIGIV program.

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

- formulation development activities, along with screening of molecules within the series, related to our EV-035 series of molecules; and
- preparation for a clinical trial related to our ZIKV-IG program (which was completed in 2018).

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.

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 Income (Expense), Net

Total other income (expense), net 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, we 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%.

Liquidity and Capital Resources

Sources of Liquidity

We have historically financed our operating and capital expenditures through cash on hand, cash from operations, debt financing and development funding. We also obtain financing from 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, 2018. As of December 31, 2018, we had cash and cash equivalents of $112.2 million. As of December 31, 2018, we believe that we have sufficient liquidity to fund our operations over the next 12 months.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2018, 2017 and 2016.

Year ended December 31,

(in millions)	2018	2017	2016
Net cash provided by (used in):			
Operating activities(1)	$41.6	$208.1	$54.7
Investing activities	(897.2)	(249.9)	(76.2)
Financing activities	788.7	(51.4)	(19.8)
Net decrease in cash and cash equivalents	$(66.9)	$(93.2)	$(41.3)

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

Operating Activities:

Net cash provided by operating activities including the impact of foreign currency of $41.6 million in 2018 was primarily due to our net income excluding non-cash items of $160.9 million, offset by $119.1 million of negative changes in working capital. Cash outflow includes an increase in accounts receivable related to the timing of collection of amounts billed under our contract with the USG for BioThrax in the fourth quarter of 2018, a decrease in accrued expenses and other liabilities, accounts payable and prepaid expenses and other assets.

Net cash provided by operating activities including the impact of foreign currency 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 including the impact of foreign currency of $54.7 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.

Investing Activities:

Net cash used in investing activities of $897.2 million in 2018 was primarily due to our acquisitions of Adapt and PaxVax, along with software, infrastructure and equipment investments.

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 $76.2 million in 2016 was primarily due to expansion at our Bayview CIADM site, along with software, infrastructure and equipment investments.

Financing Activities:

Net cash provided by financing activities of $788.7 million in 2018 was primarily due to $798.0 million of proceeds from long-term debt borrowings used to finance a portion of the Adapt and PaxVax acquisitions and for general corporate purposes and $15.9 million in proceeds from the issuance of common stock pursuant to our employee equity awards plan, partially offset by $6.6 million associated with the taxes paid on behalf of employees for equity activity.

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.

Long-term debt

2017 Credit Agreement

On September 29, 2017, we entered into a senior secured credit agreement (the "2017 Credit Agreement") with four lending financial institutions. The 2017 Credit Agreement provided for a senior secured credit facility of up to $200 million through September 29, 2022.

Amended and Restated Credit Agreement

On October 15, 2018, we entered into an Amended and Restated Credit Agreement (the "Amended Credit Agreement"), which modified the 2017 Credit Agreement. The Amended Credit Agreement (i) increased the revolving credit facility (the "Revolving Credit Facility") from $200 million to $600 million, (ii) extended the maturity of the Revolving Credit Facility from September 29, 2022 to October 13, 2023, (iii) provided for a term loan in the original principal amount of $450 million (the "Term Loan Facility," and together with the Revolving Credit Facility, the "Senior Secured Credit Facilities"), (iv) added several additional lenders, (v) amended the applicable margin such that borrowings with respect to the Revolving Credit Facility will bear interest at the annual rate described below, (vi) amended the provision relating to incremental credit facilities such that we may request one or more incremental term loan facilities, or one or more increases in the commitments under the Revolving Credit Facility (each an "Incremental Loan"), in any amount if, on a pro forma basis, our consolidated secured net leverage ratio does not exceed 2.50 to 1.00 after such incurrence, plus $200 million and (vii) amended the maximum consolidated net leverage ratio financial covenant from 3.50 to 1.0 (subject to 0.50% step up in connection with material acquisitions) to the maximum consolidated net leverage ratio described below.

In October 2018, we borrowed $318 million under the Revolving Credit Facility and $450 million under the Term Loan Facility to finance a portion of the consideration for the PaxVax and Adapt acquisitions and related expenses.

For the years ended December 31, 2018 and 2017, we capitalized $13.4 million and $1.4 million, respectively, of debt issuance costs.

Borrowings under the Revolving Credit Facility and the Term Loan Facility will bear interest at a rate per annum equal to (a) a eurocurrency rate plus a margin ranging from 1.25% to 2.00% per annum, depending on our 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 0.25% to 1.00%, depending on our consolidated net leverage ratio. We are required to make quarterly payments under the Amended Credit Agreement for accrued and unpaid interest on the outstanding principal balance, based on the above interest rates. In addition, we are required to pay commitment fees ranging from 0.15% to 0.30% per annum, depending on our consolidated net leverage ratio, in respect of the average daily unused commitments under the Revolving Credit Facility. We are to repay the outstanding principal amount of the Term Loan Facility in quarterly installments based on an annual percentage equal to 2.5% of the original principal amount of the Term Loan Facility during each of the first two years of the Term Loan Facility, 5% of the original principal amount of the Term Loan Facility during the third year of the Term Loan Facility and 7.5% of the original principal amount of the Term Loan Facility during each year of the remainder of the term of the Term Loan Facility until the maturity date of the Term Loan Facility, at which time the entire unpaid principal balance of the Term Loan Facility will be due and payable.

We have the right to prepay the Term Loan Facility without premium or penalty. The Revolving Credit Facility and the Term Loan Facility mature (unless earlier terminated) on October 13, 2023.

The Amended Credit Agreement also requires mandatory prepayments of the Term Loan Facility in the event that we or our Subsidiaries (a) incur indebtedness not otherwise permitted under the Amended Credit Agreement or (b) receive cash proceeds in excess of $100 million during the term of the Amended Credit Agreement from certain dispositions of property or from casualty events involving their property, subject to certain reinvestment rights.

The Amended Credit Agreement contains affirmative and negative covenants customary for financings of this type. Negative covenants in the Amended Credit Agreement, among other things, limit our 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 merger or consolidation transactions. The Amended Credit Agreement also contains financial covenants, including (1) a minimum consolidated debt service coverage ratio of 2.50 to 1.00, and (2) a maximum consolidated net leverage ratio of 4.00 to 1.00 through September 29, 2019, 3.75 to 1.00 from September 30, 2019 through September 29, 2020 and 3.50 to 1.00 thereafter, which may be adjusted to 4.00 to 1.00 for a four quarter period in connection with a material permitted acquisition, subject to the terms and conditions of the Amended 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 period.

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 Facilities 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;
- the extent to which we repurchase additional common stock under our authorized 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.

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 Credit Facilities, 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 2.875% Convertible Senior Notes due 2021 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 Facilities 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, operating results, financial condition and cash flows would be adversely affected, and we could be forced to delay, reduce the scope of or eliminate many of our planned activities.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2018:

	Payments due by period				
(in millions)	Total	Less than 1 year	1 to 3 Years	3 to 5 Years	More than 5 years
Contractual obligations:					
Long-term indebtedness	$836.6	$14.3	$103.3	$719.0	$ -
Operating lease obligations	15.5	3.4	5.0	4.6	2.5
Deemed mandatory repatriation tax (1)	11.3	1.1	4.2	6.0	-
Purchase commitments	66.7	60.1	6.6	-	-
Total contractual obligations	$930.1	$78.9	$119.1	$729.6	$ 2.5

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

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with GAAP, which requires management to make estimates, judgments and assumptions that affect the amounts reported in the consolidated financial statements included in Item 8, "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K and accompanying notes. Management considers an accounting policy to be critical if it is important to reporting our financial condition and results of operations, and if it requires significant judgment and estimates on the part of management in its application. We consider policies relating to the following matters to be critical accounting policies:

§ Revenue recognition;
§ Mergers and acquisitions;
§ Contingent consideration; and
§ Income taxes.

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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For a discussion of additional risks arising from our operations, see “Item 1A—Business—Risk Factors” in this 2018 Annual Report.

Market Risks

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.

Interest Rate Risk

We have debt with a mix of fixed and variable rates of interest. Floating rate debt carries interest based generally on the eurocurrency, as defined in our Amended Credit Agreement, plus an applicable margin. Increases in interest rates could therefore increase the associated interest payments that we are required to make on this debt. See Note 11, "Long-term debt," to the Notes of our consolidated financial statements included in this 2018 Annual Report under the caption Item 8, "Financial Statements and Supplementary Data.”

We have assessed our exposure to changes in interest rates by analyzing the sensitivity to our operating results assuming various changes in market interest rates. A hypothetical increase of one percentage point in the eurocurrency rate as of December 31, 2018 would increase our interest expense by approximately $8.0 million annually.

Foreign Currency Exchange Rate Risk

We have exposure to foreign currency exchange rate fluctuations worldwide and primarily with respect to the Euro, Canadian dollar, Swiss franc and British pound. We manage our foreign currency exchange rate risk primarily by incurring, to the extent practicable, operating and financing expenses in the local currency in the countries in which we operate.

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, 2018 and 2017, 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, 2018, 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 financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, 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 21, 2019 expressed an unqualified opinion thereon.

Adoption of ASU No. 2014-09
As discussed in Note 2 to the consolidated financial statements, the Company changed its method for accounting for revenue in 2018 due to the adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), and the amendments in ASUs 2015-14, 2016-08, 2016-10, 2016-12, 2016-20 and 2017-14.

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.
Baltimore, Maryland
February 21, 2019

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

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$112.2	$178.3
Restricted cash	0.2	1.0
Accounts receivable, net	262.5	143.7
Inventories	205.8	142.8
Income tax receivable, net	8.6	2.4
Prepaid expenses and other current assets	31.5	17.2
Total current assets	620.8	485.4
Property, plant and equipment, net	510.2	407.2
Intangible assets, net	761.6	119.6
In-process research and development	50.0	-
Goodwill	259.7	49.1
Deferred tax assets, net	13.4	2.8
Other assets	13.7	6.1
Total assets	$2,229.4	$1,070.2
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$80.7	$41.8
Accrued expenses and other current liabilities	30.7	4.8
Accrued compensation	58.2	37.9
Long-term indebtedness, current portion	10.1	-
Contingent consideration, current portion	5.6	2.4
Income taxes payable, net	4.5	-
Deferred revenue, current portion	10.6	13.2
Total current liabilities	200.4	100.1
Contingent consideration, net of current portion	54.4	9.9
Long-term indebtedness, net of current portion	784.5	13.5
Deferred tax liability	67.5	-
Income taxes payable	11.2	12.5
Deferred revenue, net of current portion	62.5	17.3
Other liabilities	38.0	4.6
Total liabilities	1,218.5	157.9
Stockholders’ equity:		
Preferred stock, $0.001 par value; 15.0 shares authorized, 0 shares issued and outstanding at both December 31, 2018 and 2017	-	-
Common stock, $0.001 par value; 200.0 shares authorized, 52.4 shares issued and 51.2 shares outstanding at December 31, 2018; 50.6 shares issued and 49.4 shares outstanding at December 31, 2017	0.1	0.1
Treasury stock, at cost, 1.2 common shares at both December 31, 2018 and 2017	(39.6)	(39.5)

Additional paid-in capital	688.6	618.3
Accumulated other comprehensive loss	(5.5)	(3.7)
Retained earnings	367.3	337.1
Total stockholders' equity	1,010.9	912.3
Total liabilities and stockholders' equity	$2,229.4	$1,070.2

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

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

	Year Ended December 31,		
	2018	2017	2016
Revenues:			
Product sales	$606.5	$421.5	$296.3
Contract manufacturing	98.9	68.9	49.1
Contracts and grants	77.0	70.5	143.4
Total revenues	782.4	560.9	488.8
Operating expenses:			
Cost of product sales and contract manufacturing	322.3	187.7	126.3
Research and development	142.8	97.4	106.9
Selling, general and administrative	202.5	142.9	143.1
Amortization of intangible assets	25.0	8.6	7.0
Total operating expenses	692.6	436.6	383.3
Income from operations	89.8	124.3	105.5
Other income (expense):			
Interest expense	(9.9)	(6.6)	(7.6)
Other income (expense), net	1.6	0.9	1.3
Total other income (expense), net	(8.3)	(5.7)	(6.3)
Income from continuing operations before provision for income taxes	81.5	118.6	99.2
Provision for income taxes	18.8	36.0	36.7
Net income from continuing operations	62.7	82.6	62.5
Net loss from discontinued operations	-	-	(10.7)
Net income	$62.7	$82.6	$51.8
Net income per share from continuing operations-basic	$1.25	$1.98	$1.56
Net loss per share from discontinued operations-basic	-	-	(0.27)
Net income per share-basic	$1.25	$1.98	$1.29
Net income per share from continuing operations-diluted	$1.22	$1.71	$1.35
Net loss per share from discontinued operations-diluted	-	-	(0.22)
Net income per share-diluted (1)	$1.22	$1.71	$1.13
Weighted-average number of shares - basic	50.1	41.8	40.2
Weighted-average number of shares - diluted	51.4	50.3	49.3

(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 millions)

	December 31,		
	2018	2017	2016
Net income	$62.7	$82.6	$51.8
Other comprehensive income (loss), net of tax:			
Currency translation adjustments	(1.6)	0.6	(1.6)
Unrealized losses on pension benefit obligation	(0.2)	-	-
Other comprehensive income (loss), net of tax	(1.8)	0.6	(1.6)
Comprehensive income	$60.9	$83.2	$50.2

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

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

	Year Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net income	$62.7	$82.6	$51.8
Adjustments to reconcile to net cash provided by (used in) operating activities:			
Stock-based compensation	23.2	15.2	18.5
Depreciation and amortization	62.2	42.6	38.2
Deferred income taxes	8.6	3.3	5.2
Change in fair value of contingent obligations	3.1	7.8	(10.8)
Impairment and abandonment of long-lived assets	-	1.9	5.6
Excess tax benefits from stock-based compensation	-	-	(10.6)
Other	1.1	1.0	1.0
Changes in operating assets and liabilities, net of business acquisitions:			
Accounts receivable	(94.2)	(4.8)	(22.4)
Inventories	(1.9)	6.1	(9.0)
Income taxes	(5.1)	20.1	(3.4)
Prepaid expenses and other assets	(7.9)	(3.7)	(2.1)
Accounts payable	(7.0)	16.1	(14.8)
Accrued expenses and other liabilities	(11.6)	1.6	0.6
Accrued compensation	8.4	3.3	2.2
Deferred revenue	0.2	15.0	4.6
Net cash provided by operating activities	41.8	208.1	54.6
Cash flows from investing activities:			
Purchases of property, plant and equipment	(72.1)	(54.8)	(76.2)
Proceeds from sale of assets	2.6	-	-
Asset acquisitions	-	(77.6)	-
Business acquisitions, net of cash acquired	(827.7)	(117.5)	-
Net cash used in investing activities	(897.2)	(249.9)	(76.2)
Cash flows from financing activities:			
Proceeds from long-term debt obligations	798.0	-	-